

# Materials Management – Drug Take-Back

## Agenda

### Rulemaking Advisory Committee Meeting #1

Tuesday, March 24, 2020, noon – 2:15 p.m.

Time	Topic
12 p.m.	<b>Welcome, Overview of Today's Meeting</b> <ul style="list-style-type: none"><li>Brief overview of committee's role and DEQ's plan for program rollout</li></ul>
12:10 p.m.	<b>Introductions</b> <ul style="list-style-type: none"><li>Share background and expertise of committee members</li></ul>
12:30 p.m.	<b>Presentation on Drug Take-Back</b> <ul style="list-style-type: none"><li>Gain an understanding of advisory committee's role, program timeline, key provisions of <a href="#">House Bill 3273 (2019)</a> and initial rule concepts</li></ul>
1 p.m.	<b>Discussion: Proposed Rule Concepts</b> <ul style="list-style-type: none"><li>Introduction to DEQ's proposed rule concepts</li><li>Committee discussion of fiscal impact</li></ul>
1:30 p.m.	<b>Discussion: Other Issues</b> <ul style="list-style-type: none"><li>Committee discussion of administrative needs, program rollout issues, concerns</li></ul>
2:00 p.m.	<b>Opportunity for Public Input</b>
2:15 p.m.	<b>Adjourn meeting</b>

#### Teleconference Information

Call-in number: 888-363-4734

Participant ID: 1910322

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

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#### Alternative formats

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Call DEQ at 800-452-4011 or email [deqinfo@deq.state.or.us](mailto:deqinfo@deq.state.or.us).



State of Oregon  
Department of  
Environmental  
Quality

#### Materials Management

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water.*

## Draft Rule Concepts

### Rulemaking Advisory Committee Meeting #1

#### 1. Set criteria for when DEQ may allow a drug take-back program to provide convenient access through other services instead of establishing and maintaining a required drop-off site

Rule Concept: Establish criteria for DEQ's approval of waivers from the requirement to provide a drop-off site in every county in Oregon and for DEQ's approval of additional services and collection events where a drug take-back program cannot establish or maintain the required number of drop-off sites. Draft criteria:

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 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.

Related HB 3273 Sections: Sections 4(3), 7(3)

#### 2. Fees

Rule Concept: DEQ will charge three fees, as required by HB 3273.

- *A one-time fee for reviewing a program plan: \$95,000\**
  - Due with the initial submission.
- *An annual fee for expenses associated with ongoing costs of administering sections 1 to 23 of HB 3273*
  - For ongoing operating costs.
  - Set a cap for annual fee. First annual fee will be higher than later annual fees.  
Example:
    - \$450,000\* – first annual fee
    - \$250,000\* – subsequent years
  - Annual fees will not exceed cap and will reasonably reflect DEQ's actual operating costs.
  - DEQ will report its past and projected program expenditures yearly.
  - If multiple 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.
- *An hourly fee for any other work DEQ must do on behalf of a drug take-back program*



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\* Numbers are preliminary and may change subject to cash flow modeling.

- - For costs beyond ongoing operating costs. Example: audit, litigation.
  - Set cap for an hourly fee (\$300\* per hour). DEQ will bill at an hourly fee reasonably calculated to reflect DEQ's actual costs. Hourly fee will not exceed cap.
  - DEQ will bill quarterly.
  - If multiple programs exist, DEQ will make a reasonable effort to divide the fee by:
    - Charging DEQ's costs associated other work on behalf of a specific program to that program; and
    - Splitting the balance evenly among all programs.

Related HB 3273 Sections: Sections 15, 4(7)

### **3. Requiring Manufacturer License Numbers in Program Plans**

Rule Concept: Program plans must include each manufacturer's Oregon Board of Pharmacy-issued license number.

Related HB 3273 Section: Section 4(2)(a)

### **4. Enforcement and Discipline**

Rule Concept: Delegate EQC's enforcement and discipline powers under HB 3273 to DEQ.

Related HB 3273 Section: Section 14

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## Drug Take-Back Program 2020 Rulemaking Rulemaking Advisory Committee Members

Name	Title	Affiliation
Scott Barrie		Association for Accessible Medicines
Rob Bovett	Legal Counsel	Association of Oregon Counties
Marcus Cox	Chief Pharmacy Officer	Klamath Health Partnership, Inc.
Allyn Cripe	Substance Abuse Community Prevention Program Coordinator	Lines for Life
Naomi Hunsaker	Addictions Program Coordinator	Washington County Department of Health and Human Services
Shawn Miller		NW Grocery Association
Steven Miller	Staff Pharmacist	Cascade Pharmacy
Marc Rizzo	Board Member	Oregon State Pharmacy Association
Joseph Schnabel	Executive Director	Oregon Board of Pharmacy
Cara Simaga	Director, Regulatory Affairs	Stericycle
Suzie Smith	Executive Director	Oregon Association of Clean Water Agencies
David Spangler	General Counsel and SVP of Policy and Government Affairs	Consumer Healthcare Products Association
Donna Steward	Senior Director, State Policy	Pharmaceutical Research and Manufacturers of America
Jim Wilson	Senior Director, Compliance and Risk Management	MED-Project
Scott Winkels		League of Oregon Cities

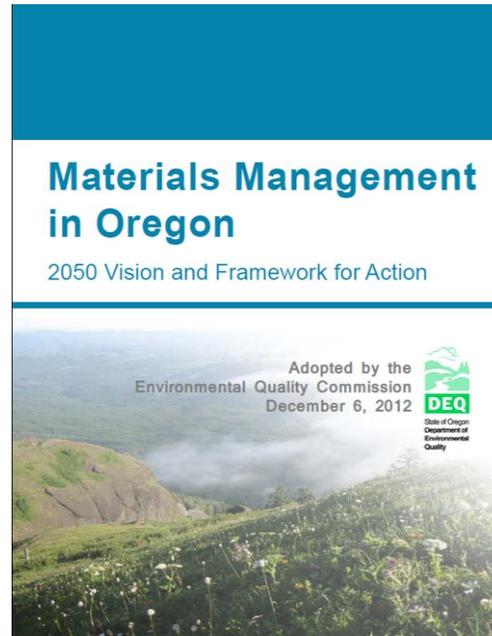
# Drug Take-Back Rulemaking Advisory Committee

## Materials Management

March 24, 2020

Webinar

# Introduction: Materials Management Program



# Role of Advisory Committee in Rulemaking

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## **Give input**

- First meeting: rule concepts
- Second meeting: fiscal impact

# Anticipated Timeline

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# What is Product Stewardship?

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- Sharing responsibility for environmental impacts of consumer goods
- Producers taking most responsibility
- Extended Producer Responsibility (EPR)
  - Manufacturers and program operators develop and implement services
  - Standards set by law, DEQ and program plans

# Overview of Drug Take-Back Program

## DEQ

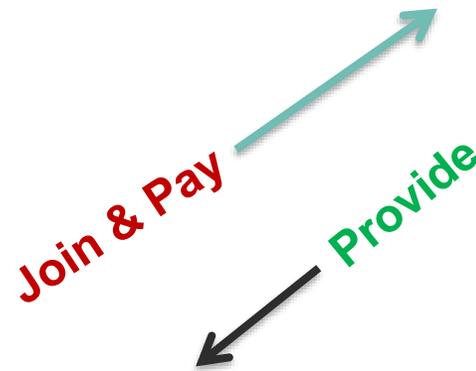
- ✓ Reviews plans
- ✓ Approves changes to programs
- ✓ Oversees compliance with **Board of Pharmacy**
- ✓ Reviews annual reports

## 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

- ✓ Join a take-back program



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



# Who is a drug take-back program for?

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## **“Covered entity” includes:**

- Oregon residents
- Nonbusiness entities
- Ultimate users

## **Does not include:**

- Law enforcement agencies
- Entities that generate pharmaceutical waste:
  - Hospital
  - Health care clinic
  - Veterinary clinic
  - Pharmacy

# What drugs are covered?

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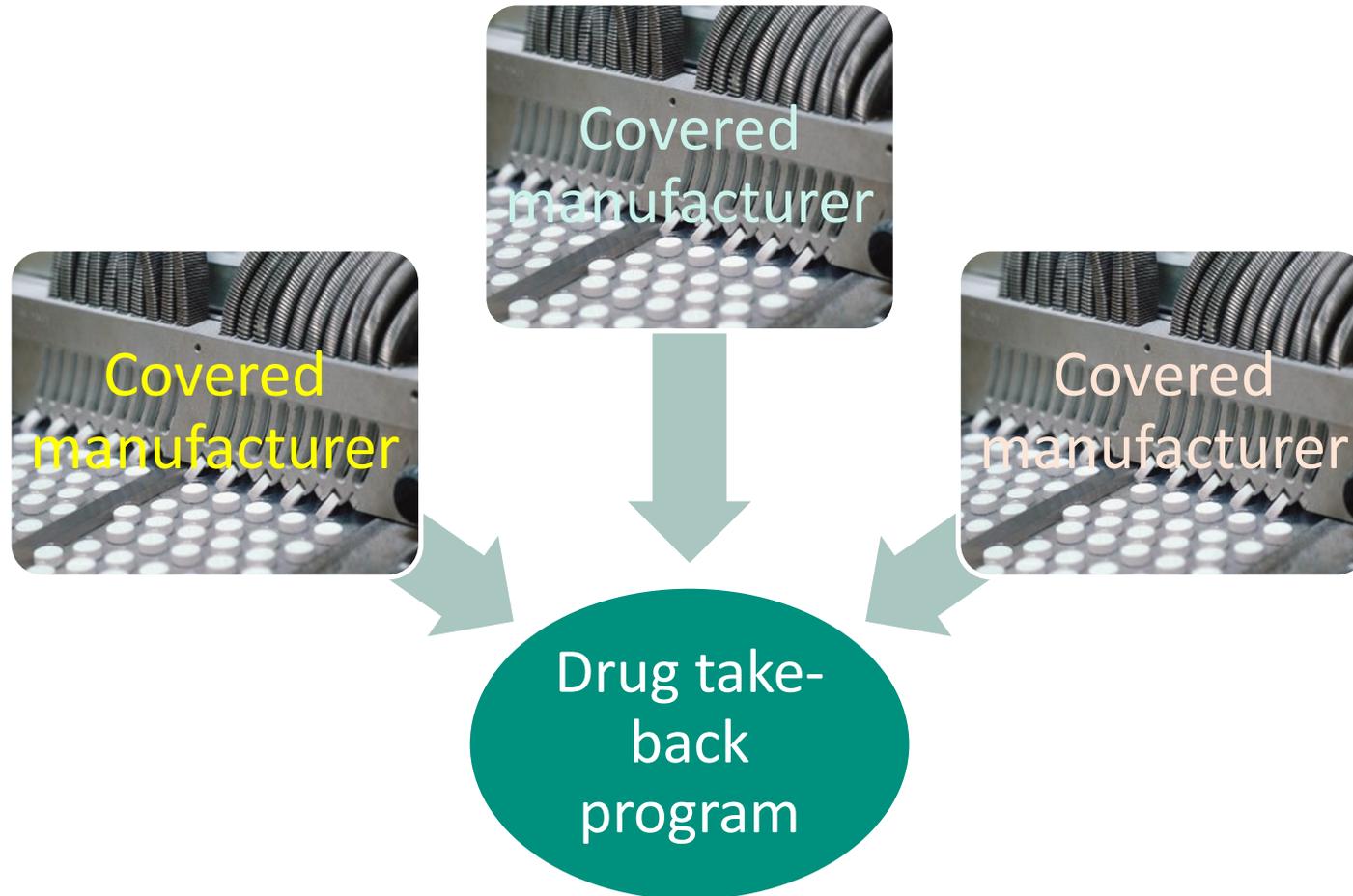
## **Drugs covered:**

- Prescription drugs
- Over-the-Counter (OTC) drugs
- Brand name drugs
- Generic drugs

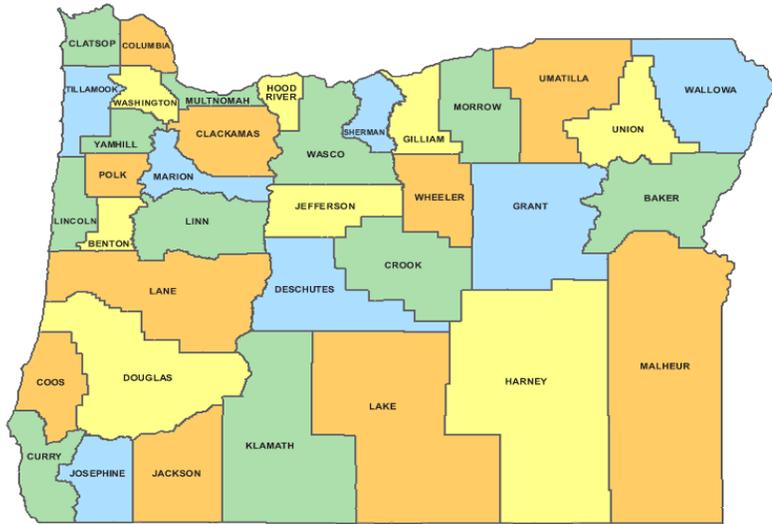
## **Drugs not covered (examples):**

- Exposed sharps
- Drug administered in a clinical setting
- Drugs used for animal medicines
- Biologics

# Requirements for Manufacturers



# What will a drug take-back program provide?



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Convenient statewide service



Collection, transportation, disposal

<https://www.productstewardship.us/page/PSI-Resource-Library#home/product-details2/5d1269195d5d552c26a16ece/>

# Convenient Service

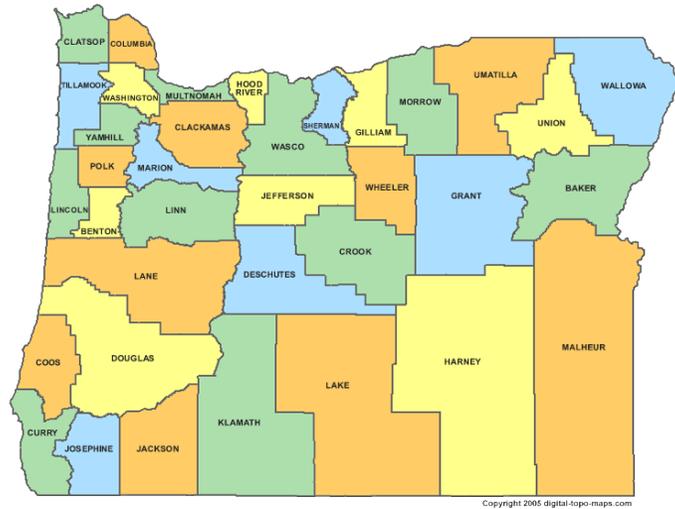


Drop-off site in each county, plus additional sites per population center

# Authorized Collectors for Drop-Off Sites



# Services in Place of a Required Drop-Off Site



Convenient statewide service



<https://www.co.benton.or.us/sheriff/page/special-event-drug-take-back>

# Collection and Public Awareness Requirements

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Outreach and education



Goals for collection  
and awareness

# HB 3273: Reporting and update



- Annual reports
- Biennial surveys



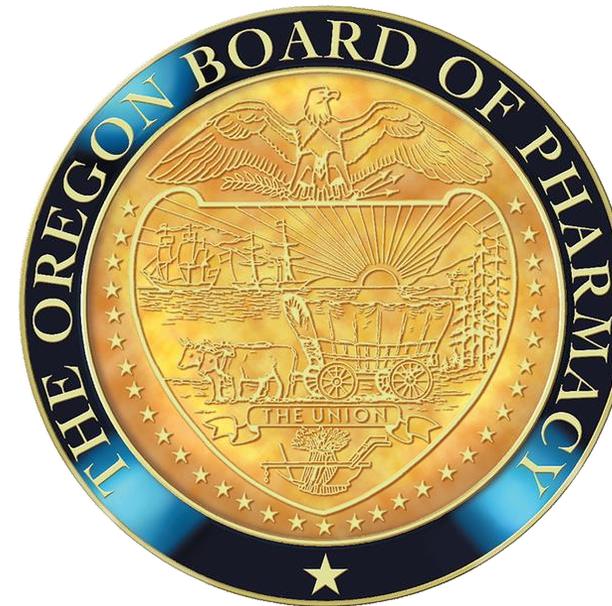
- Plan update to DEQ every four years

# HB 3273: Role of DEQ and Board of Pharmacy

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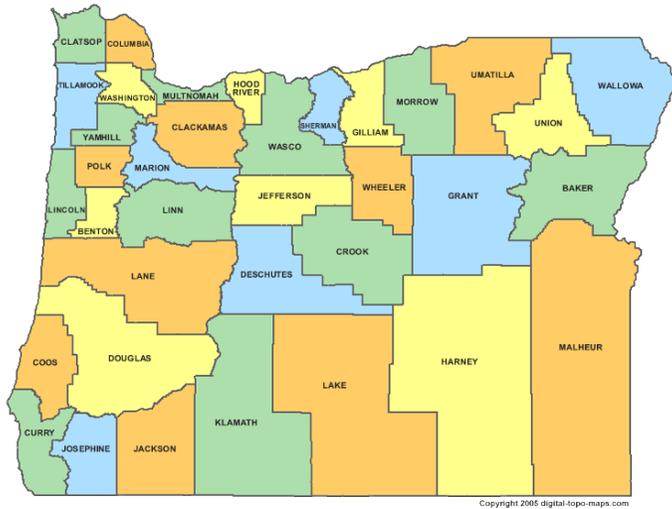


# Questions?



# Draft Rule Concepts

# Concept #1: Criteria for Services in Place of Drop-Off Sites



Convenient statewide service



# Concept #1: 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



# Concept #2: Fees

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## Fee types:

- One-time fee for plan review
- Annual fee for ongoing administration
- Hourly fee for other work

## Who pays:

- Program operators

# Concept #2: One-Time Fee

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## Features:

- Fee for plans and updated plans
- Due with submission of initial plan and plan updates

# Concept #2: Annual Fee

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Annual fee features:

- Define a cap
- Billed with DEQ's approval of all plans

DEQ will report program expenditures

# Concept #2: Hourly Fee

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Hourly fee features:

- Define a cap
- Bill quarterly

Examples of “other work”:

- Audit
- Litigation

# Concept #2: Multiple Programs

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Annual and hourly fees:

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

# Concepts #3 and 4

- Require program plan to list Board of Pharmacy license numbers
- Delegate EQC powers under HB 3273 to DEQ



# Next Time

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## **Give input on fiscal impact**

- Whether rule will have a fiscal impact
- Extent of impact
- Whether rule will have a significant adverse impact on small businesses
- If so, what DEQ can do to reduce the adverse impact on small businesses