



State of Oregon Department of Environmental Quality
Drug Take-Back Program 2020
Advisory Committee Meeting #2 Materials

This package contains the following documents:

- Agenda
- Draft rule concepts
- Draft fiscal impact statement
- Meeting #1 summary
- DEQ responses to questions
- Meeting #2 presentation

Note for Readers:

This package contains multiple documents. If you want to read more than one document at a time, you can open multiple copies of this PDF by downloading the PDF and then opening it in Adobe. You can then either:

- Click on the “Windows” item in the top ribbon
- Click on “New Window”
- A second copy of the PDF will open in a new window

Or:

- Click on “File” in the top ribbon
- Click on “Open” in the top ribbon
- Double click on the name of the PDF you want to open
- A second copy of the PDF will open in a separate tab in the same window

Drug Take-Back Program 2020 Rulemaking

Agenda

Rulemaking Advisory Committee Meeting #2

Tuesday, April 28, 2020, 11 a.m. – 1:15 p.m.

Location: Webinar and teleconference

Time	Topic
11 a.m.	Welcome, Overview of Today's Meeting <ul style="list-style-type: none">Brief overview of committee's role and DEQ's plan for program rollout
11:10 a.m.	Introductions <ul style="list-style-type: none">Share background and expertise of committee members
11:20 a.m.	Presentation: Proposed Rule Concepts <ul style="list-style-type: none">Review revised rule concepts
11:45 a.m.	Presentation and Discussion: Draft Fiscal Impact Statement <ul style="list-style-type: none">Review fiscal impactCommittee discussion and questions on fiscal impact statement
12:10 p.m.	Discussion: Rule Concepts Proposed by Committee Members <ul style="list-style-type: none">Discuss rule concepts proposed by committee members
12:30 p.m.	Discussion: Other Issues <ul style="list-style-type: none">Discuss responses to previous questionsDiscuss future opportunities to address other issues
1 p.m.	Opportunity for Public Input
1:15 p.m.	Adjourn meeting

Meeting Materials

- ❖ Agenda
- ❖ Draft rule concepts
- ❖ Draft fiscal impact statement
- ❖ Meeting #1 summary
- ❖ DEQ's responses to questions from Meeting #1
- ❖ Meeting #2 presentation

Teleconference Information

Call-in number: 888-363-4734

Participant ID: 1910322

Webinar login: <https://www.teleconference.att.com/servlet/AWMlogin>

Teleconference/webinar instructions: [Click Here](#)

Alternative formats

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

Materials Management

700 NE Multnomah St.,
Suite 600
Portland, OR 97232
Phone: 503-229-5696
800-452-4011
Fax: 503-229-6124
Contact: Michael Lee

www.oregon.gov/DEQ

DEQ is a leader in restoring, maintaining and enhancing the quality of Oregon's air, land and water.

Draft Rule Concepts Rulemaking Advisory Committee Meeting #2



State of Oregon
Department of
Environmental
Quality

Land Division
700 NE Multnomah St.
Suite 600
Portland, OR 97232
Phone: 503-229-5696
800-452-4011
Fax: 503-229-6124
Contact: Michael Lee

www.oregon.gov/DEQ

DEQ is a leader in restoring, maintaining and enhancing the quality of Oregon's air, land and water.

1. Require Manufacturer License Numbers in Program Plans

ORS 459A.209(2)(a) requires a drug take-back program plan to list each covered manufacturer participating in the proposed program.

Rule Concept: A program plan must include each manufacturer's Oregon Board of Pharmacy-issued license number.

2. Enforcement and Discipline

ORS 459A.239 provides the Environmental Quality Commission with enforcement and discipline powers to ensure participation in drug take-back programs and compliance with ORS 459A.200 to 459A.266.

Rule Concept: Delegate EQC's enforcement and discipline powers under ORS 459A.200 to 459A.266 to DEQ.

3. Set criteria for when a drug take-back program can provide mail-back or other service in place of a required drop-off site

ORS 459A.209 requires a program plan to describe how the drug take-back program will provide convenient service in every county in Oregon, including establishing a drop-off site:

- In each county, and
- For each population center (a city or town and the unincorporated area of the county within a 10-mile radius from the center of the city or town) plus an additional drop-off site for every 50,000 residents of a town or city within a population center.

The county drop-off site can be the same as the drop-off site required in a population center.

DEQ may waive the requirement to establish a drop-off site in a county if the submitted program plan describes how the program will provide mail-back service in that county.

Additionally, under ORS 459A.218, where a drug take-back program is unable to establish and maintain a sufficient number of drop-off sites to meet the requirements for plans, DEQ may approve a plan to provide additional services, such as mail-back services and holding collection events, to ensure the program provides the convenient service for the area affected.

Rule Concept: Require the following information for DEQ to consider when determining whether to approve a program's request for a waiver from providing a drop-off site in a particular county and a program's request to provide additional services and collection events where the program cannot establish or maintain the required number of drop-off sites.

To obtain a waiver or approval of alternative services in lieu of a required drop off site, a drug take-back program must:

- Demonstrate good-faith efforts to solicit and enter into agreements with potential authorized collectors;

- Demonstrate why the program cannot establish or maintain a drop-off site;
- Demonstrate local government concurrence with alternate services being proposed or reasons why the program could not obtain such concurrence could with good faith efforts;
- Describe how proposed alternative services will be designed and implemented to provide convenient service for all residents;
- Agree to solicit potential authorized collectors for the affected county, city or town on at least an annual basis.

4. Fees

ORS 459A.242 requires DEQ to establish three types of fees. Fees must be reasonably calculated to cover DEQ's costs of administering the Drug Take-Back Law (ORS 459A.200 to 459A.266).

Rule Concept: DEQ will charge the following fees.

- A one-time fee for reviewing a program plan: \$75,000
 - Due with the initial submission of plan or updated plan.
- An annual fee for expenses associated with ongoing costs of administering the drug take-back law. Annual fee will not exceed the following caps:
 - Cap for first annual fee: \$345,000
 - Cap for annual fee in subsequent years: \$210,000
 - Annual fees will be calculated to reasonably reflect DEQ's actual costs.
 - If multiple programs exist, DEQ will make a reasonable effort to divide the fee by:
 - Charging DEQ's costs associated with a specific program to that program; and
 - Splitting the balance evenly among all programs.
- An hourly fee for any other work DEQ must do on behalf of a drug take-back program
 - Hourly fee will not exceed \$250 per hour.
 - DEQ will bill other work at an hourly fee calculated to reasonably reflect DEQ's actual costs.
 - If multiple programs exist, DEQ will make a reasonable effort to divide the fee by:
 - Charging DEQ's costs associated with a specific program to that program; and
 - Splitting the balance evenly among all programs.

Additional provisions for rule concept:

- DEQ will report its past and projected program revenue and expenditures yearly.
- At its discretion, DEQ may include the costs of other work in the annual fee instead of charging the hourly fee for that work.
- If revenue from the plan review fee, annual fee and hourly fee for other work exceeds DEQ's actual costs for program work in a given year, DEQ will reduce the annual fee by the excess amount in a subsequent year.

Alternative formats

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

Draft Fiscal Impact Statement

Drug Take-Back Program 2020 Rulemaking

Introduction

The Oregon legislature adopted HB 3273 (2019) establishing a drug take-back program in Oregon. The bill also requires DEQ to adopt rules for that program.

DEQ invites public input on proposed permanent rule amendments to chapter 340 of the Oregon Administrative Rules. The proposed rule amendments will support DEQ's oversight of statewide drug take-back programs in Oregon. Such programs will be product stewardship programs offering safe and secure collection, transportation, and disposal of prescription, over-the-counter, brand, and generic drugs. Manufacturers of drugs covered by ORS 459A.200 and sold in Oregon are required to participate in such programs. Program operators will develop and implement the programs under program plans approved by DEQ. DEQ will provide oversight to ensure that these programs comply with ORS 459A.200 through ORS 459A.266 and program plans. All DEQ-approved programs must be operational by July 1, 2021.

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 through ORS 459A.266. EQC authority to act on the proposed fees is ORS 459A.242.

Brief description of proposed fees

The proposed rules would establish:

- A one-time fee for reviewing a drug take-back program plan;
- 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 of drug take-back programs or proposed drug take-back programs. If DEQ approves multiple programs, DEQ will apportion its annual and hourly fees by charging costs associated with a particular program

to that program and dividing the remainder evenly among the number of approved programs.

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 through ORS 459A.266.

Fee proposal alternatives considered

DEQ considered the following alternatives:

- Maintain the status quo by not establishing fees. This would cause DEQ to disregard legislative direction under ORS 459A.242 to establish these fees.
- Apportion the annual and hourly fees, if multiple drug take-back programs exist, by the number of the drug manufacturers participating in the respective programs. This may be difficult to implement if manufacturers switch programs during program years. In addition, DEQ's proposed allocation, apportioning the portion of the fee associated with costs related to a specific program and dividing the remainder evenly among the number of programs, better approximates the amount of work DEQ has spent on a specific program and the amount of time and resources DEQ has spent on behalf of all programs.
- 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 would require programs to disclose the market data of their participants and may be administratively burdensome for both DEQ and program operators. It would also be difficult to implement if manufacturers switch programs.

Fee payer

Entities seeking to operate drug take-back programs in Oregon will pay the one-time plan review fee. Program operators of DEQ-approved drug take-back programs will pay annual and hourly fees on behalf of the drug manufacturers participating in their respective programs.

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.

DRAFT

Persons submitting a plan to operate a drug take-back program will pay a one-time fee of \$75,000 for DEQ's to review their proposed plan. The fee is due with the initial plan submission. Due to the complexity of operating a drug take-back program that can meet the requirements of ORS 459A.200 through ORS 459A.266, DEQ anticipates receiving only one or two program plans.

Program operators with approved drug take-back programs will pay an annual fee not to exceed \$345,000 in the first year and \$210,000 in subsequent years. DEQ will calculate the annual fee each year to reasonably reflect DEQ's ongoing costs in administering the Drug Take-Back Program. If multiple drug take-back programs exist, the combined sum of their annual fees will not exceed \$345,000 in the first year and \$210,000 in subsequent years.

Program operators with approved drug take-back programs will pay an hourly fee for any other work DEQ must do on behalf of a drug take-back program. The hourly fee will not exceed \$250 per hour. DEQ will calculate the combined amounts of the annual and hourly fees to reasonably reflect DEQ's total annual costs for administering the Drug Take-Back Program.

Other proposed rules not related to fees will result in a small increase in administrative costs. These proposed rules relate to requirements for DEQ and drug take-back programs under laws set forth in ORS 459A.200 through ORS 459A.266. The law requires a program operator to submit a plan for proposed drug take-back programs to DEQ. The plan must include the contact information of all manufacturers participating in the program. One proposed rule requires a program operator to also include the license number each participating manufacturer's Oregon Board of Pharmacy license number. This may result in an incidental administrative cost to program operators and drug manufacturers.

Another proposed rule relates to the requirement that a drug take-back program provide convenient statewide service. The law defines convenient statewide service as including at least one drop-off site in each county in Oregon. This is a location where drugs can be disposed of in-person. There must also be additional sites in each population center, defined as a city or town and the unincorporated area of the county within 10 miles from the center of the city or town. However, the law allows DEQ to waive the requirement for program operators to establish drop-off sites in a particular county if an operator describes how the program will offer mail-back service in that county.

The law also allows DEQ, when a drug take-back program is unable to establish or maintain a required drop-off site, to approve additional services, such as mail-back services and collection events. This allows a drug take-back program to continue providing convenient service in the affected area. DEQ has proposed a rule specifying DEQ's criteria for waiving drop-off sites in a particular county and for approving services in lieu of a required drop-off site.

A program operator will have administrative costs associated with demonstrating how it meets DEQ's criteria, which include:

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

Program operators seeking a waiver or DEQ approval for additional services in lieu of establishing and maintaining a required drop-off site would also bear costs associated with seeking local government concurrence and soliciting potential authorized collectors on at least an annual basis. Program operators can avoid these costs by establishing and maintaining the number of drop-off sites required by law and by their DEQ-approved program plans.

Fee payer agreement with fee proposal

DEQ will consider advisory committee input and 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 through ORS 459A.266:

https://www.oregonlegislature.gov/bills_laws/ors/ors459A.html

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	2020 FY21	2021 FY22	2022 FY23	2023 FY24
Annual operating costs	\$184,000	\$191,000	\$106,000	\$111,000

Table 1 Drug Take-Back Program Revenue Need				
Repay loan and create operating balance	\$236,000	\$19,000		
Revenue need	\$420,000	\$210,000	\$106,000	\$111,000

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

Proposed Fees		
Expected change in revenue in FY 2021 (+/-)	\$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	One-time fee will apply by November 1, 2020. First annual fee expected to be charged no later than June 30, 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.

Transactions and Revenue				
Biennium	Number of transactions	Number of fee Payers	Impact on revenue (+/-)	Total revenue (+/-)
Current biennium	2-4	1-2	\$420,000	\$420,000
Next biennium	1-2	1-2	\$316,000	\$316,000

Transactions and Revenue
<p>Number of transactions and fee payers, impact on revenue, and total revenue are estimated and based on the assumption of one to two program operators submitting program plans and DEQ approving one to two programs. If DEQ approves both programs, then each program operator will pay through two transactions in current biennium: (1) paying one-time plan review fee and (2) paying first annual fee. If DEQ approves multiple programs, DEQ will divide the revenue need among all programs, as described in “Brief description of proposed fees,” above.</p>

Fee schedule

Table 1 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	
Maximum fee – first annual fee	\$345,000
Maximum fee – subsequent annual fees	\$210,000
<p>If multiple drug take-back programs exist, DEQ will make a reasonable effort to divide the fee by charging DEQ’s operating costs associated with a specific program to that program and splitting the balance evenly among all programs.</p>	
Hourly Fee for Other Work on Behalf of a Drug Take-Back Program	
Maximum hourly fee	\$250
<p>If multiple programs exist, DEQ will make a reasonable effort to divide the fee by charging DEQ’s costs associated with other work on behalf of a specific program to that program and splitting the balance evenly among all programs. DEQ will charge at actual hourly rate not to exceed the maximum hourly fee.</p>	

Statement of fiscal and economic impact

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 and additional administrative costs for complying with proposed rules. These proposed rules and their associated costs are described above under “Summary of Impacts.”

The fiscal burden on affected businesses will be reduced by the fact that a large number of drug manufacturers will share the cost. Based on inquiries DEQ has received and the complexity of operating drug take-back programs, DEQ anticipates that at most two entities will submit plans to operate a drug take-back program 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 and the Oregon Board of Pharmacy’s website lists over 2,000 drug manufacturers registered to sell drugs into Oregon. DEQ may not require all manufacturers to participate in drug take-back programs in Oregon.

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 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, DEQ’s combined one-time plan review fee and maximum first annual fee (\$420,000) would represent approximately 10.5% of a drug take-back program’s annual operating costs. After the first year startup, subsequent annual fees will not exceed \$210,000, or approximately 5.3% of the estimated overall annual cost. 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 further pass this cost on to other entities in the drug supply and distribution chains or onto consumers. Entities in the drug supply and distribution chains include wholesalers, insurance providers and distributors, such as pharmacies, and healthcare providers. The United States 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 <https://www.gao.gov/assets/690/688472.pdf>. As also mentioned, 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 on 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 discussed 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 discussed 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.

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

Entities that submit a plan to DEQ for operating a drug take-back program would have to pay the one-time plan review fee. If DEQ approves the plan, the program operator will then pay the annual fee and hourly fee as needed. Participating drug manufacturers will fund approved programs, some of which may be small businesses. Program operators and drug manufacturers will likely handle payment of DEQ's fees within the administrative processes the program operators develop for their approved programs. ORS 459A.242 directs DEQ to set these fees.

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

- Entities submitting a program plan to operate a drug take-back program must include each participating drug manufacturer's Oregon Board of Pharmacy license number.
- Entities acting as a program operator and seeking a waiver from establishing drop-off sites in a particular county, or seeking DEQ approval to provide additional services and collection events where it is unable to establish and maintain a required drop-off site, must provide information in their request for a waiver or approval. This could include why a drop-off site cannot be established or maintained and how the proposed services will continue to provide convenient service. Such a 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. Seeking a waiver or DEQ approval is optional and not required if a drug take-back program is able to establish and maintain all drop-off sites required by law and its program plan.

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: https://www.doh.wa.gov/Portals/1/Documents/2300/2019/Med-ProjectProgramProposal.pdf
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: https://www.gao.gov/assets/690/688472.pdf

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 will review the draft fiscal and economic impact statement.

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 because 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.

Drug Take-Back Program 2020 Rulemaking

Meeting Summary

Rulemaking Advisory Committee Meeting #1

Date: March 24, 2020

Location: Teleconference

List of attendees:

Advisory Committee

Members

- Scott Barrie
- Rob Bovett
- Marcus Cox
- Allyn Cripe
- Naomi Hunsaker
- Shawn Miller
- Steven Miller
- Marc Rizzo
- Joseph Schnabel
- Cara Simaga
- Suzie Smith
- David Spangler
- Donna Steward
- Jim Wilson
- Scott Winkels

DEQ Staff

- Michael Lee
- Jill Inahara
- Abby Bourdouris
- Loretta Pickerell
- Blake Bennett
- Camilla Picollo

Members of the Public

- Ashley Schmidt
- Chris Desiderati
- David Skakel
- Eric Lintner
- Grant Feichtinger
- Jenny East
- John Day

Members of the Public cont'd

- Joanie Cosgrove
- Julio Rios
- Leah Rabkin
- Kristin Alstad
- Nicole
- Scot Ziegler
- Scott Klag
- Sharon Olson
- Victoria Travis
- Wendy Janey



State of Oregon
Department of
Environmental
Quality

Materials Management

700 NE Multnomah St.,
Suite 600
Portland, OR 97232
Phone: 503-229-5696
800-452-4011
Fax: 503-229-6124
Contact: Michael Lee

www.oregon.gov/DEQ

*DEQ is a leader in
restoring, maintaining and
enhancing the quality of
Oregon's air, land and
water.*

Time Agenda Topic

- | | |
|------------|--------------------------------------|
| 12:00 p.m. | Welcome, Overview of Today's Meeting |
| 12:10 p.m. | Introductions |
| 12:30 p.m. | Presentation on Drug Take-Back |
| 1:00 p.m. | Discussion: Proposed Rule Concepts |
| 1:30 p.m. | Discussion: Other Issues |
| 2:00 p.m. | Opportunity for Public Input |
| 2:15 p.m. | Adjourn meeting |

Meeting Summary

Welcome, Overview of Today's Meeting

Jill Inahara facilitated the meeting. She opened the meeting and noted the shortened meeting time from the original agenda. Jill went over the agenda and explained that the rulemaking advisory committee's primary purpose is to advise DEQ on rulemaking related to the Drug Take-Back Program, which was established by House Bill 3273 (2019). DEQ has identified the few rules needed for program implementation. Discussion will be limited to DEQ and committee members until 2 p.m., when the public will have an opportunity for input. The original agenda scheduled time for public input from 3:30

pm – 4 pm. Jill and Michael Lee will check the teleconference line at 3:30 pm in case any members of the public call in at that time.

Presentation on Drug Take-Back

Michael Lee presented on HB 3273, the committee’s role in rulemaking, and the rulemaking timeline. Manufacturers of drugs HB 3273 covers must participate in a product stewardship program in Oregon if they manufacture covered drugs sold in Oregon. Program operators, who will develop and implement drug take-back programs for drug manufacturers, must submit program plans to DEQ by 11/1/20. All drug take-back programs must be operational by 7/1/21. DEQ intends to propose rules to the Environmental Quality Commission in September. Committee will give input on DEQ’s rule concepts at this meeting and fiscal impact of the rules in the second meeting. Michael previewed the fiscal impact issues to be discussed in the second meeting. In considering fiscal impact, DEQ will be seeking the committee’s recommendations on four questions:

- Whether the rule will have a fiscal impact
- What the extent of that impact will be
- Whether the rule will have a significant adverse impact on small businesses
- And if so, what DEQ can do to reduce the adverse impact on small businesses

A question was raised about whether hazardous waste programs could act as authorized collectors and enter into agreements with drug take-back programs to operate sites where people can drop off drugs for disposal. HB 3272 allows the following to be authorized collectors: law enforcement agencies and persons who are registered with the DEA who qualify under federal law to collect and dispose of controlled substances or qualify under federal law to have their registration modified in such a way to authorize the person to collect and dispose of controlled substances.

A question was raised about whether a pharmacy or law enforcement agency on tribal land can operate a drop-off site. DEQ will seek clarity on this point and provide a response after the meeting.

Discussion: Proposed Rule Concepts

Michael presented on DEQ’s proposed rule concepts.

Rule concept #1: Criteria for services in place of drop-off sites

HB 3273 requires a drug take-back program to provide convenient statewide service, including a drop-off site in each county and additional drop-off sites, based on number of residents in a city or town, for each city or town, and the unincorporated area of the county within a 10-mile radius from the center of the city or town. HB 3273 allows DEQ to waive drop-off sites in a specific county if a program describes in its plan how it will provide mail-back services in the county. In addition, where a drug take-back program is unable to establish and maintain a sufficient number of drop-off sites to meet the requirements for plans, DEQ may approve a program to provide additional services, such as mail-back services, and hold collection events to ensure the program provides the convenient service for the area affected.

Proposed rule concept: to obtain a waiver or DEQ approval of services in lieu of a required drop off site, a drug take-back program must:

- Demonstrate good-faith efforts to solicit and enter into agreements with potential authorized collectors;
- Demonstrate why a drop-off site cannot be established or maintained;

- Demonstrate local government concurrence with alternate services being proposed or reasons why such concurrence could not be obtained with good faith efforts;
- Describe how proposed alternative services will be designed and implemented to provide convenient service for all residents;
- Agree to solicit potential authorized collectors for the affected county, city or town on at least an annual basis.

Rule concept #2: Fees

HB 3273 requires DEQ to establish three types of fees, to be paid by program operators. DEQ proposes to structure the fees as follows:

- One-time fee for plan review – this will be a flat fee due with initial plan submission.
- Annual fee for DEQ’s ongoing costs of administration – set a cap or ceiling in rule that annual fee may not exceed. DEQ will notify program operators of actual fee each year. Fees could be higher or lower depending on ongoing costs of oversight. DEQ will report program revenue and expenditures annually.
- Hourly fee for other work – set a cap or ceiling in rule that hourly fee may not exceed. DEQ will charge hourly fee that reflects actual cost to DEQ. DEQ will bill quarterly. Examples of other work: third-party audits, litigation, and doing work that program should be doing.

If multiple programs exist, DEQ proposes to split the annual and hourly fees as follows: DEQ will make reasonable efforts to charge program-specific costs to a specific program and will split remainder equally among the multiple programs.

Committee comments: Scott Barrie and David Spangler expressed concern that there was no cap on the total amount that DEQ could charge through the hourly fee. DEQ could escalate the cost unnecessarily through extended back-and-forth with a program. Also, nothing would preclude DEQ from using the fee to bring more money into agency or state rather than for the Drug Take-Back Program’s use.

DEQ staff clarified that HB 3273 requires fees to be reasonably calculated to cover DEQ’s costs of administering the Drug Take-Back Program. DEQ also stated that, as contemplated in proposed rule concept, the ongoing back-and-forth between DEQ and a program would likely fall under the cost of the annual fee, which does have a ceiling. The hourly fee would be for other work, such as a third-party audit or litigation.

Rule concept #3: Require program plan to include Board of Pharmacy license numbers for participating manufacturers

HB 3273 requires program plans to list manufacturers participating in their proposed program. This rule concept would require plans to include the participating manufacturers’ Board-of-Pharmacy-issued license numbers. This rule concept would help DEQ identify which manufacturers are participating in a drug take-back program, per HB 3273.

Rule concept #4: Delegation of enforcement and discipline powers

HB 3273 provides the EQC with enforcement and discipline powers to ensure participation in drug take-back programs and compliance with HB 3273. This rule concept would delegate EQC’s enforcement and discipline powers under HB 3273 to DEQ.

Discussion: Other Issues

Shawn Miller expressed interest in proposing a rule concept to clarify HB 3273’s exemption for biologics from the definition of “covered drugs.” Shawn will email the concept to Michael, who will share with the

committee. Other committee members were invited to email Michael if they have ideas for other rule concepts.

The committee then discussed potential issues beyond rulemaking for DEQ to consider in implementing the Drug Take-Back Program. As part of the discussion, committee members shared their experiences with local or private drug take-back programs. Issues include:

- Drop-off sites overfilling too quickly or not being located in a safe or visible place;
- Difficulties in maintaining an up-to-date list of drop-off sites;
- Whether existing drop-off sites can transition to a HB 3273 drug take-back program and how to support this transition (such as through the use of toolkits);
- Whether existing programs must close when the statewide program starts;
- Whether a drug take-back program must accept all existing drop-off sites into the program, or only enough to meet the convenience standard;
- Whether DEQ has collection goals for the Drug Take-Back Program;
- Challenges in rural counties;
- How drug take-back programs will serve unincorporated areas of a county;
- How to address unexpected situations such as COVID-19, which may impact how drop-off sites and other collection services should be managed; and
- Whether drop-off sites operating outside an HB 3273 program can be counted towards a program's convenience standard.

DEQ staff stated that HB 3273 does not prohibit local or private drop-off sites from continuing to exist after the statewide program starts. HB 3273 requires a drug take-back program to enter into agreements with all willing potential authorized collectors. DEQ will provide additional responses after this meeting to the questions raised.

Opportunity for Public Input

With no additional items, Jill moved to the opportunity for public input. Members of the public noted additional online resources for locating drop-off sites and asked if the meeting materials will be on the webpage. DEQ staff noted that the advance meeting materials had been taken down in error when the revised agenda was posted. DEQ will post the advance meeting materials as well as the meeting presentation. Another member of the public asked DEQ to clarify who will be doing the oversight. DEQ stated that DEQ will be doing the primary oversight, but DEQ and BOP will coordinate on inspection and enforcement.

With no additional comments, the meeting was adjourned. Jill and Michael checked the teleconference line from 3:30 pm to 4 pm. No one else joined the line.

Action Items

Cami Picollo will resend the Doodle poll for second committee meeting.

DEQ will post meeting materials and provide additional responses to questions raised at the meeting.

Alternative formats

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

Responses to Questions about Drug Take-Back Program

Drug Take-Back Program 2020 Rulemaking

To help provide better understanding of Oregon’s Drug Take-Back Program, DEQ is sharing written responses to questions raised during the Drug Take-Back Program 2020 Rulemaking Advisory Committee’s first meeting, on March 24, 2020. These responses are intended to supplement information set forth in the Drug Take-Back Law ([ORS 459A.200 to 459A.266](#)). DEQ encourages the public and interested parties to consult the Drug Take-Back Law for a more complete understanding of the drug take-back law’s requirements.

What will drug take-back programs approved under the Drug Take-Back Law provide?

Drug take-back programs approved under the state program must offer statewide convenient service free of charge to Oregon residents and other specified entities for the collecting, transporting and disposing of prescription and OTC drugs. Collection services include: drop-off sites where people can drop off drugs intended for disposal; a mail-back service option that is prepaid by the program and available on request; and providing mail-back service supplies to an in-home hospice service provider, on request, for use by the hospice services patient. Programs may also offer collection events.

The drugs covered and entities that must be served by a drug take-back program are identified in ORS 459A.200.

How will drug take-back programs be funded and who will operate them?

Drug manufacturers will fund programs. Program operators will develop and implement by program operators, which must be 501(c)(3) organizations.

When will the programs go into effect?

Entities interested in operating drug take-back programs must submit a program plan by November 1, 2020, to DEQ for approval. DEQ will update its website with additional information about how to submit a plan in the coming months. Approved drug take-back programs must begin operations no later than July 1, 2021.

How is DEQ providing oversight of drug take-back programs?

DEQ’s administrative responsibilities will include reviewing and approving drug take-back program plans and changes to program plans and ensuring a program complies with its approved plan and the Drug Take-Back Law. DEQ will share inspection and enforcement responsibilities with the Oregon Board of Pharmacy.

Does the law require a certain number of drop-off sites?

Yes. The law requires that convenient statewide service include at least one drop-off site in each county in Oregon and for each population center (defined as a city or town, and the unincorporated area of the

county within 10 miles from the center of the city or town). There must be an additional drop-off site for every 50,000 residents of the city or town located within a population center.

The law allows DEQ to waive required drop-off sites for a particular county if the program operator, in its program plan, describes how the proposed program will offer mail-back service in that county. Additionally, if a drug take-back program is unable to establish or maintain a required drop-off site, the law allows DEQ to approve additional services, such as mail-back services and collection events, so that a drug take-back program can continue to provide convenient service in the affected area.

Will a drug take-back program serve the unincorporated areas of a county?

Yes. Unincorporated areas of a county within the 10-mile radius of a city or town are considered part of a population center. A drug take-back program must establish a drop-off site in each population center in Oregon and additional sites for every 50,000 residents in the city or town located within the population center. Drop-off sites required for a population center must be located to provide reasonably convenient and equitable access to all residents of the population center.

Who can operate a drop-off site?

Authorized collectors will enter into agreements with a program operator to operate drop-off sites. Under ORS 459A.200,

“Potential authorized collector” means:

(a) A person that:

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

(B) Qualifies under federal law to collect and dispose of controlled substances, or qualifies under federal law to have the person’s registration modified in such a way that authorizes the person to collect and dispose of controlled substances.

(b) A law enforcement agency.

How many drug take-back collection sites does Oregon currently have?

At last check in October 2019, DEQ, working with Oregon Association of Clean Water Agencies (ORACWA), found at least 115 collection sites in Oregon. More information about these sites can be found on DEQ’s website at <https://www.oregon.gov/deq/Hazards-and-Cleanup/hw/Pages/Pharmaceuticals.aspx>.

What will happen to existing collection sites? Will they be rolled into a statewide program?

The Drug Take-Back Law does not require existing collection sites to roll into a statewide program. They may continue to operate outside a DEQ-approved drug take-back program in compliance with applicable laws. Alternatively, if they qualify as potential authorized collectors, they may choose to enter into agreements with approved drug take-back programs to operate drop-off sites within a state program. ORS 459A.215 requires a program operator, before submitting a program plan to DEQ, to solicit potential authorized collectors and enter into agreements with all willing authorized collectors to collect covered drugs under the drug take-back program.

Can a potential authorized collector become an authorized collector if a drug take-back program already has enough drop-off sites to meet the law’s requirements for convenient statewide service?

Yes. The law does not preclude a drug take-back program from establishing more drop-off sites than the minimum required for convenient statewide service. Additionally, the law requires a program operator, before submitting a program plan to DEQ, to enter into agreements with all willing authorized collectors to collect covered drugs under the drug take-back program. Such agreements must require an authorized collector to comply with all state laws and rules and federal laws and regulations governing keeping covered drugs, as Oregon Board of Pharmacy identifies by rule. Otherwise, program operators will negotiate the terms of such agreements with potential authorized collectors,

Can a collection site outside the statewide program be counted towards the convenience standard of the statewide program?

No. If a collection site is not being operated as part of an agreement between a statewide program operator and an authorized collector, a program operator may not count it towards the number of drop-off sites the program operator must establish to ensure statewide convenience.

Will tribal people in Oregon have access to an approved drug take-back programs?

Yes. Approved drug take-back programs must serve residents of Oregon. Tribal people are considered state residents.

Will there be a comprehensive list of drop-off sites?

Approved drug take-back programs must publicize information on the location of drop-off sites and collection events. DEQ will encourage programs to provide such information through the use of a website.

Alternative formats

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.

Drug Take-Back Rulemaking Advisory Committee

Materials Management

April 28, 2020
Webinar

Overview of Drug Take-Back Program

DEQ

- ✓ Reviews plans
- ✓ Approves changes to programs
- ✓ Oversees compliance with **Board of Pharmacy**
- ✓ Reviews annual reports

Drug take-back programs

- ✓ Convenient statewide service
- ✓ Collect, transport and dispose
- ✓ Promote programs
- ✓ Meet collection and awareness goals
- ✓ Report to DEQ
- ✓ Conduct survey on program

Manufacturers



**Drop-off Sites,
Mail-Back, Other
Collection Services**



**Oregon residents,
nonbusiness entities
and ultimate users**



**Incinerator
(pharmaceutical
waste)**

**Hazardous
waste facility**

Anticipated Rulemaking Timeline

Today



- Give input on fiscal impact

Rule Concepts Review

Rule Concepts on Enforcement

Concept:

Require program plan to list Board of Pharmacy license numbers

Concept:

Delegate EQC enforcement and discipline powers to DEQ



Rule Concept: Criteria for Services in Place of Drop-Off Sites

- Good-faith efforts
- Why can't a drop-off site be established or maintained?
- Local government concurrence?
- How will alternate services provide convenience?
- Continue to solicit annually



Rule Concept: Fees

Type of Fee	Who Pays
One-Time Fee	Entities Submitting Plans
Annual Fee	Program Operators and Drug Manufacturers
Hourly Fee	Program Operators and Drug Manufacturers

Fees: General Provisions

- Fees reasonably calculated to cover DEQ's costs
- DEQ will report program revenue and expenditures yearly
- Rule will set ceilings for annual fees and hourly fee rate
- If revenue exceeds actual costs in a given year, DEQ will reduce annual fee by excess in a subsequent year.

One-Time Fee

- \$75,000 per plan and updated plan
- Due with initial plan and plan updates
- Plans must be updated at least once every four years

Annual Fee

- For ongoing costs of administration
- First year: won't exceed \$345,000
- Subsequent years: won't exceed \$210,000
- Billed upon DEQ's approval of all plans

Hourly Fee

- For any other work on behalf of a drug take-back program
- Fee cap: \$250 per hour

If Multiple Programs Exist



Divide annual and hourly fees:

- Charge program-specific costs to program
- Split the balance evenly

Questions?



Fiscal Impact Statement

Input on Fiscal Impact

Answer four questions:

- Fiscal impact?
- Extent of impact?
- Significant adverse impact on small businesses?
- If so, what DEQ can do to reduce adverse impact on small businesses?

**Do not consider impact of statutory requirements*

Direct fiscal impact

Yes: fees and administrative costs.

- Prospective and approved program operators
 - Likely 1-2 small businesses
- Participating drug manufacturers
 - Likely hundreds
 - Most will be large businesses; some may be small

Indirect fiscal impact

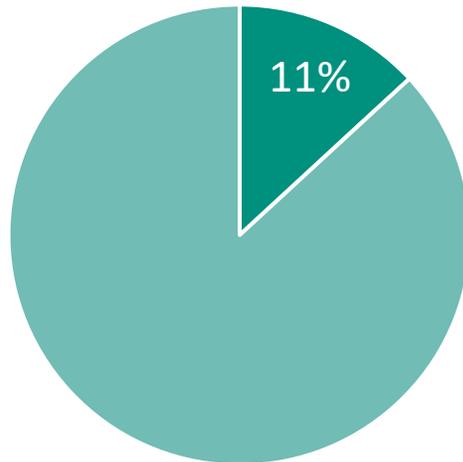
Possible:

- Increase in supply and distribution costs
- Increase in drug prices

Extent of fiscal impact

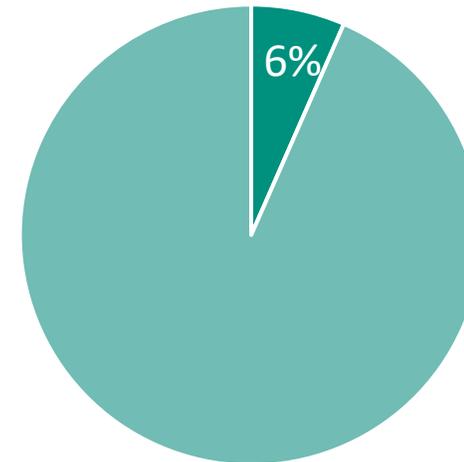
Est. annual operating cost of a drug take-back program: \$4 million

Proportion of DEQ's plan review fee and maximum first annual fee to total annual operating cost



■ DEQ plan review and first annual fee ■ Other operating costs

Proportion of DEQ's annual cap in subsequent years to total annual operating cost



■ DEQ's annual cap after year 1 ■ Other operating costs

Extent of fiscal impact

Other considerations:

- Impact will be spread among manufacturers (likely hundreds)

Fiscal Impact Questions

1. Fiscal impact?

- Yes, in fees and administrative costs
- Direct impact on prospective and approved program operators and participating drug manufacturers
- Possible indirect impact on businesses in drug supply and distribution chains and drug purchasers

Fiscal Impact Questions

2. Extent of fiscal impact?

- Direct impact:
 - Small relative to a program's operating costs
 - Can be spread among participating manufacturers
- Indirect impact: likely negligible

Fiscal Impact Questions

3. Significant adverse impact on small businesses?

- No.
- Program operators and some drug manufacturers may be small businesses
- But direct impact is small relative to operating costs and will be spread among manufacturers
- Indirect impact likely negligible

4. If so, what can DEQ do to reduce that impact?

- N/A

Bonus Question

Effect on development cost of a 6,000-square-foot parcel and construction of a 1,200-square-foot detached, single-family dwelling on that parcel?

- No or negligible impact

Questions?





State of Oregon
Department of
Environmental
Quality

State of Oregon Department of Environmental Quality
**Drug Take-Back Rulemaking
Committee Member Rule Concepts**

April 10, 2020

Mr. Michael Lee
Oregon Rules Advisory Committee Chair, HB 3273
Oregon Department of Environmental Quality
800 Summer St NE
Salem, OR 97310

By electronic mail

Re: HB 3273 State Drug Take-Back Program

Dear Chair Lee:

Thank you for the opportunity for Lines for Life to serve on the Rules Advisory Committee for House Bill 3273. While Lines for Life is excited about the notion of more Oregonians having access to safe medication disposal, we are deeply concerned that without careful implementation this legislation we will fall short of delivering equitable drug take-back access for everyone in our state. More than half of people who misuse prescription opioids obtain them from a friend or relative¹. Oregon has one of the highest rates of prescription opioid misuse in the nation² and prescription drug overdose hospitalizations remain elevated³. Now is the time to act to reduce the number of leftover or expired dangerous opioids and other drugs in circulation in our communities by providing universal access to safe medication disposal.

To effectively expand safe medication disposal access, we call on the DEQ to do the following:

1. Publish all known current authorized collection sites in Oregon publicly for potential program operators to access.

It is essential that the DEQ publish a centralized list of current authorized collection sites accessible to the public and potential drug take-back program operators. By clearly establishing the scope of current drug take-back in Oregon before implementation of the state program, it sets a baseline standard that can be used to track the growth of authorized collection sites in Oregon due to House Bill 3273.

2. Require potential program operators to include all current authorized collection sites in their proposed drug take-back program plan, unless a current authorized collection site opts out.

Current authorized collectors have voluntarily elected to shoulder the burden of Oregon's prescription opioid crisis by providing critical drug take-back services at their own expense. They

are leaders on the forefront of preventing opioid abuse and misuse in their communities. Anything short of enabling all current authorized collectors to participate in the state drug take-back program would be a dramatic step back for the health of all Oregonians.

3. Include Oregon tribal governments and the Indian Health Service as principal partners in the state drug take-back program by allowing their potential authorized collection sites to participate.

There is an urgent need to provide drug take-back services to tribal members on both tribal and state lands. Native Americans die more frequently from prescription opioid overdoses than any other racial or ethnic group⁴. To achieve health equity for all, we must prioritize working together with the sovereign tribal governments and services to build creative community solutions to achieve universal access to safe disposal.

4. Incentivize potential program operators to provide drug take-back services above the convenience standard established in House Bill 3273.

We are troubled that the current convenience standard falls short of establishing universal safe medication disposal for all Oregonians and fails the public health education imperative of the risk of misused opioids. For example, the convenience standard would require a mere 10 disposal locations in all of Multnomah County – which is about how many we have already. 10 locations for all of Portland from the West Hills to Multnomah Falls simply does not represent a serious or even adequate response to the urgent need for disposal.

At bottom, it should be as easy to dispose of opioids as it is to get them in the first place. Accordingly, we urge that the rules adopted be designed to incentivize operators to offer *more* disposal locations than the convenience standard. Our goal, quite simply, should be that every retail pharmacy in the state have a disposal kiosk.

Data demonstrate that pharmacies with disposal kiosks are more likely to educate consumers about safe medication disposal practices and consumers are more likely to utilize these practices in pharmacies with drug take-back receptacles⁵. The goal should be that every potential authorized collector in Oregon participates in the state drug take-back program.

In short, we believe the statutory standard should be the *floor and not the ceiling* for this program – and the rules should be designed to include incentives to exceed the standard.

5. Allow potential or current authorized collection sites to operate independently of the state drug take-back program.

Restricting authorized collection sites would be a direct violation of the essence of House Bill 3273. We need to do everything in our power to increase drug take-back access, not limit it. If authorized collection sites want to continue offering safe medication disposal without participating in the state program, they should be permitted to do so.

We believe these concerns can be summarized as five critical rule concepts for consideration by the Committee:

1. Publish all known current authorized collection sites in Oregon publicly for potential program operators to access.
2. Require potential program operators to include all current authorized collection sites in their proposed drug take-back program plan, unless a current authorized collection site opts out.
3. Include Oregon tribal governments and the Indian Health Service as principal partners in the state drug take-back program by allowing their potential authorized collection sites to participate.
4. Incentivize potential program operators to provide drug take-back services above the convenience standard established in House Bill 3273.
5. Allow potential or current authorized collection sites to operate independently of the state drug take-back program.

Lines for Life looks forward to our continued partnership with the DEQ in order to successfully implement House Bill 3273 and bring universal access for safe medication disposal to our state.

Sincerely



Dwight Holton
Chief Executive Officer
Lines for Life

cc: The Honorable Kate Brown, Governor of Oregon
The Honorable Elizabeth Steiner Hayward, Senate District 17
The Honorable Sheri Schouten, Representative, House District 27
The Honorable Dallas Heard, Representative, House District 2
Caroline Cruz, Sovereign Nation of the Confederated Tribes of the Warm Springs
Reservation
Jackie Mercer, Chief Executive Officer, Native American Rehabilitation Association
Tina Edlund, Office of the Governor
Jeff Rhoades, Office of the Governor
Julie Johnson, Oregon Health Authority
Cami Picollo, Department of Environmental Quality

LEE Michael

From: Miller Public Affairs <Shawn@MillerPublicAffairs.com>
Sent: Thursday, April 9, 2020 9:18 PM
To: LEE Michael
Subject: Re: Drug Take-Back Program Rulemaking Advisory Committee - Revised Agenda

Follow Up Flag: Follow up
Flag Status: Flagged

Michael,

I hope you are doing well.

I wanted to offer a definition of “biologics” for the rules because HB 3273 was inadvertently based on an outdated definition in federal regulations. The definition we suggest is based on newer federal statutory law and reflects a more modern definition of biologics (FDA is working to amend their regulatory definition). The agreement and legislative intent on HB 3273 was to exclude all biologics, which is achieved by using the newer federal definition below...

The term “biologics” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

On behalf of BIO. Thanks.



Shawn Miller
PO Box 12732
Salem, Oregon 97309
503.551.7738 p
Shawn@MillerPublicAffairs.com
www.MillerPublicAffairs.com

On Mar 25, 2020, at 11:24 AM, LEE Michael <Michael.LEE@state.or.us> wrote:

Dear Rulemaking Advisory Committee Members,

Thank you for your attendance and participation yesterday. A question came up about submitting rule concepts to the committee for consideration. I ask that you submit all rule concepts and questions to me or other DEQ staff rather than to the full committee. An email discussion among the full committee can constitute a meeting and be subject to public meeting laws. I will collect other rule concepts and questions and present them in the second meeting.

Thank you for your understanding.

Best,
Michael Lee

From: LEE Michael
Sent: Monday, March 23, 2020 11:53 AM
To: 'CSimaga@STERICYCLE.com'; 'smith@oracwa.org'; 'AllynC@linesforlife.org'; 'rbovett@oregoncounties.org'; 'swinkels@orcities.org'; 'naomi_hunsaker@co.washington.or.us'; 'dsteward@phrma.org'; 'scott@barriehughes.com'; 'jwilson@med-project.org'; 'Joseph.SCHNABEL@oregon.gov'; 'Shawn@MillerPublicAffairs.com'; 'mcox@kodfp.org'; 'marc.rizzo@gmail.com'; 'srmiller@butler.edu'; 'dspangler@chpa.org'
Cc: Drugtakeback2020 ; PICKERELL Loretta ; PICOLLO Camilla ; BOUDOURIS Abby ; BENNETT Blake ; INAHARA Jill
Subject: Drug Take-Back Program Rulemaking Advisory Committee - Revised Agenda

Dear Drug Take-Back Rulemaking Advisory Committee Members,

The online-only meeting tomorrow is now scheduled to run from noon – 2:15 pm. Please see the attached revised agenda and let me know if you have any questions.

Thank you,

Michael Lee
Operations and Policy Analyst
Materials Management Program
Oregon Department of Environmental Quality
Phone: (503) 229-6832
lee.michael@deq.state.or.us