

Oregon Drug Take-Back Program Report to the Legislature

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Executive Summary

This report describes the administration of Oregon Revised Statutes 459A.200 to 459A.266, also referred to as Oregon's Drug Take-Back Law, and is submitted pursuant to Section 24, chapter 659, Oregon Laws 2019 (Note under ORS 459A.266). This report includes an evaluation of whether the collection of covered drugs by drug take-back programs that are operational in this state is safe and secure, and a comprehensive review of the strategies employed by drug take-back programs to achieve the requirements of ORS 459A.200 to 459A.266.

Leftover or expired medicines can pose several serious environmental and health risks. If not disposed, unused medicines can lead to accidental poisonings, addiction or abuse. Medicines can also have health and environmental impacts when they end up in a landfill or are flushed down the toilet or drain. Wastewater treatment plants and septic systems are usually not equipped to treat pharmaceuticals, which means chemical compounds from these medicines can pass through treatment plants or septic systems to rivers and groundwater.

With the Drug Take-Back Law (2019), Oregon became one of the first states to offer its residents a statewide producer responsibility program for the safe and secure disposal of unused medicines. Oregon has similar producer responsibility programs for postconsumer architectural paint and electronics that have operated for over ten years, and is implementing new laws for similar programs to manage mattresses and packaging.

Producer responsibility programs reflect a waste management strategy that requires producers to share in the responsibility for the end-of-life management of their products and materials. In line with this strategy, the Drug Take-Back Law sets forth requirements for pharmaceutical manufacturers to participate in and fund a drug take-back program that offers Oregon residents safe, secure, and convenient disposal of unwanted medicines. These manufacturers must also designate a program operator to implement the program; the program must be implemented in accordance with the Drug Take-Back Law and pursuant to a program plan approved by DEQ.

In spring 2021, DEQ approved program plans by two program operators: The Drug Takeback Solutions Foundation and MED-Project USA, LLC. These program operators offer drop-off sites at pharmacies and law enforcement agencies where medicines can be disposed into secure kiosks; program operators also offer prepaid, preaddressed envelopes for people to mail their unwanted medicines off for destruction. They have also held collection events with local law enforcement agencies.

While operating independently, the program operators coordinate on a joint website, medtakebackoregon.org, and a joint toll-free telephone number, 844-482-5322 (844-4-TAKEBACK), that residents can access to find information about program services. Based on the program operators' first annual reports, the Drug Take-Back Program collected a total of over 65,000 pounds of unwanted medicines between July 1, 2021 through June 30, 2022, with MED-Project reporting 56,839.3 pounds of collection and the Foundation reporting 8,524.53 pounds of collection. The program operators' program plans and reports are available on DEQ's Drug Take-Back Program webpage.

Safety and Security of Drug Collection and Strategies to achieve the Drug Take-Back Law's Requirements

The Drug Take-Back Law, the program plans, DEQ oversight, and the program operators' required reporting all help to ensure the programs' collection systems are safe and secure. The Law includes many operational requirements that align with federal regulations for the handling of controlled substances. Program plans outline a program operator's policies and procedures for ensuring these requirements are met. In the first

program year, the program operators reported six safety and security problems for 412 drop-off sites. DEQ will monitor the frequency of security incidents to evaluate whether changes to a program operator's policies or operations are needed to effectuate safety and security.

Program operators use a number of strategies to meet the Drug Take-Back Law's requirements. To achieve a safe, secure and convenient system, the program operators work to establish drop-off sites throughout Oregon and to offer, with DEQ approval, alternative services and collection events where they have been unable to establish the required number of drop off sites. MED-Project operated 251 secure repositories at participating drop-off sites for the first program year while the Foundation reported 161 drop-off sites for the first program year. The program operators also provide free mail-back envelopes through online and telephone ordering. To raise public awareness, the drug take-back programs provide outreach and education through television, radio, direct mail, newspaper, social media and by making outreach materials available to pharmacies and other organizations for distribution to the public. The program operators also provide targeted outreach to minority, low-income, rural, and other historically underserved communities. In their first biennial surveys to measure public awareness of the Program, MED-Project reported 40% awareness among state residents over the age of 18, with 37% awareness in urban areas and 45% awareness in rural areas; the Foundation reported that 47.19% of its survey respondents were aware of the Oregon Drug Take-Back Program.

DEQ expects both program operators to build on their achievements in the first program year and will monitor their performances to ensure that the Program continues to offer the people of Oregon permanent and convenient options for safe and secure medicine disposal.

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Program overview

Why Drug Take-Back is needed

The Drug Take-Back Program was created to get unwanted drugs out of medicine cabinets and keep them from being misused or from contaminating our waters. Leftover or expired medicines can pose several serious environmental and health risks. If not disposed, unused medicines can lead to accidental poisonings, addiction or abuse. Medicines can also have health and environmental impacts when they are disposed in a landfill or flushed down the toilet or drain. Because wastewater treatment plants and septic systems are usually not equipped to treat pharmaceuticals, chemical compounds from medicines can pass through treatment plants or septic systems to rivers and groundwater. In a recent study sampling 113 bonefish in Florida, researchers detected an average of 2.1 pharmaceuticals per bonefish, with the most common being cardiovascular medications, opioid pain relievers and psychoactive medications. Studies have also found pharmaceuticals in landfill leachate, which can be discharged to surface waters following onsite or offsite wastewater treatment. Drug take-back programs, which offer household medicine disposal through secure kiosks at collection sites, mail-back envelopes, or collection events, are recommended by the U.S. Food & Drug Administration, the Drug Enforcement Administration of the United States Department of Justice and the U.S. Environmental Protection Agency as the best method for safe and secure disposal of unused medicines.

Before the Drug Take-Back Law, many Oregon residents had limited options for drug take-back. Law enforcement agencies, local governments, and pharmacies that offered take-back programs usually had to do so at their own expense. In many communities, these entities simply could not afford to start up and operate take-back programs. Where voluntary programs existed, these programs often did not have long-term or adequate funding. They frequently had different standards for the types and forms of drugs accepted, which could cause confusion and inconvenience for residents.

Drug Take-Back Law (2019)

With the passage of House Bill 3273 (2019), Oregon became one of the first states to create a statewide product stewardship program for the safe and secure disposal of unused medicines. The Drug Take-Back Law addressed many of the challenges of voluntary take-back programs:

 The law requires manufacturers to fund the program, which must be free for residents to use. This means access to drug take-back options is not dependent on local funding.

- The law requires convenient service in every county in Oregon, with an emphasis on access to permanent collection sites, known as "drop-off sites," that provide disposal options year-round. The Law also requires the program to provide a free mail-back service for residents to mail in their unwanted medicines for safe and secure disposal.
- The law standardizes the list of medicines accepted at participating drop-off sites and through mail-back offered by the program. Specifically, the program accepts prescription and over-the-counter medicines as well as brand-name and generic medicines. As set forth in ORS 459A.200, certain types of drugs and other healthcare products, such as exposed sharps,

What is Product Stewardship?

Product stewardship programs differ from traditional government programs, where the government provides the services to the public. Product stewardship is an environmental management strategy in which all parties involved in the design, production, sale, and use of a product take responsibility for minimizing the product's environmental impact throughout all stages of the product's life. The greatest responsibility lies with whoever has the most ability to affect the life cycle environmental impacts of the product—typically, the producer of the product.

Oregon has product stewardship programs for paint and electronics that have operated for over ten years, with forthcoming programs for mattresses and packaging. These programs focus on the management of unwanted products at the end of their useful life. Under these programs, the producers of the products covered must participate in programs to collect and safely manage their unwanted products. In the typical framework, statutes set the standards that these programs must meet, but give producers flexibility to design systems and processes to meet those standards. DEQ's role is much narrower: the Department oversees the producers and programs to ensure they meet required standards. For the Drug Take-Back Program, DEQ works in partnership with the Board of Pharmacy for program oversight.

supplements, and OTC cosmetics, are not covered.

- The law requires a single website and toll-free telephone number for the program.

 This means residents can find all drop-off sites and services offered by a program easily.
- The law requires a program to educate the public about the importance of safe medicine disposal. A program must also set goals for collection and for fostering full public awareness to ensure continuous improvement.

Per ORS 459A.200, services are available to the following "covered entities": Oregon residents, nonbusiness entities in Oregon, and ultimate users, as defined by 21 U.S.C. 802(27). Program services are not intended for law enforcement agencies or entities that generate pharmaceutical

waste, such as a hospital, health care clinic, health care provider's office, veterinary clinic, or pharmacy.

Program implementation

Under the Drug Take-Back Law, pharmaceutical manufacturers must designate a 501(c)(3) program operator to develop and implement a drug take-back program in accordance with the Drug Take-Back Law and pursuant to a program plan approved by DEQ. In 2020, DEQ completed the development of administrative rules to clarify a program operator's responsibilities; these rules are found in <u>Oregon Administrative Rules, Chapter 340, Division 98</u>. From fall 2020 to spring 2021, DEQ reviewed and ultimately approved program plans by two program operators: The Drug Takeback Solutions Foundation and MED-Project USA, LLC. These program operators offer drop-off sites and other program services independently but coordinate on certain elements as required by the Law.

Both programs launched on July 1, 2021. Residents can search for drop-off sites of both programs or order prepaid, preaddressed mail-back envelopes by visiting the program operators' joint website, medtakebackoregon.org, or by calling the toll-free telephone number 844-482-5322 (844-4-TAKEBACK).

On November 1, 2022, both program operators submitted their first annual report. MED-Project reported 56,839.3 pounds of unwanted medicines through drop-off sites, mail-back services, and collection events between July 1, 2021 through June 30, 2022. The Foundation reported collecting 8,524.53 pounds in the same period. Program plans and reports are available on DEQ's Drug Take-Back Program webpage. DEQ approved MED-Project's first annual report and is still reviewing the Foundation's first annual report. DEQ can provide more information about its review to the legislature upon request.

Safety and security of drug collection

The Drug Take-Back Law sets operational and reporting requirements that help ensure drug collection is safe and secure. The programs set policies and procedures, as described in the program plans approved by DEQ, that ensure these requirements are met. A program operator's reporting obligations also keep DEQ aware of safety and security problems that occurred during the collection, transportation or disposal of drugs. In their first annual reports, the program operators reported a total of six safety and security problems for their combined network of 412 drop-off sites. DEQ will monitor the frequency of security incidents to evaluate whether changes to a program operator's policies or operations are needed to effectuate safety and security.

Statutory and plan requirements for safety and security

Many of the Drug Take-Back Law's requirements for a drug take-back program's collection system are based on federal regulations for the collection, transportation and disposal of collected drugs, including the Drug Enforcement Administration of the United States Department of Justice's <u>Final Rule on the Disposal of Controlled Substances</u> (21 CFR 1300, 21 CFR 1301, 21 CFR 1304, 21 CFR 1305, 21 CFR 1307, and 21 CFR 1317). Among the Drug Take-Back Law's requirements:

- Consistent with DEA regulations, a drop-off site may only be hosted by a law
 enforcement agency, or a person that is registered with the DEA and qualifies under
 federal law to collect and dispose of controlled substances or to have the person's
 registration modified in such a way that authorizes the person to collect and dispose of
 controlled substances. See ORS 459A.200(15).
- A program operator's program plan must include policies and procedures to ensure the safe and secure handling of covered drugs and to ensure the security of patient information that may be printed on the packaging of a covered drug and compliance with any applicable federal laws and regulations, per ORS 459A.209.
- A program operator's drug take-back system must be safe and secure to use on an ongoing basis, per ORS 459A.218. This includes using a kiosk in compliance with all state laws and rules and federal laws and regulations governing the keeping of covered drugs in kiosk, as identified by rule by the Oregon Board of Pharmacy. This also includes servicing each kiosk as often as necessary to avoid reaching capacity; transporting collected drugs to a disposal facility in a timely manner; and providing authorized collectors a method to notify the program operator about the need for additional collections at a drop-off site.
- ORS 459A.221 requires a collection event to be conducted in accordance with applicable DEA regulations and protocols and in coordination with the local solid waste management officials who have jurisdiction over the impacted area.
- ORS 459A.224 requires covered drugs to be disposed of at a hazardous waste disposal facility or a municipal solid waste incinerator, consistent with the <u>EPA's</u> <u>Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs</u>.

The program plans outline policies and procedures the program operators implement to meet these requirements. These policies and procedures include:

- Requiring authorized collectors and service providers to agree to comply with applicable federal and state laws as a condition of participation;
- Providing resources for authorized collectors to understand applicable regulations and to contact the program operator if an issue arises with the kiosk or additional liners are needed;
- Performing semi-annual cleaning and inspections of drop-off sites;

- Conducting periodic on-site audits of service provider facilities annually; and
- Offering mail-back envelopes that are compliant with DEA regulations.

Once a plan is approved, a program operator must seek DEQ approval for any changes in a program involving methods used to collect or dispose of covered drugs; changes to policies and procedures for handling and disposing of covered drugs; and changes to policies and procedures for securing patient information on drug packaging. See ORS 459A.212.

Reporting of safety and security problems

Under ORS 459A.230(1)(j), a program operator must include in its annual reports any safety or security problems that occurred during the collection, transportation or disposal of drugs. For the first program year, the two program operators reported six problems:

- A secure repository was broken into and its inner liner removed. A report was filed with the local police department. The program operator's service provider repaired the secure repository.
- A drop-off site notified a program operator of a large prescription bottle causing its secure repository's drop-door not to close properly. The program operator determined this could pose as a security risk and upgraded 121 secure repositories at drop-off sites in its network.
- A service provider notified a program operator of an apparent shipping discrepancy for a
 box and liner originating from a drop-off site in Oregon. The carrier declared the box and
 liner to be lost in transit. The program operator reported that the carrier has policies and
 procedures for managing such packages, including destruction and a permanent
 medical waste incinerator.
- A service provider reported receiving from the carrier one shipment without an exterior shipping container. Drop-off site staff provided statements and evidence supporting that the shipment was shipped intact with both the inner liner and exterior shipping container. The vendor reported that the liner weight received was as expected and destroyed the shipment in accordance with state and federal regulation. The vendor also reportedly reiterated delivery instructions to the carrier.
- Five injector mail-back packages were incorrectly returned for treatment to a permitted autoclave facility in Fowler, California. The program operator confirmed the facility has all required permits and that treatment of the waste was performed in accordance with state and federal regulations. The program operator's service provider made arrangements to have any additional injector mail back packages received at this facility to be rerouted to a permitted hazardous waste incinerator facility, pursuant to ORS 459A.224.
- One box and liner were apparently incorrectly returned for destruction to a permitted
 medical waste incinerator not listed in the program operator's approved plan. The
 program operator instructed its service provider to immediately stop using any disposal
 facilities for destruction of unwanted medicine that are not approved in writing by the
 program Operator. The program operator confirmed that the destruction was performed

at a facility with all required permits and that the treatment of the waste was performed in accordance with state and federal regulations.

See page 3 of <u>the Foundation's first annual report</u> and Appendix G of MED-Project's first annual report at <u>MED-Project's first annual report for more information on these occurrences and resolutions.</u>

Strategies employed to achieve drug take-back law requirements

The Drug Take-Back Law requires a drug take-back program to be safe, secure and convenient to use. To ensure that the people of Oregon know about and use the program, the Drug Take-Back Law also requires a drug take-back program to provide outreach and education to promote safe and secure storage of medicines, to conduct a biennial survey to measure awareness of the program, and to work towards full public awareness.

To achieve a safe, secure and convenient system, the program operators operate drop-off sites throughout Oregon and offer, with DEQ approval, alternative services and collection events where they are unable to establish the required number of drop-off sites. The program operators also provide free mail-back envelopes through online and telephone ordering. For public awareness, the program operators provide outreach and education by advertising through television, radio, direct mail, newspaper, social media and by making outreach materials available to pharmacies and other organizations for distribution to the public.

Convenient statewide service

Drop-off sites

The Drug Take-Back Law requires a program operator to provide convenient service in every county in Oregon, with an emphasis on access to drop-off sites. ORS 459A.209(2)(i) requires an approved plan to describe how the program operator will establish at least one drop-off site in each county and per population center—defined as 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 the city or town located within a population center. Based on population estimates produced by the Population Research Center at Portland State University, the Law required 271 drop-off sites throughout Oregon for the first program year.

MED-Project operated 251 secure repositories at participating drop-off sites for the first program year and reported collecting 55,903 pounds of unwanted medicines through drop-off sites. The Foundation reported collecting 8,023 pounds of unwanted medicines through 161 drop-off sites for the first program year. The majority of drop-off sites in the programs are hosted by pharmacies and law enforcement agencies. The programs continue to solicit potential authorized collectors to meet the statutory standard for number of drop-off sites.

Under ORS 459A.218(3), a drug take-back program that is unable to establish and maintain a sufficient number of drop-off sites to meet its plan requirements shall provide alternative services and hold collection events to ensure the convenient service described in the program plan, subject to DEQ's approval. In the first two program years, both program operators offered such services and collection events, as described in "Alternative services and events where drop-off sites cannot be established," below.

Mail-back services

A drug take-back program must provide a pre-paid mail-back service option for a covered entity. Oregon residents and other covered entities can order pre-paid, pre-addressed envelopes for unwanted medicines disposal from either program operator through medicakebackoregon.org or by calling 844-4-TAKEBACK. Each program operator offers three types of envelopes: a mailer for inhalers; a pre-filled injector package for auto-injector medicines, and a standard mailer for other covered drugs.

ORS 459A.209(2)(L) requires a program operator to provide mail-back service supplies to inhome hospice service providers, for use by the providers' patients. To meet this requirement, the Foundation reported providing bulk shipments of envelopes to hospice providers. MED-Project worked with some hospice providers as mail-back distribution locations, or locations that can distribute mail-back envelopes to the public.

Alternative services and events where drop-off sites cannot be established

To support communities where an insufficient number of drop-off sites have been established, the drug take-back programs received DEQ approval for the first two program years to offer the following types of services:

- Mail-back distribution locations or sites: these are locations where the public can pick up a free mail-back envelope and then mail in the unwanted medicines for disposal.
- For some very small cities (Greenhorn, Lonerock, and Antelope), DEQ approved the programs to send free envelopes or educational materials about the program directly to households.

MED-Project reported collecting 741 pounds through mail-back services, which includes envelopes distributed through mail-back distribution locations. The Foundation reported collecting 160 pounds through mail-back services.

The programs also separately held collection events in the first program year. Per their program plans and ORS 459A.224, the programs partnered with local law enforcements for these events..

The Foundation reported collecting 342 pounds through five events (held in Gold Beach, Hines, Roseburg, Prairie City and Maupin) while MED-Project reported collecting 195 pounds through three events (held in Bend, Gladstone and Ontario).

The program operators must submit a request to provide alternative services and events for the third program year by June 1, 2023.

Public awareness

Coordination on website and common logo

In the event of multiple program operators, ORS 459A.227(3) requires a program operator to coordinate with other program operators on public awareness to ensure that covered entities can easily identify, understand and access the services provided by all of the drug take-back programs. At a minimum, all drug take-back programs must provide a single toll-free telephone number and a single website address that a covered entity may use to contact program operators about the drug take-back programs and to acquire information about the location of the drop-off sites and the collection processes of the drug take-back programs.

medtakebackoregon.org lists both programs' drop-off sites and mail-back distribution locations or sites. The list is searchable by zip code and includes a drop-off site or mail-back distribution location or site's contact telephone number and hours of operation. Residents can also call 844-4-TAKEBACK to obtain similar information about drop-off sites and mail-back distribution sites or locations.

The website also provides links to the program operators' individually-branded websites where covered entities can order mail-back envelopes and access educational materials. Residents and other covered entities can also order mail-back envelopes through 844-4-TAKEBACK.

The program operators also developed a common logo to identify their services as part of the Oregon Drug Take-Back Program. This logo is included on medtakebackoregon.org and affixed to kiosks at participating drop-off sites.



Figure 1. Drug Take-Back Program Logo

Written materials upon a covered entity's request and other outreach methods

ORS 459A.227(4) requires that, upon a covered entity's request, a retail pharmacy, hospital with an on-site pharmacy or health care clinic with an on-site pharmacy must provide written materials provided by a program operator for the purpose of promoting the safe and secure collection of covered drugs at the time that a covered drug is delivered to a covered entity. To implement this provision, the program operators provide brochures, posters and promotional materials to pharmacies and to hospitals and health clinics with on-site pharmacies to distribute. Please see Appendix K of MED-Project's report and Appendix C of the Foundation's report for a list of pharmacies and other sites that received promotional materials. The program operators also make written promotional materials available for download. See the Foundation's website and MED-Project's website, which are accessible through medtakebackoregon.org.

MED-Project also promotes the program through print, digital, radio and television campaigns and posted information on social media sites. The Foundation conducts outreach through direct mail, print advertisements, programmatic media and social media and influencer marketing.

Outreach to historically underserved communities

Both program operators have educational materials available on their websites in English, Spanish, Russian, Somalia, Vietnamese, and Chinese. The website medtakebackoregon.org is also translatable into these languages.

Separately, MED-Project contracted with a local organization to conduct a statewide public engagement process focused on historically underserved communities. The organization, Oregon's Kitchen Table, is a program of the National Policy Consensus Center housed in the Mark O. Hatfield School of Government in the College of Urban and Public Affairs at Portland State University; the program works to empower Oregonians from every corner of the state to contribute feedback, ideas and resources to decision-makers, public projects and initiatives. A summary of Oregon's Kitchen Table's work with MED-Project is available on the Oregon's Kitchen Table website. To reach a wider variety of audiences identified by Oregon's Kitchen Table, MED-Project deployed a print media campaign across numerous publications in multiple languages.

The Foundation provided direct mail outreach in English and Spanish that focused on historically underserved communities through geographic and demographic targeting.

Biennial survey

ORS 459A.227 requires a program operator to conduct a biennial survey of covered entities and of pharmacists and health care providers who interact with covered entities. Surveys must measure awareness of the program, assess the extent to which program services are convenient and easy to use, and assess knowledge and attitudes about the risks of improper medicine storage and disposal. To meet this requirement, the program operators conducted independent surveys. MED-Project reported 40% awareness among state residents over the age of 18, with 37% awareness in urban areas and 45% awareness in rural areas. MED-Project's survey results are available on MED-Project's website. The Foundation reported that 47.19% of its survey respondents were aware of the Oregon Drug Take-Back Program. The Foundation included survey highlights in its first annual report (p. 7). DEQ expects both program operators to take appropriate steps to ensure they meet their goals for fostering full awareness of the program.

Looking forward

The Oregon Drug Take-Back Program is a successful producer responsibility program that has collected over 65,000 pounds of drugs for safe and secure disposal in a single year, preventing such drugs from falling into the wrong hands or contaminating our waterways. DEQ will continue to oversee the programs to ensure their continuous improvement in the years to come. Such

improvements can include more drop-off sites to serve residents and more outreach and education to increase public awareness about drug take-back, including awareness in minority, lower-income, rural and other historically underserved populations.

DEQ meets regularly with the program operators to understand program operations and implementation challenges. DEQ will also review annual reports to evaluate, among other things, the programs' safety, security and convenience and the program operators' progress towards their collection and public awareness goals.

In 2025, each program operator must submit an updated plan for DEQ's approval. In reviewing the updated plans, DEQ will consider each program operator's track record in consistently meeting its goals and in operating a safe, secure, convenient, and compliant program. DEQ will apply its oversight to ensure that the people of Oregon will continue to have permanent and convenient options for safe and secure medicine disposal, as the Oregon Legislature intended.