Oregon Department of Environmental Quality

Guide for Oregon Drug Take-Back Programs

Disclaimer

This document, and its references to Oregon Revised Statues 459A.200 to 459A.266 and related administrative rules in Oregon Administrative Rules Chapter 340, Division 98 (collectively, the Drug Take-Back Law), are provided for information and guidance only. This guide does not constitute rulemaking by the Environmental Quality Commission and may not be relied upon to create an enforceable right or benefit, substantive or procedural, enforceable at law or in equity, by any person. This guide also does not supplant, replace, or amend any of the legal requirements of the Drug Take-Back Law. An omission or truncation of legal requirements in this guidance document does not relieve a drug take-back program operator or other parties of their legal obligations to fully comply with all regulatory requirements. DEQ anticipates revising this guide or providing additional guidance on drug take-back program submissions periodically as conditions warrant.

Purpose

This guide is intended to assist covered manufacturers and drug take-back program operators in complying with Oregon's Drug Take-Back Law. Oregon's Drug Take-Back Law requires manufacturers of covered drugs sold within Oregon to participate in a statewide drug take-back program for the collection, transportation and disposal of covered drugs that is available to covered entities free of charge. Program operators that develop and implement such programs must submit proposed program plans to DEQ for approval. Each plan must demonstrate that the program will provide statewide, convenient, safe, and secure collection, management, and disposal of covered drugs in compliance with the Drug Take-Back Law and all other applicable state and federal regulations.

Terms used in this guide are defined in Oregon Revised Statues 459A.200 and, for "population center," 459A.209. The Drug Take-Back Law can be found in ORS 459A.200 to 459A.266, with related rules in Oregon Administrative Rules, Chapter 340, Division 98.

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Section I. Manufacturer participation

Covered manufacturers may participate in a drug take-back program as individual manufacturers, a group of manufacturers, or through a drug take-back organization.

Under ORS 459A.203(2), a covered manufacturer is not required to participate in a drug take-back program if it provides sufficient proof to DEQ that it manufactures covered drugs for fewer than 50 patients in Oregon. A manufacturer can claim this exemption by providing a statement to DEQ that the covered manufacturer currently manufactures covered drugs for fewer than 50 patients in Oregon and will notify DEQ within 30 days of beginning to manufacture covered drugs for 50 or more patients in Oregon. The statement should be accompanied by the following declaration: *I/We hereby declare under penalty of false swearing (Oregon Revised Statute 162.075 and ORS 162.085) that the above information and all of the statements, documents and attachments submitted with this claim are true and correct*. Both the statement and declaration should be signed and certified by the manufacturer's chief operating officer or equivalent.

The covered manufacturer may submit additional proof to demonstrate that it manufactures covered drugs for fewer than 50 patients in Oregon. DEQ may also request additional information. For questions about confidentiality of information submitted, please consult Section VII of this guide. The statement may be sent to DEQ by email to drugtakeback@deq.oregon.gov with the subject line "Pharmaceutical Manufacturer – Exemption from Participation in Drug Take-Back Program."

DEQ will notify manufacturers of receipt of statement. DEQ will also maintain a list of covered manufacturers claiming exemption under ORS 459A.203(2) on DEQ's Drug Take-Back Program web page.

Section II. Plan submittal timeline

A program operator must implement and operate a drug take-back program in accordance with a program plan approved by DEQ. An approved plan is valid for four years.

Initial plans: A program operator must submit a one-time plan review fee of $75,000 for an initial plan submitted to DEQ. Please contact DEQ at drugtakeback@deq.oregon.gov regarding payment before submitting an initial plan. Use the subject line: "Drug Take-Back Program – Initial Plan and Plan Review Fee."

Updated plans: A program operator must submit an updated plan no later than four years after DEQ approved the previous plan.

Section III. Plan format

Please use Sections III to V of this Guide for the format, content and submission process for plans, including initial, updated and revised plans.

The plan should include a table of contents that clearly denotes where each required component under the Drug Take-Back Law can be found in the plan.

Please use the outline below. The next section explains these components in greater detail.

1. Definitions
2. Financing
3. Management
4. Operation

5. Education and outreach
6. Goals
7. Closure plan
8. Coordination
9. Implementation timeline
10. Certification and attestation
11. Appendices:
    A. List of participating manufacturers.
    B. List of authorized collectors participating in the plan and established drop-off site locations.
    C. List of potential authorized collectors that the program operator has solicited or plans to solicit.
    D. List of potential authorized collectors that have expressed interest to the program operator about becoming an authorized collector for the program.

Section IV. Plan content

Please include the following information in your plan, and any additional information you believe necessary, to demonstrate that your program will meet the requirements of the Drug Take-Back Law. Please describe the steps and resources you will commit to ensure you implement your plan, if your plan is approved by DEQ, and how DEQ will be able to confirm you are implementing according to your plan.

1. Definitions

The plan should use terms as defined in ORS 459A.200 to 459A.266. The plan may include definitions for any additional terms that are used in the plan.

2. Financing

a. Describe how the program will cover all costs associated with the Oregon drug take-back program, with the costs apportioned among each participating covered manufacturer.
    i. Describe whether the program operator uses generally accepted accounting principles for operations, including for the program operator's collection process and for apportioning all Oregon program costs on an annual basis among each participating covered manufacturer.
    ii. Describe whether the program operator will maintain a minimum ending fund balance from manufacturers for unexpected expenses.
    iii. Describe the process the program operator uses to determine allowance for bad debt and how the full amount of bad debt will be apportioned among participating covered manufacturers.
    iv. To demonstrate compliance with ORS 459A.209(2)(f) and 459A.230, DEQ requests the program operator annually submit Oregon-specific audited financial statements by state that demonstrate all costs of the program operator's Oregon program were collected from participating manufacturers for each program year.
b. Include an estimated annual budget for providing the statewide program, broken down by administrative costs, collection and disposal costs, and communication costs. Please include the following expenses in each category:
    i. Administrative costs. A total for all administrative costs must include, but is not limited to:
        1) Contracted and employed personnel overhead costs;

2) Legal fees;
3) Local and state business licensing fees;
4) Local, state, and federal taxes;
5) Property costs, including rentals;
6) Utilities, phone, and internet; and
7) General equipment and supplies.

ii. Collection and disposal costs. A total for all collection and disposal costs must include, but is not limited to:

1) Collection, transportation, and disposal of drugs;
2) Purchase, maintenance, and replacement of collection repositories;
3) Compensation, including payments, incentives, reimbursement, discounts, rebates, and other financing arrangements, provided to authorized collectors, if separate from personnel costs in Category 1; and
4) Production, distribution, and postage of mail-back envelopes.

iii. Communication costs. Please specify the minimum amount of funds that will be spent on communication costs and whether the program operator will increase spending on communication to achieve public awareness goals. The total for communication costs must include, but is not limited to:

1) Advertising;
2) Marketing;
3) Website creation and maintenance; and
4) Operation of a toll-free phone number.

3. Management

a. Describe the program operator's experience in operating drug take-back programs. Describe how the program's overall day-to-day management will be handled, including management of contracts, record keeping, reporting, and compliance oversight of service providers. Identify and provide the contact information for key personnel responsible for running various aspects of the program, including the authorized representative.

b. Please confirm that the program operator retains legal responsibility to meet all of the program operator's obligations under the program plan and applicable laws and regulations. Please also confirm that the program operator understands that failure to meet its responsibilities under the program plan or the Drug Take-Back Law, regardless of the cause for such failure, could result in enforcement under ORS 459A.239.

c. Does the program operator maintain insurance, including liability insurance, sufficient to ensure the program operator can implement the program successfully and to cover any liability resulting from program operations, such as liability in the event of safety or security incidents?

4. Operation

Describe the statewide network to collect covered drugs from covered entities in Oregon.

a. **Collection system**

Describe how the program will meet the requirements for a collection network under ORS 459A.209, 459A.215, 459A.218, and 459A.221, including, but not limited to:

i. **Solicitation of potential authorized collectors**

1) Describe the program operator's process for identifying, soliciting, and responding to potential authorized collectors.

a) How will the program operator solicit potential authorized collectors to participate in the Drug Take-Back Program? Will the program operator solicit all identified available pharmacies and law enforcement agencies that are not currently participating in a drug take-back program? What is the frequency of this solicitation? Please note whether the program operator will conduct additional solicitation in certain circumstances—for example, upon learning of the loss of a drop-off site by another drug take-back program.

b) Will the program operator enter into agreements with all willing authorized collectors for the purpose of collecting covered drugs?

2) Please confirm whether all authorized collector agreements, per ORS 459A.215(2), will require the authorized collector to comply with all state and federal laws and rules governing the keeping of covered drugs, as identified by the Oregon Board of Pharmacy by rule.

ii. **Drop-off sites**

Describe how the program will meet the convenience requirements of ORS 459A.209(2)(i). Include in detail the geographical distribution of drop-off sites in a county or population center and how they will provide equitable and reasonably convenient access to all residents of that county or population center, including access for minority, lower-income, rural, and other historically underserved communities. Under ORS 459A, "population center" means a city or town and the unincorporated area of the county that is within a 10-mile radius from the center of the city or town. DEQ interprets "city" and "town" to mean an incorporated city and town, respectively, in Oregon. Describe how the program operator will monitor population growth to ensure that it is establishing the minimum number of drop-off sites required by ORS 459A.209(2)(i). For example, the program operator may propose conducting an annual evaluation of drop-off site need based on the most recent Certified Population Estimate provided by the Population Research Center at Portland State University.

1) Describe how the program's policies and procedures will ensure that drop-off sites will provide safe and secure operations required in ORS 459A.218. Include, for example, how the program operator will verify that each drop-off site in its network is open and operational on a regular basis.

2) Include secure repository and inner liner specifications. Describe the repository installation process and how the program operator will confirm that secure repositories are properly installed.

3) Describe repository collection system standards.

4) Describe the general repository service schedule and how it will ensure that repositories avoid reaching capacity and that covered drugs are transported for disposal in a timely manner.

a) How will covered entities be able to report if a repository has reached capacity or if there are other issues with a repository? Include response times for reported issues and how the program operator will maintain records of such reporting to monitor whether a drop-off site has recurring issues and track resolution.

b) Does the program operator monitor drop-off site collection frequency? Is there a time period after which the program operator will schedule a pick-up at a drop-off site if the authorized collector has not done so?

5) Describe how the program operator will ensure, and confirm for DEQ, that all drop-off sites are operating in compliance with the requirements of ORS 459A.218. This may include conducting:

   a) At least semi-annual (twice a year) reviews with each authorized collector in the program operator's network, where the program operator reviews, with the authorized collector, safety and security procedures; repository maintenance and operations to ensure compliance with the Drug Take-Back Law; and instructions for ordering additional liners, supplies, educational materials, and pre-injector packages.

   b) At least an annual in-person inspection of each drop-off site in the program operator's network. One of the semi-annual reviews may be performed during the inspection.

   c) Additional follow-up with specific drop-off sites as needed to ensure compliance with ORS 459A.218.

6) Describe how an authorized collector may notify the program operator of need for additional collections at the drop-off site, when kiosk repairs are needed, or other issues with collection repositories. Include response times for reported issues.

7) Demonstrate that repository signage prominently displays a toll-free telephone number where covered entities can speak to a live person about the drug take-back program and a website where a covered entity may provide feedback to the program operator about the program.

8) Describe how the program operator will ensure that a drop-off site can allow a resident or other covered entity to dispose of covered drugs contained in pre-filled injector products. For example, the program operator may provide each drop-off site with an initial stock of five packages for pre-filled injector products and information for the drop-off site to order more packages for pre-filled injector products from the program operator.

9) Describe how the program operator will ensure that drop-off sites at long-term care facilities will be available for use only to individuals who reside or have resided at those facilities, as required under ORS 459A.218(2)(f).

10) Describe how the program will maintain its network of drop-off sites to continuously ensure convenient service in every county in Oregon, such as by:

   a) Soliciting and entering into agreements at least annually with all willing potential authorized collectors for the purpose of collecting covered drugs under the drug take-back program;

   b) Conducting outreach to minority, low-income, rural and other historically underserved communities; and

   c) Evaluating the need for additional drop-off sites based on population growth on an annual basis.

11) Describe how the program operator, in case of an unplanned security event such as vandalism, a flood, earthquake, or fire, will ensure the security and integrity of drop-off sites. Please include:

   a) The process for an authorized collector to report such unplanned security events and the program operator to respond, including resolution of disagreements regarding the response;

b) How the program operator will promptly notify DEQ of any issues concerning the security and integrity of drop-off site repositories, including possible temporary suspension of services and any disagreement between an authorized collector and the program operator about the response to an unplanned security event; and

c) How the program operator will maintain updated information for the public through its toll-free number and website about the status of any drop-off site affected by an unplanned security event.

iii. **Mail-back services**

Describe how the program, in providing mail-back services, will offer prepaid, preaddressed mailing envelopes to covered entities and in-home hospice providers at no cost, including:

1) How Oregon residents, other covered entities, and in-home hospice service providers can request and get access to the mail-back service option and mail-back service supplies;

2) How the program will track and respond promptly to such requests;

3) How the program operator will track and address any issues with mail-back requests, including unfulfilled mail-back requests, such as by offering covered entities and in-home hospice providers a confirmation email with each request that lists a point of contact that can resolve mail-back issues;

4) Whether the program operator will offer bulk shipment of mail-back supplies to in-home hospice service providers;

5) How the mail-back service option will be promoted so that covered entities and in-home hospice providers know they can access such services by request;

6) An example of the prepaid, preaddressed mailing envelopes to be offered including options for inhalers and pre-filled injector products; and

7) If mail-back envelopes will be offered at locations in a population center, a list of these locations and a description of how the program operator will ensure that mail-back supplies at these locations will be replenished to meet demand.

iv. **Covered drug collection events**

Describe the process for planning and scheduling any collection event, including:

1) How the program operator will schedule and conduct collection events to ensure compliance with applicable regulations and protocols of the United States Drug Enforcement Administration;

2) How the program operator will coordinate with local solid waste management officials who have jurisdiction over the impacted area on the frequency and location of collection events;

3) How the program operator will notify DEQ, in form and manner prescribed by DEQ, at least 60 days before a proposed event with information on the proposed date, time, and location, and contact information for the local solid waste management officials, local law enforcement, and service provider involved with the event; and

4) How collection events will be promoted to residents and how residents can find collection event information on the program operator's website and through the program operator's toll-free number.

b. **Policies, procedures, and management practices**

Describe the policies, procedures, and practices the program operator will require to ensure that service providers, such as authorized collectors, transporters, disposal sites, and other vendors, will

responsibly manage the collection, handling, and disposal of covered drugs under all applicable federal and state laws and rules. The description should include:

i. The name and contact information for the program's logistics manager;

ii. A list of vendors, transporters, and disposal facilities to be used; and

iii. A description of policies and procedures for:

1) Ensuring all persons handling or disposing of covered drugs collected under the drug take-back program will safely and securely track covered drugs from collection through final disposal and report any safety and security problems to the program operator;

2) The program operator to monitor and track safety and security problems and report them to DEQ.

3) Protecting patient information on drug packaging during processing, collection, transportation, and disposal of medications, and the process for tracking and addressing any issues.

4) Requiring service providers to track information required for the annual reports submitted under ORS 459A.230; verifying and auditing the service providers' information for accuracy; ensuring that service providers provide to the program operator the information and records the program operator needs to satisfy its plan and reporting requirements; and maintaining the records needed to demonstrate compliance with the plan and any other requirements of the Drug Take-Back Law.

a) Please confirm that the program operator may propose to retain all records for at least three years or for the period of time required by applicable laws and regulations, whichever is longer, and for longer upon DEQ's request.

b) Please confirm that the program operator will cooperate with DEQ on any audit requests under ORS 459A.236(3) and to demonstrate compliance with the Drug Take-Back Law.

5) Requiring all pharmacies participating in collection to register with the Oregon Board of Pharmacy and all authorized collectors to comply with all state and federal laws and rules governing the keeping of covered drugs, as identified by the Oregon Board of Pharmacy by rule.

5. Education and outreach

Include an outreach plan that describes public education efforts and promotion strategies in compliance with ORS 459A.227.

a. Outline specific tools (such as signage, newsletters, in-store displays, social media, press releases, print or digital advertisements, and radio and TV spots) and how the program will use these tools (for instance, the timing and frequency of radio ads and newsletters).

b. Describe any public education strategies and tools the program operator will use to meet the needs of minority, low-income, rural and other historically underserved communities. Describe if the program operator will provide educational materials to interested Oregon tribes or community-based organizations to promote drug take-back services among underserved communities.

c. Provide copies of or links to online and written materials developed that meet requirements in ORS 459A.227(1). Describe how the materials will be readily understandable to all residents, including residents with limited English proficiency—for example, by using plain language, translations, or explanatory images.

d. Describe communication tools and implementation methods the program will use to inform covered entities about drop-off site locations and hours of operation, mail-back and other services, and collection events.

e. Describe work with authorized collectors on developing a readily recognizable and consistent design for repositories to be used at drop-off sites and on developing clear, standardized instructions on how to use those repositories; and provide examples of design and instructions.

f. Describe how the program operator will coordinate with other program operators to ensure covered entities can easily identify, understand and access the services provided by all drug take-back programs that are operational in Oregon. Describe in detail the website and the toll-free number (which will include an option for covered entities to speak to a live person) that a covered entity may use to contact program operators about all drug take-back programs, provide feedback to program operators and get information about drop-off sites and the collection processes, such as information on mail-back services and collection events, of all drug take-back programs. Describe how the website and the toll-free number will be promoted to covered entities.

g. Provide a timeline, including deliverables and milestones, for developing and conducting the biennial survey required under ORS 459A.227.

    i. Describe how the program operator will conduct the survey. Otherwise, describe how the program operator will submit a survey project plan to DEQ for pre-approval concurrently with survey questions and will conduct a survey according to a project plan approved by DEQ. A description of how the program operator will conduct a biennial survey should include details about the survey and method of delivery, planned sample sizes, the related margins of error and confidence intervals, and the methodology to ensure an accurate representation of different demographic and geographic groups in Oregon. A survey project plan should address these elements as well.
    ii. Describe how the program will use survey results to improve program effectiveness.

h. Describe how the program operator will distribute promotional written materials to retail drug outlets, hospitals with an on-site pharmacy and health care clinics with an on-site pharmacy so that they can, upon request, provide these materials to covered entities at the time that a covered drug is delivered to a covered entity, as required by ORS 459A.227(4). Describe how retail drug outlets, hospitals with an on-site pharmacy and health care clinics can obtain more promotional written materials.

6. Goals

a. Set forth, for each program year, goals for the amount of drugs collected. The goals should reflect collection numbers based on Oregon population trends and providing convenient service as required by ORS 459A. 209(2)(i). Please describe how the program operator will make changes to ensure it meets its goals. For updated plans, please describe how proposed updates will improve the program to serve the public better or maintain the program’s success.

b. Set forth goals for fostering full public awareness, including a goal for fostering public awareness in minority, low-income, rural or other historically underserved communities. Describe how the program operator will measure achievement of goals and report results to DEQ in annual reports. Public awareness goals should be tied to awareness as measured by survey results. Please describe how the program operator will make changes to ensure it meets its goals.

7. Closure plan

Describe the program operator's closure plan to settle affairs in the event of dissolution or cessation of the program. For example, please describe:

a. How the program operator will notify DEQ by email of its intent to close the program at least six months before program closure;

b. How, during the six-month closure period, the program will continue to meet plan and statutory requirements for drug take-back services, including providing drop-off site and mail-back services and holding scheduled events;

c. How the program operator will maintain or transfer contracts, including contracts with drop-off sites, and whether and how any equipment will be removed from drop-off sites or mail-back distribution areas;

d. How the program operator will inform the public about program closure and provide educational materials and resources to direct the public to other take-back services after program closure;

e. How the program operator will retain staff and insurance to ensure operational requirements during the six-month closure period are met until all covered drugs collected through secure repositories, inner liners, or events are safely and securely disposed of;

f. How and when the program operator will provide DEQ a final annual program report, including information on the final disposition of collected drugs;

g. The amount the program operator will hold in reserve or through financial assurance to cover the costs of the six-month closure period, including the costs of uninstalling and decontaminating secure repositories at drop-off sites.

8. Coordination

If a program will provide services jointly with another program, describe how the programs will coordinate those services (including oversight of service providers, allocation and reporting of collections, program promotion). Each program is responsible for meeting the Drug Take-Back Law's requirements and cannot delegate that responsibility to another program.

a. Identify all drop-off sites, events, collection services and service providers, such as authorized collectors, in the program's network that will be shared through contracts with another program. For each shared service or event, identify which program has contracted with the authorized collector (i.e., the contracting program). The contracting program should further list all other programs that will share those services or events through contracts with the contracting program.

b. Describe how recordkeeping and reporting systems will accurately track and report data for all shared drop-off sites, events and other services.

c. Please include a statement in the plan that:

   i. Any agreement with a drug take-back program that your program relies on to provide any service under your plan requires that all services provided to your program pursuant to that agreement will comply with the terms of the other drug take-back program's plan and all applicable federal and state laws and regulations, including the Drug Take-Back Law.

   ii. The program, upon request, will provide a copy of the agreements to DEQ. Do not include copies of the agreements with other programs unless specifically requested.

9. Implementation timeline

Provide an implementation timeline with deliverables and milestones for implementing the proposed plan.

10. Certification and attestation

Please provide:

a. Contact information for the program's authorized representative, including name, address, phone number, and email address.

b. The following certifying statement with the signature of the program's authorized representative: *I/We hereby declare under penalty of false swearing (Oregon Revised Statute 162.075 and ORS 162.085) that the above information and all of the statements, documents and attachments submitted with this claim are true and correct*.

11. Appendices

Attach as appendices any required information not included in the body of the plan, such as:

a. Appendix A: List of Participating Manufacturers

Please provide a table that includes for each participating manufacturer:

- The covered manufacturer's name;
- The covered manufacturer's street address;
- The name of the manufacturer's contact or representative for purposes of the Drug Take-Back Program;
- The email address of the manufacturer's contact or representative;
- You may include an additional notes column to explain the participation of the manufacturer as an affiliate or subsidiary of the parent company or the participation of the parent company.

b. Appendix B: List of Participating Drop-off sites

Please include a list of the drop-off sites the program operator has secured for the proposed program, with the following information:

Drop-Off Site Name	Street Address	City	County	Zip code

Section V. Plan format, submittal, and DEQ review process

1. Use any templates, lists, letters or forms provided.
2. Submit electronic file to DEQ's Program Coordinator for the Drug Take-Back Program, with a copy to drugtakeback@deq.oregon.gov. A program operator should submit the program plan as a searchable electronic file. A program operator should additionally submit its lists of participating manufacturers, potential authorized collectors, and authorized collectors and drop-off sites as separate spreadsheet files. A program operator may be required to submit paper copies at DEQ's request. Note that plans are available to the public pursuant to ORS 459A.209(8).
3. DEQ will review a submitted plan by the schedule in ORS 459A.209(7) and inform the authorized representative by email whether the plan is approved, conditionally approved, or rejected. If a plan is rejected, DEQ may require a program operator to submit a revised plan according to the schedule set forth in ORS 459A.209(7).

4. If a program operator is submitting a revised plan, please submit (1) a clean version of the revised plan and (2) a version that notes any changes between the revised plan and the previously submitted plan in track changes or in otherwise clear notation.

Section VI. Annual Reports, Program Change Requests, Variance Requests, and Other Submissions to DEQ

Please contact DEQ for guidance on how to submit other requests, such as annual reports, program change requests pursuant to ORS 459A.212, and a variance request if a program operator is unable to meet the number of drop-off sites required in its plan.

For annual reports, please note that a drug take-back program must provide a report to DEQ by Nov. 1 of each year that details the program's development, implementation and operation in the previous program year. For example, the annual report for the program year running from July 1, 2025 to June 30, 2026 is due Nov. 1, 2026.

Section VII. Confidentiality

DEQ will protect any information you identify as confidential to the extent required by ORS 459A.254 and allowed under the Oregon Public Records Law (ORS 192.311 to 192.478). This includes information or records that DEQ may request for program oversight and audit purposes. You must clearly mark the information as confidential and submit it as follows:

1. If you provide the information by mail: Label the information in the document as "Confidential." Place it in a separate, sealed envelope marked "Confidential."
2. If you provide the information by email: Do NOT include the information in the body of the email. Attach the information as a separate document labeled as "Confidential." Mark the email as "Confidential" in the subject line and body of the email.

Contact

For questions about this Guide, please email drugtakeback@deq.oregon.gov with the subject line, "Drug Take-Back Program Guide."

Non-discrimination statement

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