A Product Stewardship Plan
For Unwanted Medicine from Households

Tacoma-Pierce County, Washington
September 29, 2017
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I. Introduction

MED-Project LLC (“MED-Project”), on behalf of the participating companies as described in Appendix A, submits this Product Stewardship Plan (“Plan”) for Unwanted Medicine in compliance with the Tacoma-Pierce County Board of Health Secure Medicine Return Regulations, Environmental Health Code Chapter 7 (“Regulations”). The Regulations require pharmaceutical Producers\(^1\) to develop a Product Stewardship Program to finance and manage the collection, transportation, and disposal of Unwanted Medicine from Tacoma-Pierce County households. MED-Project is requesting Standard Stewardship Plan status.

II. Contact Information

The primary contact person for MED-Project is:

Irina Butler, Plan Development Director
MED-Project
1800 M Street NW, Suite 400S
Washington, DC 20036
202-495-3125
ibutler@med-project.org

\(^1\) All capitalized terms used but not otherwise defined herein shall have their respective meanings set forth in the Regulations.
III. Plan Definitions

**Carrier** is United Parcel Service, Inc., the common carrier used by Vendor to transport Unwanted Medicine.

**County** means the unincorporated and incorporated areas of Pierce County.

**DEA** is the U.S. Drug Enforcement Administration.


**Kiosk Drop-Off Site** is a location hosting a MED-Project kiosk for the collection of Unwanted Medicine.

**Kiosk Drop-Off Site Host** is the designated contact person or persons at the Kiosk Drop-Off Site.

**Law Enforcement Agency** or **LEA** is a federal, state, tribal, or local law enforcement office or agency.

**Mail-Back Package Distribution Location** is a facility, such as a town hall or library, that will provide MED-Project Mail-Back Packages to residents.

**Mail-Back Services** is the provision of pre-paid, pre-addressed envelopes or other packages for the collection and disposal of Unwanted Medicine.

**Maintenance Technicians** are service personnel who are trained to provide services related to kiosks that are part of the Program. This includes, but is not limited to, responding to damaged kiosks.

**Plan** or **Product Stewardship Plan** is the product stewardship plan presented in this submittal by MED-Project.

**Program** or **Product Stewardship Program** is the product stewardship program set forth in this Product Stewardship Plan.

**Residents** or **Covered entities** mean human beings residing in the County. “Residents” does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor’s offices, veterinary clinics, pharmacies, or airport security and law enforcement drug seizures.

**Service Technicians** are service personnel trained to remove and transport the Unwanted Medicine from Program kiosks. Service Technicians will be managed by Vendor.

**Take-Back Event** is an event conducted by MED-Project with oversight by law enforcement for the collection of Unwanted Medicine.

**Unwanted Medicine** is defined in Section IV of this Plan.

**Vendor** is Stericycle Specialty Waste Solutions, Inc. (“Stericycle”), the collection and transportation vendor for this Plan, and any other such vendor as retained by MED-Project to carry out its obligations under the Program.
IV. Unwanted Medicine

For the purposes of the Plan, “Unwanted Medicine” includes all materials identified as “Covered drug[s]” under Regulations § 4.B that qualify as “Unwanted covered drug[s]” under Regulations § 4.W. Per the Regulations, Covered Drug means “a drug sold in any form and used by covered entities, including prescription and nonprescription drugs, brand name and generic drugs, drugs for veterinary use, and drugs in medical devices and combination products, including pre-filled injector products with a retractable or otherwise securely covered needle.” § 4.B. Pre-filled injector products with a retractable or otherwise securely covered needle will be collected to the extent that medicine cannot be removed from them or they contain more than trace amounts of covered drugs (“Pre-filled Injector Products”) § 4.C.6. Unwanted Medicine does not include the following:

i. Expired undispensed samples direct from physicians’ offices;
ii. Unused or expired drugs from hospitals and institutions;
iii. Bulk animal pharmaceuticals from farms (business use);
iv. Vitamins or supplements;
v. Herbal-based remedies and homeopathic drugs, products, or remedies;
vi. Compressed cylinders, mercury containing thermometers, aerosols and inhalers;
vii. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9);
viii. Hard surface and toilet disinfectant cleaners;
ix. Drugs administered in a healthcare setting;
x. Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy (Title 21 U.S.C. § 355-1);
xii. Drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of the Regulations if the Producer already provides a pharmaceutical product stewardship or take-back program;
xiii. Pre-filled Injector Products and medical devices or their component parts or accessories from which Unwanted Medicine can be removed or that contain no Unwanted Medicine or no more than trace residual amounts of Unwanted Medicine;
xiv. Used, empty containers, vials, and pouches;
xv. Schedule I or other illicit drugs;
xvi. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms; and
xvii. Any other items excluded pursuant to the Regulations.

See Section XIV.A for collection limitations imposed by the DEA Rule.
V. Collection of Unwanted Medicine

The Plan provides services to collect Unwanted Medicine, including controlled substances, in any dosage form. The collection methods and any applicable legal requirements are described below.

A. Unwanted Medicine Collection Program Implementation

1. Outreach

Per Regulations § 5.D.2, MED-Project initially notified 153 pharmacies and 17 LEA locations in the County of the opportunity to participate as a Kiosk Drop-Off Site Host. MED-Project continually performs outreach to these locations through calls and emails with the goal of establishing Kiosk Drop-Off Sites distributed as uniformly as possible throughout the County. As part of this outreach, MED-Project asked if the sites were interested in participating in the Program, whether the sites currently host a kiosk or other services for the disposal of Unwanted Medicine, whether pharmacies are DEA registrants, and if the sites would like more information regarding the Program.

LEAs and pharmacies that currently host kiosks in the County may transition into the Program upon entering into an agreement with MED-Project. Existing LEA and pharmacy kiosk hosts are available at the following locations:

<table>
<thead>
<tr>
<th>LEA kiosk hosts:</th>
<th>Pharmacy kiosk hosts:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Buckley Police Department</td>
<td>1. Walgreens Pharmacy – Lakewood</td>
</tr>
<tr>
<td>2. Dupont Police Department</td>
<td>2. Walgreens Pharmacy – Tacoma</td>
</tr>
<tr>
<td>3. Eatonville Police Department</td>
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<td>4. Edgewood Police Department</td>
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<td>5. Fife Police and Courts</td>
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<td>6. Gig Harbor Police Department</td>
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<td>7. Lakewood Police Department</td>
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<td>8. Pierce County Sheriff’s Department Parkland Spanaway Precinct</td>
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<td>9. Pierce County Sheriff’s Department South Hill Precinct</td>
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<td>10. Puyallup Police Department</td>
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<tr>
<td>11. Steilacoom Public Safety Building</td>
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<tr>
<td>12. Sumner Police Department</td>
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<td>13. Tacoma Police Department – Headquarters</td>
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<td>14. Tacoma Police Department – Sector One</td>
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<td>15. Tacoma Police Department – Sector Two</td>
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<td>16. Tacoma Police Department – Sector Three</td>
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<tr>
<td>17. Tacoma Police Department – Sector Four</td>
<td></td>
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</tbody>
</table>
2. Implementation
MED-Project has begun work with LEAs and pharmacies identified during outreach (see Section V.A.1.) to obtain Kiosk Drop-Off Site Host signed agreements. MED-Project is working to satisfy the Service Convenience Goal established in Regulations § 7.D.2 through signed agreements with Kiosk Drop-Off Site Hosts. Ninety days after Plan approval, MED-Project will satisfy the Service Convenience Goal in any city or town with a Potential Authorized Collector and in the unincorporated areas of the County through targeted Take-Back Events and/or Mail-Back Services if signed agreements have not been obtained from the minimum number of Kiosk Drop-Off Sites in those locations. See Sections V.C and V.E.3 for details of how the Program will satisfy the Service Convenience Goal.

Collection of Unwanted Medicine (excluding iodine-containing medication and Pre-filled Injector Products) will begin at collection locations once agreements have been executed with each location, kiosks have been installed, sites have been trained, and, in the case of pharmacies, all requirements of the DEA and the Washington State Pharmacy Quality Assurance Commission (“WSPQAC”) have been met.

3. Convenience
Per Regulations § 7.D.2, MED-Project will strive to establish a Kiosk Drop-Off Site in each city and town with a Potential Authorized Collector and in the unincorporated county, as well as an additional Kiosk Drop-Off Site for every 30,000 Residents at the locations of pharmacies, hospitals/clinics with an on-site pharmacy, or LEAs. If the minimum number of Kiosk Drop-Off Sites cannot be established, Take-Back Events and/or Mail-Back Services shall be provided to supplement the disposal of Unwanted Medicine by Residents in those areas.

Mail-Back Services shall be available upon request to differentially-abled and homebound Residents, thereby offering more opportunities to dispose of Unwanted Medicine.

4. Flexible Expansion
MED-Project will continuously assess performance, gauge feedback, and revise its approach as appropriate. As implementation proceeds, MED-Project shall continue to approach organizations that may be available as future Kiosk Drop-Off Site Hosts on an annual basis. These organizations are listed in Appendix B.

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites, Take-Back Events, and Mail-Back Services. Current activities taking place prior to Plan approval include outreach to LEAs and pharmacies regarding their interest and ability to participate in the Program as Kiosk Drop-Off Sites, outreach to potential Mail-Back Package Distribution Locations, and outreach to potential Take-Back Event Hosts. Over the course of implementation, additional Kiosk Drop-Off Sites will be established to the extent that (1) additional eligible LEAs and/or DEA-registered pharmacies agree to participate, and (2) contracts can be executed with such entities. MED-Project will conduct supplemental Take-Back Events and/or Mail-Back Services for underserved areas. For every engagement with LEAs and pharmacies, including the establishment of Kiosk Drop-Off Sites, Take-Back Events, or availability of Mail-Back Services, contracts outlining the responsibilities of all involved parties will be drafted, reviewed by appropriate entities, and signed by all parties before MED-Project installs kiosks, schedules Take-Back Events, or provides Mail-Back Services.2

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2 MED-Project may determine that contracts are not necessary for certain Mail-Back Services.
Take-Back Events and/or Mail-Back Services shall supplement Kiosk Drop-Off Sites if the Service Convenience Goal is not met through signed agreements with Kiosk Drop-Off Site Hosts. As MED-Project obtains additional agreements with Kiosk Drop-Off Site Hosts, these supplemental services will decrease.

For more information regarding Take-Back Event scheduling, coverage, and frequency, see Section V.C.

Mail-Back Services will be available upon request to differentially-abled and home-bound Residents upon request and will be reviewed for availability and effectiveness. Mail-Back Services may also be made available if agreements have been obtained from fewer than the required number of Kiosk Drop-Off Site Hosts. See Section V.E.3 for more information about the availability of Mail-Back Services.

Although Kiosk Drop-Off Sites will not provide kiosk collection for Pre-filled Injector Products and iodine-containing medication, Mail-Back Packages for Pre-filled Injector Products and iodine-containing medication will be available through the call center and website for all Residents.

B. Kiosk Drop-Off Sites
Kiosk Drop-Off Sites will be strategically placed across the County to best meet the Service Convenience Goal established by the Regulations. This network will provide Residents several different outlets to participate in the Plan. All Kiosk Drop-Off Site Hosts shall provide residents with access to Program kiosks during all regular business hours.

1. Kiosk Drop-Off Site Locations
MED-Project contacted 153 pharmacies and 17 LEAs located in the County about the opportunity to serve as a Kiosk Drop-Off Site Host. Of the locations contacted, 56 pharmacies and 11 LEAs expressed interest in participating in the Program. These interested Kiosk Drop-Off Site Hosts are identified in Appendix C.

A map of the interested and potential Kiosk Drop-Off Site Host locations is below.
MED-Project will continue outreach to potential Kiosk Drop-Off Site Hosts that have not expressed interest in Program participation until the Service Convenience Goal has been met and annually thereafter. These sites are listed in Appendix D.

In areas where a potential Kiosk Drop-Off Site is not available, MED-Project will seek to establish additional Kiosk Drop-Off Sites in nearby cities or towns, provide Mail-Back Services, or work with LEAs to schedule Take-Back Events. Additionally, within 120 days of Plan implementation, MED-Project will establish Mail-Back Package Distribution Locations and/or schedule Take-Back Events if fewer than the required number of interested Kiosk Drop-Off Site Hosts sign an agreement to participate in the Program in any city or town.

As required under Regulation § 7.D.1, within ninety days of their offer to participate (unless the collector requests a longer time-frame), the Program will include as a Kiosk Drop-Off Site any retail pharmacy, hospital/clinic with an on-site pharmacy, or LEA willing to serve voluntarily as a Kiosk Drop-Off Site for Unwanted Medicine and able to meet all applicable laws, regulations, and other legal requirements. Locations currently serving as a drop-off site may participate in the Program by signing agreements with MED-Project and modifying their DEA registrations if required. The process for modifying DEA registrations is outlined in Section XIV.A.1. MED-Project will work with the Kiosk Drop-Off Site Host to transition to the Program and Vendor.

See Section V.C for more information on Take-Back Events and Section V.E et seq. for Mail-Back Services.

2. Drop-Off Site Kiosk Placement and Maintenance Program
Kiosk installation shall be the responsibility of MED-Project at LEAs and pharmacy Kiosk Drop-Off Sites if the Kiosk Drop-Off Site Host has identified a placement location. All kiosks in the Program must be securely placed and maintained inside a collector’s registered location or LEA’s physical location in accordance with DEA Rule §§ 1317.75(d)(1) and 1317.35(a). At pharmacies, kiosks will be placed in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (i.e., can be seen from the counter), pursuant to § 1317.75(d)(2). At a hospital or clinic with an on-site pharmacy, kiosks will be placed in an area regularly monitored by employees but not near areas of the facility where emergency or urgent care is provided. § 1317.75(d)(2)(i). Costs associated with installation and maintenance will be paid by MED-Project per the contracts with the Kiosk Drop-Off Sites.

The maintenance program will address items such as:

- Periodic inspection of kiosks to monitor general wear and tear;
- Service Technician access to the kiosks during the regularly scheduled pick-ups and notification of a Maintenance Technician if necessary; and
- Reporting by the Kiosk Drop-Off Site Host of damage to a kiosk or requested maintenance service.
3. **Kiosk Specifications**

A kiosk will be offered to all host locations. Pursuant to § 1317.75(e), MED-Project kiosks at pharmacies will:

- Be securely fastened to a permanent structure;
- Be securely locked, substantially constructed containers with a permanent outer container and removable inner liner;
- Include a small opening in the outer container that allows contents to be added to the inner liner, but does not allow removal of the inner liner’s contents;
- Prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances are acceptable to be placed in the kiosk; and
- Have the small opening in the outer container locked or made inaccessible to the public when a Kiosk Drop-Off Site employee is not present.

The proposed design of the pharmacy kiosk and proposed signage (Appendix E) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the drop slot; a tamper-proof slot; and commercial hinges. The design will increase the likelihood of consumer participation by providing easy access to wheelchair users. The locking mechanism on the drop slot will prevent kiosk over-flow once the container has reached its maximum level and is locked by the Kiosk Drop-Off Site Host. MED-Project pharmacy kiosks will come with appropriate regulatory signage and instructions, including an instruction to remove or strike out personal information from any Unwanted Medicine and packaging before depositing them and language required under the DEA Rule. Kiosk signage will provide information about what is and is not accepted in the kiosk.

Additionally, under § 1317.60(a), MED-Project kiosk inner liners will:

- Be waterproof, tamper-evident, and tear-resistant;
- Be removable and sealable immediately upon removal without emptying or touching kiosk contents;
- When sealed, make the contents of the inner liner not viewable from the outside;
- Clearly indicate the size of the inner liner; and
- Bear a permanent, unique barcode for tracking purposes.

While the DEA Rule does not require LEA kiosks to meet these same requirements, MED-Project will offer these kiosks and inner liners to LEAs. See DEA Rule at 53531.

4. **Kiosk Collection**

Under § 1317.05(c)(2)(iv), pharmacy Kiosk Drop-Off Sites must dispose of sealed inner liners and their contents either on-site, through common or contract carrier delivery to or pick-up by a distributor or reverse distributor, or with DEA assistance.
Section 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, § 1317.60 limits inner liner access to employees of the collector and requires two employees to immediately seal the inner liner upon its removal from the pharmacy kiosk’s permanent outer container. See § 1317.60(b), (c). Section 1317.75(g) provides that pharmacy kiosk inner liner installation or removal shall be performed “by or under the supervision of at least two employees of the authorized collector.” The pharmacy kiosk sealed inner liner must not be opened, x-rayed, analyzed, or otherwise penetrated. See § 1317.60(c).

At LEA Kiosk Drop-Off Sites, Vendor and the LEA will maintain any records of removal, storage, or destruction of the collected Unwanted Medicine in a manner consistent with the LEAs’ recordkeeping requirements for illicit controlled substances evidence pursuant to § 1317.35. Law enforcement will record the unique barcode number and size of the sealed inner liner transferred to Vendor. See § 1317.35. Additionally, any Unwanted Medicine will be stored in a manner to prevent the diversion of controlled substances and consistent with the LEA’s standard procedures for storing illicit controlled substances. See § 1317.35. Collected Unwanted Medicine will be transferred to the disposal facility in a manner to prevent the diversion of Unwanted Medicine and consistent with the LEA’s standard procedures for transferring illicit controlled substances. See § 1317.35.

MED-Project’s Kiosk Drop-Off Site collection system complies with these DEA requirements for pharmacy and LEA Kiosk Drop-Off Sites. Vendor, pharmacies, and LEAs participating in the Plan will keep all records required under the DEA Rule, including those required under §§ 1304 and 1317.35. Pharmacy Kiosk Drop-Off Site Hosts and Vendor will be instructed never to count, sort, inventory, or individually handle kiosk contents. However, pharmacy kiosks will be located where an employee is present affording employees the opportunity to visually inspect Unwanted Medicines Residents attempt to deposit. See Section V.B.2. LEA kiosks will be located inside the LEA’s physical location. See Section V.B.2.

Pick-up of Unwanted Medicine collected at Kiosk Drop-Off Sites will be scheduled for all Kiosk Drop-Off Sites year-round based on their regular business hours and volume collected. When arriving at a Kiosk Drop-Off Site, the kiosk will be reviewed by the Service Technicians for any damage.

A Service Technician will arrive at the Kiosk Drop-Off Site with a pre-printed shipping label. Unwanted Medicine will be securely removed from the kiosk by Service Technicians and Kiosk Drop-Off Site employees following standard operating procedures meeting all DEA requirements. Specifically, two Kiosk Drop-Off Site employees will hold the two keys to unlock the kiosk. Once the kiosk is unlocked, the inner liner will be removed from the kiosk and immediately sealed, a new inner liner will be installed, and the two Kiosk Drop-Off Site employees will lock the kiosk. The inner liner provided in the kiosk will be opaque to prevent visual recognition of the contents. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Under the supervision of two Kiosk Drop-Off Site employees, the Service Technicians will package the sealed inner liner for shipping. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The Service Technician will schedule a pickup from the Carrier to be completed within a few business days and leave the packaged, sealed inner liner with the Kiosk Drop-Off Site Host for storage in compliance with all applicable laws, regulations, and other legal requirements until Carrier pickup.
Vendor will prepare the materials for shipment and perform applicable pre-transportation functions to comply with Department of Transportation (DOT) Hazardous Materials Regulations.

5. Frequency of Pick-Up
Initially, all Kiosk Drop-Off Site Hosts not previously hosting a kiosk will be scheduled for a monthly pick-up from the kiosk. Vendor will communicate with the Kiosk Drop-Off Site Host in the event the frequency of pick-up needs to be changed based on the volumes collected over time. Vendor will monitor volumes collected per service to ensure that all sites are receiving the appropriate service frequency. Vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Kiosk Drop-Off Site. Moreover, Vendor will monitor the weight of Unwanted Medicine generated at each participating Kiosk Drop-Off Site.

6. Procedures if a Kiosk is Full Prior to Scheduled Pick-Up
The Kiosk Drop-Off Site Host shall be instructed to lock the drop-slot to the kiosk when the kiosk is full and notify MED-Project of the need for service if prior to the scheduled service date.

Vendor shall provide a network of trained Service Technicians. Vendor will communicate service requests to field managers responsible for Service Technicians. Vendor will direct service to a trained Service Technician who is in closest proximity to the Kiosk Drop-Off Site requesting the service. This process provides for a timely response to Kiosk Drop-Off Sites requiring service prior to the scheduled date.

Service timelines will be assessed based on the specific characteristics of the Kiosk Drop-Off Site’s need. If necessary, Vendor will be able to respond within hours of the request. If the request does not require an urgent response, Vendor will plan the response within two to three business days of the request. Vendor will not exceed one business week from the initial request. In the interim, pharmacy Kiosk Drop-Off Site Hosts shall be instructed to secure the kiosk and its contents in accordance with DEA requirements.

7. Unplanned Event Preparedness
Vendor maintains a network of emergency responders that can be called on in the case of an emergency or spill incident. Vendor ensures compliance of all service providers through a business confidential qualification process. This process reviews the compliance history, management structure, financial stability, and other key indicators of a reliable emergency response service provider. Emergency responders will bring all necessary equipment in order to manage the specific needs of the Kiosk Drop-Off Site requiring emergency response.

A major event, such as a flood, earthquake or fire, may require response by a service team. This event can jeopardize the security characteristics of the kiosk as well as the structural integrity of the participating location. The team will assess the safety of the area along with the locations to be serviced. Once it is determined the area is safe for access, the team will work to secure the kiosk and remove its contents.

Along with major event preparedness, Vendor provides timely responses to events that may cause an inconvenience to the Kiosk Drop-Off Site Host. An example of this kind of event would be if the kiosk is giving off an odor prior to the scheduled service date. The Kiosk Drop-Off Site Host will contact MED-Project via the dedicated phone number or email address. Vendor is able to respond within two to three hours in most cases when notified of a need for emergency response. If the request is not an emergency that poses an immediate threat to the environment or health, Vendor will typically respond to a service location within two to three business days of the event.

In addition, due to restrictions imposed by the DEA rule, personal items that a resident inadvertently drops into a kiosk (i.e. dentistry, watch, keys, wallet, etc.) will not be retrieved.
C. Take-Back Events

Ninety days after Plan approval, MED-Project will conduct a gap assessment of signed agreements with Kiosk Drop-Off Site Hosts. Thirty days after the gap assessment, MED-Project will provide Mail-Back Services and/or schedule periodic Take-Back Events if the service convenience goal is not met through signed Kiosk Drop-Off Site agreements.

Targeted events can be viewed in Appendix F. Federal, state, tribal, or local law enforcement shall oversee all Take-Back Events. If possible, MED-Project will work to conduct the Take-Back Events in coordination with other scheduled events (i.e., Earth Day celebrations, Health and Wellness Fairs) to maximize convenience to Residents. In situations where a location in the community cannot be scheduled, MED-Project will work with the participating LEA to host the event at other locations available to the public.

Due to the continuously changing schedule of Take-Back Events, the list of take-back dates and locations will be maintained on the MED-Project website as events are scheduled.

1. Method

Hosting of Take-Back Events is contingent upon participation and oversight by contracted LEAs. MED-Project will work with participating LEAs to ensure Take-Back Events are compliant and successful. Events will be promoted and communicated to the public through local communication channels as outlined in Appendix G.

The process of conducting Take-Back Events will meet all applicable laws, regulations, and other legal requirements. MED-Project will contract with LEAs to oversee Take-Back Events. These contracts will provide for the collection, transportation, and disposal of Unwanted Medicine from Take-Back Events and ensure that all requirements of participating LEAs are met. MED-Project will work with LEAs to accommodate any reasonable requirements.

2. Procedures

MED-Project will partner with LEAs to ensure that at least one law enforcement officer oversees collection at all Take-Back Events pursuant to DEA Rule § 1317.65(a), (b). The law enforcement officers will maintain control and custody of all Unwanted Medicine collected at Take-Back Events from collection until secure transfer, storage, or destruction of the Unwanted Medicine, as required by § 1317.65(b). Only ultimate users and persons authorized to dispose of an ultimate user decedent’s property in lawful possession of controlled substances in Schedules II-V may transfer these substances to the LEA during the event. § 1317.65(e). No other person will handle controlled substances at Take-Back Events under § 1317.65(e); however, Vendor may assist LEAs in the collection of Unwanted Medicine at Take-Back Events. See DEA Rule at 53539.

Take-Back Events will typically be staffed by at least two Vendor employees. Vendor will work in coordination with MED-Project and LEAs to monitor and ensure collection of all material at Take-Back Events is compliant with all applicable laws, regulations, and other legal requirements and meets the expectations of the planned event. Vendor will work in conjunction with local law enforcement to ensure all material is placed in a compliant collection receptacle and securely shipped to meet all applicable laws, regulations, and other legal requirements. Any material that is not Unwanted Medicine or does not meet legal requirements will be rejected.
Vendor and the LEA will maintain all records of removal, storage, or destruction of the collected Unwanted Medicine in a manner consistent with the LEA’s recordkeeping requirements for illicit controlled substances evidence pursuant to § 1317.35. Any collected Unwanted Medicine will be stored to prevent the diversion of controlled substances and consistent with the LEA’s standard procedures for storing illicit controlled substances. Any storage of Unwanted Medicine by Vendor will also comply with the applicable security requirements of §§ 1301 and 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances.

Vendor will package Unwanted Medicine inner liners, match the unique inner liner identifier to shipping labels, and prepare the inner liners for shipment in compliance with all applicable laws, regulations, and other legal requirements. Collected material will be weighed following the completion of each event. With the sealed inner liners remaining under the control and custody of the LEA, Vendor will assist the LEA with the transportation of the sealed inner liners to the LEA’s facility. Vendor will schedule a pickup from the LEA facility to take place within a few business days of the event.

3. Fees and Costs
MED-Project shall pay all administrative and operational costs and fees associated with the Take-Back Events.

D. Disposal of Unwanted Medicine
Vendor and Carrier shall manage the Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events in compliance with all applicable laws, regulations, and other legal requirements. Carrier shall deliver Unwanted Medicine collected from Kiosk Drop-Off Sites and Take-Back Events to the reverse distributor facility identified in Section X.C.1.

All Unwanted Medicine will be destroyed no later than 30 calendar days after receipt at the reverse distributor facility from the Carrier. See Section X.C. for additional details.

All inner liners will be destroyed in accordance with all applicable laws, regulations, and other legal requirements at the disposal facility identified in Section X.C.

E. Unwanted Medicine Mail-Back Services
MED-Project will provide Mail-Back Services for Unwanted Medicine at no cost to differentially-abled and home-bound Residents. Home healthcare professionals providing services to differentially-abled or homebound residents may also request an envelope on behalf of differently-abled or homebound residents. MED-Project will also provide Mail-Back Services at no cost to Residents for certain Unwanted Medicine that cannot be commingled with other Unwanted Medicine in the kiosks, including iodine-containing medication and Pre-filled Injector Products. Mail-Back Packages will be pre-paid and pre-addressed, and Mail-Back Services shall comply with all applicable laws, regulations, and other legal requirements.
1. **Standard Mail-Back Services for Unwanted Medicine, Including Iodine-Containing Medication**

Pursuant to DEA Rule § 1317.70(c), the mail-back packages for all Unwanted Medicine except Pre-filled Injector Products (“Standard Mail-Back Services” or “Standard Mail-Back Packages”) will be:

- Nondescript and without any markings or information potentially indicating that they contain Unwanted Medicine, including controlled substances;
- Water and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with and delivered to Vendor’s registered address;
- Pre-paid;
- Provided with a unique barcode enabling tracking; and
- Provided with instructions indicating the process for mailing back the packages, accepted substances, instructions not to commingle iodine-containing medication with other Unwanted Medicine, a notice about mailing restrictions, and a notice that only packages provided by Vendor will be accepted for destruction.

Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property will not be required to provide any personally identifiable information when using Standard Mail-Back Services to dispose of Unwanted Medicine. See § 1317.70(d). As required under § 1317.70(e), Vendor will only accept Standard Mail-Back Packages it made available (or packages lawfully forwarded under DEA requirements). Within three business days of receipt, Vendor will notify the DEA if it receives Standard Mail-Back Packages likely containing controlled substances that Vendor did not make available or did not agree to receive pursuant to DEA requirements. In accordance with § 1317.70(f), when Standard Mail-Back Packages are received, only Vendor employees will handle the Standard Mail-Back Packages. Standard Mail-Back Packages will not be opened, x-rayed, analyzed, or otherwise penetrated upon receipt by Vendor. See § 1317.70(f). Vendor and MED-Project will keep all records required under the DEA Rule, including those identified in § 1304.22(f).

See Appendix H for a sample package and package specifications.

2. **Mail-Back Services for Pre-filled Injector Products**

For Pre-filled Injector Products from which Unwanted Medicine cannot be removed, MED-Project will offer residents a red FDA-approved sharps container and a pre-paid, pre-addressed Mail-Back Package for returning the sharps container (“Sharps Mail-Back Services” or “Sharps Mail-Back Package”). An instruction sheet describing how to properly dispose of sharps that explains what materials may be placed in a sharps container, how to use the sharps container, and how to return the Sharps Mail-Back Package will be included with the Sharps Mail-Back Package.

See Appendix H for a sample package and package specifications.

3. **Mail-Back Package Availability**

Differentially-abled and home bound Residents may request mail-back packages for Unwanted Medicine by calling the call center or through a link on the MED-Project website. Upon such request, Residents will be provided mail-back packages complying with all applicable federal, state, and local laws, regulations, and other legal requirements. Additionally, Mail-Back Services for iodine-containing medication and Sharps Mail-Back Services for Pre-filled Injector Products will be available to all Residents through the call center and website.
Each Mail-Back Package will contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in English, Khmer, Korean, Russian, Spanish, and Vietnamese. See Appendix H for a sample package.

Ninety days after Plan approval, MED-Project will conduct a gap assessment of established Kiosk Drop-Off Sites. If fewer than the required number of sites have been obtained through agreements signed by Kiosk Drop-Off Site Hosts, MED-Project will supplement Kiosk Drop-Off Sites through the establishment of distribution locations for Unwanted Medicine Mail-Back Packages and/or the scheduling of Take-Back Events. If supplementing Kiosk Drop-Off Sites through Mail-Back Package Distribution Locations, MED-Project will establish Mail-Back Package Distribution Locations for each missing Kiosk Drop-Off Site.

MED-Project will work with locations such as County facilities, city and town halls or libraries to provide Mail-Back Packages at centralized locations.

4. Mail-Back Package Collection and Disposal
Requests to receive mail-back packages will be taken through the call center or a link on the MED-Project website. Residents can continue to request additional packages, if necessary, by contacting MED-Project via the call center and/or through the website. As described above, Residents may also obtain certain Mail-Back Services through Mail-Back Package Distribution Locations.

Residents will be directed to follow the instructions provided in the mail-back package and to place their Unwanted Medicine in the pre-addressed/pre-paid package. The United States Postal Service (“USPS”) estimates up to three business days for delivery of First Class Mail. The mail-back package shall be sent to an approved disposal facility and handled in compliance with all Applicable Laws. For Standard Mail-Back Packages, upon arriving at the disposal facility, the mail-back packages shall be scanned for receipt verification and then rendered non-retrievable. After this destruction, any remaining Standard Mail-Back Package materials shall be incinerated at the disposal facility listed in Section X.D.2. See Appendix I for more details. Any storage of filled Standard Mail-Back Packages by Vendor will comply with the applicable security requirements of DEA Rule Section 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances. All Unwanted Medicine will be destroyed promptly.

This Plan proposes to treat Sharps Mail-Back Packages at an autoclave facility through the use of high-heat sterilization, and dispose of the treated materials in a landfill. See the facilities identified in Section X.E. In accordance with Regulations § 13.F, we request that the Health Department exercise reasonable discretion to waive strict compliance with the disposal requirement in Regulations § 9.A mandating that Unwanted Medicine be disposed of at a permitted hazardous waste disposal facility; instead, we request that the Health Department allow MED-Project to use an autoclave and municipal waste landfill to treat and dispose of Pre-filled Injector Products collected through Sharps Mail-Back Packages. MED-Project petitions the Heath Department to approve this process as an alternative final disposal technology in accordance with Regulations § 9.C. MED-Project’s request for approval to autoclave Sharps Mail-Back Packages was submitted on September 29, 2017 (see Appendix J).
VI. Plan and Collection Goals

The short- and long-term goals of the Plan are described generally as follows. Additional detail on implementation is provided in Section V.A.2.

MED-Project anticipates that establishment of Kiosk Drop-Off Sites will begin within 90 days of approval of the Plan and will continue throughout the year. Once all drop-off locations are fully operational, the program expects to collect approximately 360 pounds per Kiosk Drop-Off Site during each calendar year, based on collection totals in other jurisdictions. Assuming approximately 37 Kiosk Drop-Off Sites are operational for a full year, MED-Project anticipates collecting approximately 13,320 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2019. See section V.B. for more information about Kiosk Drop-Off Site collection.

Until the Service Convenience Goal is met, MED-Project anticipates supplementing Kiosk Drop-Off Sites through Mail-Back Services and/or Take-Back Events. Based on Take-Back Event collection totals in other jurisdictions, MED-Project anticipates collection of 50 to 200 pounds of Unwanted Medicine per take-back event.

MED-Project Standard Mail-Back Packages have a capacity of 8oz. per package. Due to the lack of information available from current MED-Project Programs, MED-Project’s estimated collection totals in 2018 could vary based on actual usage. Collection in 2018 will be used to adjust subsequent years’ collection goals.

Data from 2018 will be utilized to establish baseline collection and estimate collection goals for future years.

### Anticipated Collection Amounts (Lbs.):

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
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<tbody>
<tr>
<td>Kiosk Drop-Off Sites</td>
<td>6,500</td>
<td>13,320</td>
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<tr>
<td>Take-Back Events &amp; Mail-Back</td>
<td>1500</td>
<td>N/A</td>
</tr>
<tr>
<td>Pounds Collected</td>
<td>8,000</td>
<td>13,320</td>
</tr>
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</table>

### Goal Area

<table>
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<th>Long-Term</th>
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<td>Collection</td>
<td>Approximately 8,000 pounds of Unwanted Medicine collected through Kiosk Drop-Off Sites, Mail-Back Services, and/or Take-Back Events.</td>
<td>Approximately 13,320 pounds of Unwanted Medicine collected through Kiosk Drop-Off Sites, Mail-Back Services, and/or Take-Back Events. Increased reliance on established Kiosk Drop-Off Sites and limited or no collection through Take-Back Events.</td>
</tr>
</tbody>
</table>
Education & Public Outreach

Develop baseline number of website page views or unique visitors.

Establish a baseline of LEAs; retail pharmacies; other pharmacies (healthcare, etc.); community groups; and other third parties contacted, and report appropriate statistics as outlined in the Survey and Annual Report sections of this Plan.

Establish a baseline number of media outlets receiving press advisory, with a minimum of five outlets.

Establish a baseline percentage of community centers reached.

Establish a baseline number of messages to MED-Project returned within predetermined timeframe.

On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan.

MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the Stewardship Plan, assess to what extent Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Results of the review will be published on the website established under Section XI.D.2.

Collector Outreach

Contact LEAs and retail pharmacies and invite them to participate in the Plan. Set targets for LEAs and retail pharmacies.

Ongoing communication with pharmacies and LEAs. Evaluation of Kiosk Drop-Off Sites against the Service Convenience Goal.

VII. Patient Privacy

Instructions at each Kiosk Drop-Off Site Host location will inform people who deposit Unwanted Medicine that they should completely cross out, remove, or otherwise make unreadable all personally identifiable information on the drug containers and packaging before depositing them in the kiosk. In cases where people follow the instructions, there will be no personally identifiable information.

In addition to kiosk signage, all MED-Project promotional and educational materials encourage residents to protect their information by ensuring that identifiable information is not present before depositing containers into kiosks. Examples of MED-Project brochures, signage, and website materials are available in Appendix E and Appendix L. Vendor has additional protections available for keeping residents’ personal identifiable information safe and secure. Service Technicians are well trained in managing items containing sensitive patient information. Privacy training is part of a Service Technician’s prerequisite for field services. As added protection, the liners for the kiosk will be opaque rather than clear, in compliance with the DEA Rule. This will prevent anyone, including the Service Technician, from seeing any information on the containers placed in the kiosks.

Materials to help Residents cross out any personally identifiable information will also be available at Take-Back Events. This will ensure any patient information on drug packaging will be unreadable.
VIII. Call Center

Questions from Residents will be managed by a call center with an interactive voice response (IVR) system and the support of an operator available during business hours of 9:00am to 5:00pm PST Monday through Friday. If the operator is unavailable, a caller will be able to leave a message to which the operator will respond. All operators shall be trained to respond based on the requirements set by MED-Project. IVR support will be made available in English, Khmer, Korean, Russian, Spanish, and Vietnamese.

The IVR will answer general questions, including questions on the following topics:

1. Items that can be disposed;
2. Disposal options;
3. Direction to the Program website and call center operators for additional information; and
4. How to request for mail-back packages.

Because the list of Kiosk Drop-Off Sites is subject to change, Residents will be directed to the MED-Project website or to an operator for detailed information about kiosk locations and service hours.

Per Regulations § 8.B, MED-Project will operate a call center jointly with all other Stewardship Programs should other Stewardship Plans be approved by the County.

IX. Training

Operational procedures, including training, are the responsibility of the Kiosk Drop-Off Site. MED-Project will support training if agreed to with the Kiosk Drop-Off Site. Additionally, MED-Project will manage a support hotline to answer questions and monitor comments for participating Kiosk Drop-Off Sites.

The support hotline will support two general communication functions:

1. Answer questions and monitor comments from participating Kiosk Drop-Off Site Hosts.
2. Support and direct service requests from participating Kiosk Drop-Off Sites.

Messages received from Kiosk Drop-Off Sites will be returned within one business day.

Vendor will comply with all applicable laws, regulations, and other legal requirements. Vendor’s internal training process will address the following:

- Onboarding & on-truck observation of job functions – five days
- United States Department of Transportation (“DOT”) Training – two days
- DEA Training – one day
- United States Environmental Protection Agency (“EPA”) Waste Characterization – one day
- Occupational Safety and Health Administration (“OSHA”) Training – one day
- Waste Handling Demo – one day
- Truck Operation – one day
- DEA Handling Demo – one day
- Review & Written Test – one day
- Perform work under supervision to demonstrate proficiency prior to certification to service client accounts – ten days
A. **Service Technician Training**

The Service Technicians collecting and transporting the Unwanted Medicine will complete an initial two-week program of comprehensive in-house classroom and hands-on training under the direction of a Certified Hazardous Materials Manager certified Senior Environmental Health and Safety Manager. This training includes instruction on:

- DOT hazardous materials requirements;
- EPA waste characterization requirements;
- Resource Conservation and Recovery Act (“RCRA”) hazardous waste requirements;
- DEA controlled substances transfer protocols;
- OSHA requirements; and
- Health Insurance Portability and Accountability Act (“HIPAA”) requirements.

Service Technicians must complete a 24 or 40-hour Hazardous Waste Operations and Emergency Response Standard (“HAZWOPER”) course. Additionally, Service Technicians must complete annual refresher training that includes an 8-hour training on DOT, HAZWOPER, HIPAA, OSHA, RCRA, and safety and security. Finally, Service Technicians receive ongoing training in the form of daily “tips”, weekly meetings, and online refresher courses. All Vendor employees servicing Take-Back Events, Kiosk Drop-Off Sites, or mail-back collection will have a training base similar to that of Service Technicians, with customized training as needed.

X. **Transporter and Disposal Facility Information**

A. **Vendor**

- Name: **Stericycle Specialty Waste Solutions, Inc.** will service Kiosk Drop-Off Sites and Take-Back Events.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: 612-285-9865
- Website: [www.stericycleenvironmental.com](http://www.stericycleenvironmental.com)
- DOT ID Number: MNS 000 110 924
- US DOT Number: 1348411
- Permit Status: All relevant permits are active and in good standing. Available upon request.

B. **Transporter of Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events**

1. **Carrier**

- Name: **United Parcel Service, Inc.** will transport the Unwanted Medicine to the reverse distributor facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA, 30328
- Phone: 800-PICK-UPS
- Website: [www.UPS.com/](http://www.UPS.com/)
- Type: Common Carrier
- U.S. Small Package DOT number: 21800
- U.S. Freight DOT number: 121058
2. **Transporter**
   - **Name:** Heritage Transport will transport Unwanted Medicine from the reverse distributor facility to the disposal facility.
   - **Address:** 1626 Research Way, Indianapolis, IN 46231
   - **Phone:** (317) 486-2973
   - **Website:** [http://www.heritage-enviro.com/](http://www.heritage-enviro.com/)
   - **EPA ID#:** IND 058 484 114
   - **US DOT Number:** 314460
   - **Permit Status:** All relevant permits are active and in good standing. Available upon request.

C. **Disposal Facility for Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events**

1. **Reverse Distributor Facility**
   - **Name:** Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”) will receive Unwanted Medicine from the Carrier.
   - **Address:** 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
   - **Phone:** 317-275-7530
   - **Website:** [www.stericycleenvironmental.com](http://www.stericycleenvironmental.com)
   - **Type:** DEA-compliant and registered collector facility
   - **DEA Registration No.:** RS0331607
   - **RCRA Permit No:** INR000110197
     - **Permit Status:**
       iii. Air Quality: Exempt. Permit Number: E097-28740-00671. Expiration: N/A.

2. **Disposal Facility**
   - **Name:** Heritage Thermal Services – Ohio will incinerate Unwanted Medicine received at the Reverse Distributor Facility.
   - **Address:** 1250 Saint George Street, East Liverpool, Ohio, 43920
   - **Phone:** 800-545-7655
   - **Website:** [http://www.heritage-thermal.com/](http://www.heritage-thermal.com/)
   - **Type:** Permitted Hazardous Waste Incinerator
   - **DEA Registration No.:** RH0387628
   - **RCRA Permit No:** OHD980613541
   - **Permit Status:** Active

D. **Disposal Facility for Standard Unwanted Medicine Mail-Back Services**

1. **Primary Disposal Facility**
   - **Stericycle Facility** – see Plan § XI.C.1. will render Standard Mail-Back Packages and the controlled substances therein non-retrievable.
2. Secondary Disposal Facility
   - Name: Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility ("Covanta Facility") will incinerate non-retrievable materials from the Stericycle Facility.
   - Address: 2320 S. Harding St., Indianapolis, IN 46221
   - Phone Number: 317-634-7367
   - Website: http://www.covanta.com/facilities/facility-by-location/indianapolis.aspx
   - Type: Municipal Waste Combustor
   - Title V Air Permit No.: T097-5985-00123
   - Industrial Wastewater Discharge Permit No.: 495301
   - Solid Waste Permit No.: 49-13
   - Permit Status: All permits are current

Regulation § 9.B provides that the Health Department may approve the disposal of some or all Unwanted Medicines at a permitted large municipal waste combustor if disposal at permitted hazardous waste disposal facilities is “not feasible” based on “cost, logistics or other considerations.” MED-Project is proposing a two-phase process using the Stericycle Facility and Covanta Facility to dispose of mail-back packages. MED-Project’s request for approval to use this two-phase process for Mail-Back Package disposal resulting in destruction at a municipal waste combustor was submitted on June 5, 2017 (see Appendix I).

E. Treatment and Disposal Facilities for Pre-filled Injector Products from Mail-Back Services

1. Autoclave Facility
   - Name: Medsharps
   - Address: 17340 Bell N Dr., Schertz, TX 78154
   - Phone Number: (844) 800-6981
   - Website: www.medsharps.com
   - Type: Medical Waste Disposal Facility
   - State Permit No.: 40244
   - Permit Status: All permits are current

2. Disposal Facility
   - Name: Tessman Road Landfill
   - Address: 7000 E IH 10, San Antonio TX 78219
   - Phone Number: (210) 661-7558
   - Website: https://www.republicservices.com/customer-support/facilities
   - Type: Non-Hazardous Landfill

As discussed in Section V.E.4, the Plan proposes to treat Sharps Mail-Back Packages at an autoclave facility through the use of high-heat sterilization, and dispose of the treated materials in a landfill. MED-Project’s request for approval to autoclave and landfill Sharps Mail-Back Packages was submitted on September 26, 2017 (see Appendix J).
XI. Unwanted Medicine Educational and Outreach Programming

A. Overview
The following communications plan includes a description of the public education and outreach efforts that MED-Project will undertake to educate Residents about the collection and disposal of Unwanted Medicine from households.

While MED-Project operates an education and outreach program specific to each individual Plan, MED-Project websites, signage, and printed material will provide consistent branding across all counties to the extent possible.

As required by Regulations § 8.B, MED-Project will seek to coordinate its promotional activities with other approved Stewardship Programs.

B. Audiences
To effectively educate the public about the Plan, MED-Project has developed a comprehensive communications campaign featuring both broad communications tactics (e.g., media advisories, etc.) as well as targeted outreach to audiences directly involved in the distribution and use of medicines to Residents. These audiences include:

- General public
- Pharmacies and Retailers of Covered Drugs
- Health care providers
- Veterinary providers
- Public health facilities
- Law enforcement agencies

This Plan details Program efforts to reach the varied cultural, linguistic, geographic, and age demographics, including through outreach to ethnic, community, and alternate-language media (Appendix G); outreach to community organizations serving a broad range of audiences (Appendix B); availability of alternate language phone lines (Section XI.D.1.); and availability of educational information through a broad range of channels, including a toll free call center, broadcast media, and the internet.

Demographic information, including race/ethnicity, language, age, and geographic data, will be analyzed to appropriately direct outreach and create educational materials to best serve the unique needs of Residents. Efforts to ensure that materials are appropriately targeted, translated, and available to these populations will be pursued with associations, agencies, and organizations that can be viewed in Appendix B.
C. Messages
MED-Project messaging will focus on the following goals:

- Educating Residents about the appropriate use, storage, and disposal of Unwanted Medicine,
- Educating Residents about appropriate storage and disposal of Pre-filled Injector Products if Unwanted Medicine cannot be removed from these products,
- Educating Residents about Mail-Back Services available, and;
- Providing Residents with clear steps to properly manage the disposal of their Unwanted Medicine, iodine-containing medication, Pre-filled Injector Products including following instructions found on the medicine label, use of Kiosk Drop-Off Sites, use of available Mail-Back Services, and/or participation in Take-Back Events.

Key points of emphasis will include:

- The importance of taking medicines as prescribed by your health care provider;
- The importance of adhering to and completing your provider-prescribed therapy;
- The importance of properly and securely storing medicines;
- The importance of promptly and properly disposing of Unwanted Medicine;
- How to find and use Kiosk Drop-Off Sites;
- How to properly use the Mail-Back Services provided;
- How to properly dispose of Unwanted Medicine; and
- Privacy issues (removing personally identifiable information from labeled prescription containers).

MED-Project will also collaborate with home health care providers to promote the use of Mail-Back Services by Residents who are differentially-abled or homebound.

D. Tools/Communications Channels
The Program will include several components designed to reach consumers and provide consistent access to timely and relevant information. Distribution of materials will include audiences such as LEAs, pharmacies, health care providers and systems, health associations, local government agencies, and other community organizations and will be evaluated regularly for effectiveness. Tools and communication channels will include:

1. Phone
MED-Project will provide a toll-free telephone number (1-844-MED-PROJ) for Residents to obtain information about Kiosk Drop-Off Sites, educational materials, and other aspects of the Program. The toll-free number will provide:

- The MED-Project toll-free telephone line will initially support English and Spanish. The telephone line will also provide an option for callers to be transferred to a staffed call center.
- A recorded-line script at 1-844-MED-PROJ will provide basic information about how the Program works, where to obtain more information (e.g., the website), and will also include an option to talk with an operator to find a Kiosk Drop-Off Site, request Mail-Back Services, or find a Take-Back Event in the caller’s ZIP code or local area.
- The recorded call script will include language directing callers with medical emergencies to call 911. Patients with medication-related questions will be directed to contact their health care provider(s).
Please see Appendix K for a sample template of the recorded call script. MED-Project will expand the IVR support to include Khmer, Korean, Russian, Spanish, and Vietnamese.

2. Website
MED-Project is developing a mobile-friendly website translated into Khmer, Korean, Russian, Spanish, and Vietnamese. Information available to users will include locations of Kiosk Drop-Off Sites, educational materials, frequently asked questions and responses, Mail-Back Services information, and Take-Back Event dates and locations. The website and all materials will discourage disposal of unused, expired, or contaminated pharmaceutical wastes in the solid waste system in Pierce County per County Regulations.

- The website will be available within 90 days of Plan approval. The Plan currently includes a sample mockup of the website and its supporting pages. Appendix L provides a proof of concept for each page.
- The website will also include access to a public relations toolkit in a downloadable format (see Section XI.D.3) and contact information for Residents. A toolkit available on the website includes a brochure (See Appendix M), a public service announcement available in broadcast and audio versions (Appendix M), and a frequently asked questions (FAQ) document (Appendix M) which will be reviewed and updated periodically. Translations of the brochure and FAQ will be available in Khmer, Korean, Russian, Spanish, and Vietnamese.
- Community and government organizations and other public interest groups seeking materials to promote the Program will be encouraged to access these resources.

3. Materials
Educational materials about the Program and describing how to properly dispose of Unwanted Medicine, iodine-containing medication, and Pre-filled Injector Products will be available through the website, through potential third-party partners, community organizations, and at Kiosk Drop-Off Sites. These partners will include pharmacies, health care facilities, and veterinary facilities. MED-Project will also provide local governments and other interested parties with materials covering the proper disposal of Unwanted Medicine. Until the Service Convenience Goal has been met, MED-Project will be promoting the Mail-Back Services through additional educational materials that will be made available to all Residents (see Appendix M). To the extent possible, materials will be translated into Khmer, Korean, Russian, Spanish, and Vietnamese.

The Plan includes a sample of the educational brochure (Appendix M) and media advisory promoting Take-Back Events (Appendix N). An additional sample brochure has been created to communicate Mail-Back Services available to Residents (Appendix M). Educational materials use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency.

4. Media Outreach
The Program will conduct public outreach through mediums such as traditional and social media, posting of educational signage, and at community events. Outreach efforts will encourage media outlets and third-party groups to download and use the toolkit. MED-Project will coordinate outreach for scheduled Take-Back Events to promote participation. The following materials support the Unwanted Medicine educational and outreach programming:
• Please see Appendix K for a sample education and outreach call script with the toolkit, including flyers in Appendix M and website information included in Appendix L.
• Please see Appendix G for a sample list of key media outlets.
• Please see Appendix O for a sample list of social media outlets.
• Please see Appendix N for a sample template media advisory announcing Take-Back Events.

5. Broadcast Outreach
MED-Project will utilize local television outlets to conduct outreach to Residents. Outreach will be conducted through local print, online, television, and radio outlets, as well as through outlets specifically targeting the diverse demographic communities within the County. Please see Appendix G for a sample media list of key outlets.

E. Collaboration with County Officials and Community Organizations
MED-Project will work in collaboration with the County as appropriate to build on existing community outreach resources, such as local organizations, media lists, available public media outlets, etc. MED-Project will conduct the following outreach efforts:

• Briefing Materials Provided to Support Coordination with County Officials:
  ◊ MED-Project will provide access to Educational and Outreach Programming materials, including the sample brochure (see Appendix M), to relevant departments and officials.

• Outreach through Community Organizations:
  ◊ MED-Project will further promote the Program by engaging relevant stakeholders and community organizations, for example, by providing community organizations identified in Appendix B with the toolkit included in Appendix M.

• Briefing Materials Provided to Support Collaboration with Home Health Care Providers.
  ◊ MED-Project will collaborate with home health care providers to promote the use of Mail-Back Services by differentially-abled and homebound residents. MED-Project will be providing home health care providers with the toolkit included in Appendix M.

F. Disclaimer
The written and verbal educational materials and public outreach tools that are required by the Regulations and disseminated under this Product Stewardship Plan will include a disclaimer similar to the following: “This material has been provided for the purposes of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.”

XII. Survey
Per Regulations § 8.A.6, MED-Project will conduct a biennial survey of Residents, pharmacists, veterinarians, and health care professionals who interact with members of the community after the first full year of Program operation and biennially thereafter. Survey will be made available in English, Khmer, Korean, Russian, Spanish, and Vietnamese.

Survey questions will be designed to measure, at a minimum, (1) percent awareness of the Program, (2) whether drop-off sites and other collection methods are convenient and easy to use, and (3) knowledge
and attitudes about risks of abuse, poisoning, and overdoses from prescription and nonprescription drugs used in the home. As required by Regulation § 8.A.6, draft survey questions will be submitted to the Health Department for review and comment thirty days prior to distribution. Results of the survey will be reported to the Health Department and made public within 90 days of the end of the survey period on the website described under Section XI.D.2. The privacy of all survey respondents will be maintained.

MED-Project is unaware currently of any other Stewardship Organizations that intend to submit a Stewardship Plan in the County. Per Regulation § 8.B, MED-Project will seek to coordinate with other Stewardship Programs to conduct the survey if other Stewardship Plans are approved by the County.

XIII. Packaging

The Regulations require that a Plan consider “[s]eparating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and [r]ecycling of drug packaging to the extent feasible.” Regulations § § 6.G.b and 6.G.c.

MED-Project has considered and evaluated options for the separation and recycling of drug packaging. Separating and recycling drug packaging collected under the Plan would require the management of separate waste streams at Kiosk Drop-Off Sites and Take-Back Events: a waste stream for drug packaging and a waste stream for the drugs themselves.

While drug packaging is expected to constitute a significant amount of the waste incinerated under the Plan, MED-Project has concluded that separation of inner and/or outer packaging from Unwanted Medicine or recycling packaging would raise three significant concerns:

1. Separating and recycling drug packaging could result in the disclosure of confidential patient information appearing on prescription drug packaging;
2. Separating and recycling drug packaging could increase the potential of releases and leakage of Unwanted Medicine; and
3. Separating and recycling drug packaging could increase diversion risks by adding additional steps to the collection process and because drug packaging is used in drug counterfeiting and would be a diversion target itself.

For these reasons, the Plan does not provide for the separation and recycling of packaging from Unwanted Medicine.

XIV. Compliance with Applicable Laws, Regulations, and Other Legal Requirements

The Regulations require that a Product Stewardship Plan describe how all entities participating in the Program will “operate under” all applicable laws, regulations, and other legal requirements. Regulations § 6.C. As described in more detail below, the Plan is designed such that all entities participating in the Program shall comply with all applicable laws, regulations, and other legal requirements.

A. DEA Controlled Substances Act and Implementing Regulations

On October 12, 2010, the United States Congress enacted the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act") as amendments to the Controlled Substances Act ("CSA"). The Disposal Act amended the CSA to allow for the expansion of entities to which users can deliver pharmaceutical controlled substances for disposal, subject to regulations to be promulgated. On September 9, 2014, the
DEA adopted a rule entitled “Disposal of Controlled Substances” to implement the Disposal Act.

Under the DEA Rule, collection of controlled substances is limited to Schedule II, III, IV, or V controlled substances that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent’s property. See DEA Rule §§ 1317.75(b) (Kiosk Drop-Off Sites); 1317.65(d) (Take-Back Events); 1317.70(b) (Mail-Back Services). Schedule I controlled substances, controlled substances that are not lawfully possessed as described above, and other illicit or dangerous substances will not be collected. Additionally, as these provisions of the DEA Rule limit collection of controlled substances to those lawfully possessed by an ultimate user or certain other persons, pharmacies are prohibited from disposing their own inventory or stock through the Program. See id.; see also § 1317.05.

The DEA Rule provides that LEAs can continue to accept controlled substances for disposal. However, the DEA Rule also provides that pharmacies, reverse distributors, hospitals/clinics with on-site pharmacies, and certain other entities, can register with the DEA as “collectors” and become authorized at their discretion on a voluntary basis to accept controlled substances. The DEA Rule:

- Provides for the collection of controlled substances at Kiosk Drop-Off Sites at LEAs, pharmacies, and hospitals or clinics with on-site pharmacies;
- Provides for collection of controlled substances at Take-Back Events;
- Provides for the use of mail-back programs to collect controlled substances;
- Allows for the commingling of controlled and non-controlled substances;
- Establishes detailed collection, recordkeeping, security, and other measures for all approved collection methods; and
- Provides that all collected pharmaceutical products be destroyed so that the products are rendered non-retrievable.

The Plan is designed such that all entities that are part of the Plan, including Vendor, are individually responsible to comply with their respective compliance obligations under the DEA Rule. Vendor will ensure that the transportation of Unwanted Medicines collected from Kiosk Drop-Off Sites and Take-Back Events, including controlled substances, complies with all DEA requirements, including those in § 1317.

Controlled substances collected pursuant to the Program may be commingled with non-controlled substances at Kiosk Drop-Off Sites, Take-Back Events, and through Mail-Back Services per the DEA Rule. See §§ 1317.75(b) (Kiosk Drop-Off Sites); 1317.65(d) (Take-Back Events); 1317.70(b) (Mail-Back Services).

1. **DEA Registration Modification**

Pursuant to 21 C.F.R. § 1301.51(b), pharmacies may modify their registrations to become authorized collectors by submitting a request to the DEA or online at [www.DEAdversion.usdoj.gov](http://www.DEAdversion.usdoj.gov). This request must contain:

- The registrant’s name, address, and registration number (as printed on the registration certificate);
- The collection methods the registrant intends to conduct; and
- A signature in accordance with § 1301.13(j).

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*For Kiosk Drop-Off Site collection, only certain substances “that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected.” § 1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent’s property. See §§ 1317.65(d); 1317.70(b).*
See § 1301.51(b). MED-Project will consult with participating pharmacies, as requested, regarding how to modify DEA registrations to become authorized collectors.

B. United States Department of Transportation (USDOT)
When transporting Unwanted Medicine, Vendor will ensure compliance with the USDOT Hazardous Materials Regulations (HMR).

C. Washington State Pharmacy Quality Assurance Commission (WSPQAC)
The Regulations require that a Plan describe “how any pharmacy drop-off site will operate under applicable regulations and guidance’s of the Washington State Pharmacy Quality Assurance Commission.” Regulations § 6.C. On March 3, 2016, WSPQAC published “Pharmacy Quality Assurance Commission Guidance Document: Secure and Responsible Drug Disposal Program.” As required by the Regulation, participating pharmacies will comply with this guidance document, which, among other things, requests that pharmacies notify WSPQAC upon obtaining DEA authorized collector status.

D. State of Washington Waste Management Program
MED-Project, Vendor, and other entities participating in the Program shall comply with any applicable provisions of the State of Washington’s waste management program, including applicable “moderate-risk” waste and product take-back center requirements.

XV. Annual Report
An annual report will be provided to the Health Department within 180 days after the end of the first one-year period of operation and annually thereafter. Regulation § 11.A.

For the reporting period, the report will include:

- A list of producers participating in the Plan;
- The amount, by weight, of Unwanted Medicine collected from Kiosk Drop-Off Sites and Take-Back Events. For Mail-Back Services, MED-Project will identify the number of mail-back packages destroyed;
- A list of Kiosk Drop-Off Sites;
- The number of mailers provided and the zip codes where mailers were provided;
- The dates and locations of Take-Back Events held;
- Transporters and disposal facilities used;
- Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Medicine and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and improve safety and security;
- A description of public education, outreach, and evaluation activities implemented;
- A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- A summary of the Product Stewardship Plan’s goals, the degree of success meeting these goals in the past year, and how these goals will be achieved in the next year if they were not met;
- An evaluation of the effectiveness of the Program’s promotion, outreach, and public education activities; and
- The Plan’s total expenditures.
Appendix A

MED-Project Participants

The list of participating Producers in MED-Project’s Program in Tacoma-Pierce County is provided to the County on an ongoing basis. The list was last submitted on August 11, 2017.
Appendix B

Sample Contact List for Outreach and Education to the Community

The following are associations, agencies, and organizations that will be contacted for assistance with outreach and education to the community. They will also be contacted to participate as potential Kiosk Drop-Off Sites and/or Take-Back Event hosts.

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<th>Organizations, Districts, and Agencies:</th>
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<td>Pierce County Nurses Association</td>
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<td>Muscular Dystrophy Association</td>
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<td>Sumner Veterinary Hospital</td>
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<td>Institute for Fitness and Health</td>
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<td>MultiCare Indigo Urgent Care</td>
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<td>MultiCare Spanaway Clinic</td>
<td>Catholic Health</td>
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Appendix C

Kiosk Drop-Off Sites with Expressions of Interest

MED-Project will provide the County with a list of participating Kiosk Drop-Off Sites on an on-going basis.

Below is a list of locations that have expressed interest in participating as a Kiosk Drop-Off Site. The pharmacy and LEA responses below reflect information provided by the sites surveyed as of September 15, 2017. Chain pharmacy interest expressed was at the local pharmacy level. Chain pharmacy participation could be contingent upon agreement with regional and national offices. MED-Project will continue to outreach and work within the corporate structure where applicable.

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## Appendix D

### Potential Additional Kiosk Drop-Off Sites

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Appendix E

Picture of Kiosk Prototype

The design of the kiosk recognizes the paramount importance of security using heavy gauge steel, multiple locking mechanisms, tamper-proof slot and commercial hinges, meeting the stringent requirements under law. At the same time, the design provides accessibility and ease of use.
Sample Kiosk Signage

Front Panel Signage

SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

1. Cross out or remove personal identifying information from the medicine bottle.
2. Leave the product in its original container or place solid medicines in a sealed plastic bag.
3. Put medicine in the kiosk.

ACCEPTED: Medications in any dosage form, except for those listed below, in their original container or sealed bag.

NOT ACCEPTED: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, medical devices, pet pesticide products, sharps, illicit drugs, mercury containing thermometers and iodine-containing medications.

ONLY SCHEDULE II-V CONTROLLED AND NON-CONTROLLED SUBSTANCES THAT ARE LAWFULLY POSSESSED BY THE ULTIMATE USER ARE ACCEPTABLE TO BE PLACED IN THE KIOSK. SCHEDULE I CONTROLLED SUBSTANCES, ILICIT OR DANGEROUS DRUGS, AND ANY CONTROLLED SUBSTANCES NOT LAWFULLY POSSESSED BY THE ULTIMATE USER MAY NOT BE PLACED IN THE KIOSK.

For more information about the MED-Project program, please go to www.med-project.org or call 1-866-MED-PROJ.

MED-Project
Medication Education & Disposal
Sample Kiosk Signage

Side Panel Signage

SAFELY
DISPOSE OF
UNWANTED & EXPIRED
MEDICINES

To request kiosk service, call (844) 677-6532 or visit www.med-project.org/locations/tacoma-pierce/contact.

MED-Project™
Medication Education & Disposal
Sample Kiosk Signage

Drop Slot Signage

**ACCEPTED**: Medications in any dosage form, except for those listed below, in their original container or sealed bag.

**NOT ACCEPTED**: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, medical devices, pet pesticide products, sharps, illicit drugs, mercury containing thermometers and iodine-containing medications.
Appendix F

Community Events That May Serve as Future Take-Back Events

The following are examples of events that may be targeted for Take-Back Events based on timing and geographic needs:

**Festivals and Community Events**

- The Schooner Zodiac Tacoma Port Call at Foss Waterway Seaport
- Puyallup Spring Fair
- Taste of Tacoma at Point Defiance Park
- Washington State Fair (aka The Fair or The Puyallup)
- Victorian Country Christmas Festival
- Tacoma Jazz & Blues Festival
- Pierce County Fair
- Rainier Mountain Festival
- Oktoberfest Puyallup
The following is a representative list of key media outlets to help educate residents about proper disposal of Unwanted Medicine. The list includes local print, online, television, and radio outlets.

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<th>Radio Outlets</th>
<th>City/Coverage Area</th>
</tr>
</thead>
<tbody>
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<td>KIRO Radio News 97.3 FM</td>
<td>CBS Regional</td>
</tr>
<tr>
<td>KOMO Radio 1000 AM</td>
<td>ABC Regional</td>
</tr>
<tr>
<td>KUOW 94.9 FM</td>
<td>NPR Regional</td>
</tr>
<tr>
<td>KUPS 90.1</td>
<td>FM Regional</td>
</tr>
<tr>
<td>KLAY AM 1180</td>
<td>AM Regional</td>
</tr>
<tr>
<td>KNKX (nee KPLU) 88.5 FM</td>
<td>NPR Affiliate</td>
</tr>
</tbody>
</table>
Appendix H

A. Sample Standard Mail-Back Package

Description:
Plastic Package with Merchandise Return Label and instructional flyer

Page Size:
Package: Outer Dimension: 8.25” x 12”; Inner Dimension: 7.375” x 10.375”, 2” flap (Hot Melt Tape- Tamper Evident)
Merchandise Return Label: 4” x 4”
Instructional Sheet: 5” x 7”

Paper Stock:
Package: 4mil white/ silver poly mailer w/sequential barcode
Return Label: 60# uncoated label stock
Instructional Sheet: 80# Gloss Text

Color:
Package: 5/3 Print: Silver, white, white, + 2 PMS on clear web; Silver + 2 PMS on white web
Return Label: K/0 no bleeds (personalized barcode)
Instructional sheet: K/K
B. Sample Mail-Back Package for Pre-filled Injector Products

**Description:**
1.4 quart Sharps waste mail-back system

**Package Sizes:**
1.4 Quart and/or 1.2 gallon

PureWay mail-back solutions are an example of complete, turnkey systems to provide for the safe and compliant return of sharps waste through the United States Postal Service. All PureWay solutions are tested and permitted to USPS specification as outlined in USPS Publication 52. MED-Project retains the right to change its Vendor for Mail-Back Services at any time.
Appendix I
Request for Approval for Mail-Back Package Disposal

MED-PROJECT REQUEST FOR APPROVAL OF STANDARD MAIL-BACK PACKAGE DISPOSAL PROCESS

June 5, 2017
MED-PROJECT REQUEST FOR APPROVAL OF STANDARD MAIL-BACK PACKAGE DISPOSAL PROCESS

Pursuant to the Tacoma-Pierce County Board of Health Secure Medicine Return Regulations (“Regulations”) § 9, MED-Project LLC (“MED-Project”) requests the Health Department’s (the “Department’s”) approval to use the Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility (the “Covanta Facility”), via the Stericycle, Inc., Indianapolis, Indiana Facility (the “Stericycle Facility”), for the disposal of Standard Mail-Back Packages (as defined in MED-Project Product Stewardship Plan (“Plan”) § V.E.1). As described below, conflicting United States Drug Enforcement Administration (“DEA”) and Resource Conservation and Recovery Act (“RCRA”) or similar state requirements and an inchoate market for Standard Mail-Back Package disposal make disposal of Standard Mail-Back Packages at permitted hazardous waste facilities not feasible at this time based on cost, logistics or other considerations.

To dispose of Standard Mail-Back Packages under these constraints, MED-Project is proposing a two-phase disposal process. In phase one, the Stericycle Facility accepts Standard Mail-Back Packages (including any controlled substances therein)\(^1\) and renders them non-retrievable in compliance with DEA requirements. In phase two, the Covanta Facility incinerates any remaining non-retrievable materials from the Stericycle Facility. This two-phase process allows MED-Project to dispose of Standard Mail-Back Packages in compliance with all DEA and RCRA requirements at a municipal waste combustor. Given existing barriers rendering disposal at permitted hazardous waste facilities not feasible, MED-Project’s proposed Stericycle Facility and Covanta Facility two-phase process should be approved.

I. The Stericycle Facility and Covanta Facility Two-Phase Process for the Disposal of Standard Mail-Back Packages

Under the Plan’s mail-back program, Tacoma-Pierce County residents can request a standard mail-back envelope by calling the MED-Project call center or using the MED-Project website. When MED-Project receives a request, MED-Project provides residents a pre-addressed, prepaid standard mail-back envelope. Residents fill the standard mail-back envelope according to provided instructions and return the Standard Mail-Back Package via United States Postal Service First Class Mail to the Stericycle Facility.\(^2\) See Plan § V.E. MED-Project proposes the following two-phase process for managing and disposing of Standard Mail-Back Packages.

A. Phase I – The Stericycle Facility Accepts Standard Mail-Back Packages from Tacoma-Pierce County Residents and Renders Them Non-Retrievable Pursuant to DEA Requirements

Phase one of the proposed two-phase disposal process is the acceptance of Standard Mail-Back Packages at the Stericycle Facility. The Stericycle Facility is a DEA registered collector and complies with all applicable DEA and RCRA requirements.\(^3\) As required by 21 C.F.R. §§ 1317.05(c) and 1317.70(a), the Stericycle Facility uses an on-site method to promptly render Standard Mail-Back Packages non-retrievable. Standard Mail-Back Packages remain sealed throughout the destruction process.

\(^1\) The term “Standard Mail-Back Packages” as used in this submission means both the mail-back envelope itself and the contents therein.
\(^2\) The Stericycle Facility’s mailing address is Stericycle Inc., 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901.
\(^3\) The Stericycle Facility’s DEA Registration Number is RS0331607; its RCRA Permit Number is INR000110197.
The attached Standard Operating Procedures provides a step-by-step description of the Stericycle Facility Standard Mail-Back Package destruction process. See Appendix A. Generally, when the Stericycle Facility receives Standard Mail-Back Packages, Stericycle Environmental Solutions, Inc. (“Stericycle”) scans the Standard Mail-Back Packages’ unique barcode to record receipt and then takes the Standard Mail-Back Packages to a DEA vault for controlled substance storage. Approximately once per week (depending on volume received), Stericycle removes Standard Mail-Back Packages from the DEA vault for destruction and re-scans the Standard Mail-Back Packages to record their unique identifiers and destruction date.

Before destroying the Standard Mail-Back Packages, Stericycle passes all Standard Mail-Back Packages through a metallic screening process necessary to protect Stericycle employee safety and equipment. Stericycle then loads the Standard Mail-Back Packages into a container no larger than thirty gallons. The contents of this container are fed into the mechanical process. The end product of this mechanical process falls into a steel drum filled with fifteen gallons of an activated carbon-based solution that renders the remaining contents “non-retrievable,” as defined in 21 C.F.R. § 1300.05(b). As needed, Stericycle agitates the fifty-five gallon drum’s contents to ensure all Standard Mail-Back Packages are exposed to the activated carbon-based solution. Through this process, the Stericycle Facility renders all Standard Mail-Back Packages (and any contents therein) non-retrievable.

The end product from the mechanical process is “pea sized.” Stericycle seals these remaining non-retrievable Standard Mail-Back Package materials in the fifty-five gallon drum for secure transportation to the Covanta Facility. Stericycle places a security seal on the trailer transporting the non-retrievable materials and verifies this seal upon arrival at the Covanta Facility. A Stericycle witness follows the non-retrievable materials to the Covanta Facility and witnesses their incineration.

B. Phase II – The Covanta Facility Incinerates the Non-Retrievable Materials

Phase two of MED-Project’s Standard Mail-Back Package destruction process is incineration of the non-retrievable materials from the Stericycle Facility, including Standard Mail-Back Packages and their contents, at the Covanta Facility. As the Covanta Facility is not registered with the DEA, it cannot receive Standard Mail-Back Packages until they are first rendered non-retrievable at the Stericycle Facility. See 21 C.F.R. § 1317.70(a).

The Covanta Facility is a permitted large municipal waste combustor. An “energy-from-waste” facility, the Covanta Facility uses municipal solid waste, like non-retrievable Standard Mail-Back Packages, to generate renewable energy. Steam recovered from incineration at the Covanta Facility helps power the Indianapolis downtown heating loop, which includes Indiana University and Purdue University’s Indianapolis campus. See Covanta, Covanta Indianapolis, https://www.covanta.com/Our-Facilities/Covanta-Indianapolis.

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4. If metal is found and does not appear consistent with a pharmaceutical product (i.e., an inhaler), the Standard Mail-Back Package is segregated and returned to storage. These segregated mail-back packages are held pending notification to the DEA Field Division Office for further direction regarding the receipt of an envelope that likely contains materials Stericycle did not agree to receive. See 21 C.F.R. § 1317.70.
5. Stericycle is a DEA-registered collector. See supra note 3.
II. Standard for the Health Department to Approve a Municipal Waste Combustor for the Disposal of Standard Mail-back Packages

Under the Regulations:

The Health Department may grant approval for a producer or group of producers participating in the standard stewardship plan or an independent stewardship plan to dispose of some or all collected covered drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 CFR parts 60 and 62, if use of a hazardous waste disposal facility described under subsection A. of this section is deemed not feasible for the stewardship plan based on cost, logistics or other considerations.

Regulations § 9(B). As described below, MED-Project proposes to use the Stericycle Facility and Covanta Facility two-phase process because disposal of Standard Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to cost, logistics or other considerations.

III. The Stericycle Facility and Covanta Facility Two-Phase Process Should Be Approved under Regulations § 9 Because Disposal at Permitted Hazardous Waste Facilities is Not Feasible

MED-Project and its vendor, Stericycle, spent months attempting to identify a permitted hazardous waste facility capable of disposing of Standard Mail-Back Packages in compliance with all DEA and RCRA requirements. Unfortunately, this investigation identified barriers to destroying Standard Mail-Back Packages at permitted hazardous waste facilities.

Under DEA regulations, only law enforcement or certain DEA registrants may conduct mail-back programs. See 21 C.F.R. § 1317.70(a). MED-Project is only aware of a few hazardous waste facilities that have a DEA registration. Unfortunately, hazardous waste facility RCRA permits typically require the sampling and/or inspection of controlled substances before destruction. Such sampling or inspection is prohibited by DEA regulations, which state that “[u]pon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened . . . .” 21 C.F.R. § 1317.70(f). These conflicting DEA and RCRA regulatory regimes make it not feasible for MED-Project to dispose of Standard Mail-Back Packages at a permitted hazardous waste facility in compliance with “all applicable federal and state laws, regulations and guidelines, including those of the United States Drug Enforcement Administration . . . .” Regulations § 6(C).

The market for Standard Mail-Back Package disposal is still developing following the passage of the DEA final rule, Disposal of Controlled Substances, 79 Fed. Reg. 53520, in September 2014. As a result, MED-Project is aware of few (if any) permitted hazardous waste facilities available to destroy Stericycle Standard Mail-Back Packages in compliance with DEA and RCRA requirements at this time. MED-Project and Stericycle will continue exploring disposal at permitted hazardous waste facilities as such options become available. However, current regulatory and market barriers make disposal of such mail-back packages at a permitted hazardous waste facility, at minimum, “not feasible . . . based on cost, logistics or other considerations.” Regulations § 9(B). The only disposal method for Standard Mail-Back Packages complying with all DEA and RCRA requirements and available to MED-Project and Stericycle at this time is the two-phase disposal process proposed above. Accordingly, the Health Department should approve the disposal of Standard Mail-Back
Packages via the Stericycle Facility and Covanta Facility two phase process as proposed by MED-Project under Regulations § 9(B).

IV. Conclusion

For the foregoing reasons, MED-Project’s proposed Stericycle Facility and Covanta Facility two-phase process for the disposal of Standard Mail-Back Packages should be approved.

MED-Project Plans approved in other counties use this same disposal process, including in King County and Snohomish County. See, e.g., Approved Standard Stewardship Plan, Secure Medicine Return Regulations King County, Washington, https://kingcountysecuremedicinereturn.org/standard-stewardship-plan-2/ (King County MED-Project Plan § VIII.C.).
This SOP explains Stericycle’s Seal & Send pharmaceutical Mail Back envelope service.

**Scope and Applicability**

This SOP applies to all Stericycle Environmental Solutions Team Members who are considered a Subject Matter Expert (SME) for the Seal & Send pharmaceutical Mail Back envelope service.

**Process Flow**

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### Stericycle Pharmaceutical MailBack Envelope Destruction Process

**Envelope Reception**
- Envelopes received in mailroom
- Seal & Send envelopes sorted out from other parcels received at this facility
- Envelopes are scanned and data captured is maintained in an internal system
- Envelopes transported to the DEA vault by Stericycle Team Members
- DEA vault inventory recorded and captured in internal system
- Envelope placed in destruction
- Envelope “scanned out for destruction”
- Barcodes scanner captures unique identifier and date of destruction

**Site Preparation**
- Shipment drum, open top, properly packed, placed at the receiver
- Shipment drum filled with 10g of carbon-based solution
- Plastic tube or drum placed next to mechanical process to perform mass weighing

**Metallic Screening**
- Envelopes placed on the plastic table or desk
- X-ray detection tool is used to ensure each envelope is checked for metallic objects

**Mechanical Processing**
- Envelopes are loaded into a container no larger than 10g
- Once 10g container is full, it is dumped into mechanical process chute
- Necessary manual agitation is used to mix contents of drum to ensure end product and solvent interact as the destruction process is underway
- End product after mechanical process is sized
- When container is full, process stops until it is sized and replaced
- When mechanical process stops, the contents of the drum are sized

**Post Destruction Process**
- Container marked with numerical seal and logged
- Two team members working the process ensure area is clean and organized

**Post Destruction Reporting**
- Data of destruction recorded for each envelope
- Data maintained in an internal system
- Report of number of envelopes destroyed turns county provided to Medproject

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**Procedure**

**Part 1 Envelope Reception**

1a) The Seal&Send envelopes shall be received at the Stericycle facility in Indianapolis, via mail, and will be scanned into a tracking spreadsheet. The envelopes shall remain sealed and closed at all times.

   i) Seal&Send envelopes sorted out from all packages received at the Indianapolis facility.

   ii) Barcode scanner captures data:
       - Unique identifier
       - Date that the envelope is received

   iii) Data captured and is maintained in an internal system

1b) The envelopes will be transported by Stericycle Team Members to the DEA vault where all controlled substances are held prior to destruction.

   i) DEA vault inventory recorded and captured in internal system.

**Part 2 Envelope Destruction**

2a) Bi-weekly or as necessary, the envelopes will be “scanned out” for destruction.

   i) Barcode scanner captures data:
       - Unique identifier
       - Date that the envelope is destroyed

2b) Site Preparation

   i) A new or properly reconditioned 55g steel drum, open top, properly rated for the hazard of the product being used to render the pharmaceuticals non-retrievable, shall be placed at the end of the conveyor where the end product will be accumulated. The 55g steel drum shall be properly marked and labeled in accord with all federal and state regulations.

   ii) The accumulation drum will be filled with 15 gallons of the carbon-based solution being used to render the pharmaceuticals non-retrievable.

   iii) A plastic table or desk that contains no metal will be placed next to the mechanical
process to perform metallic screening prior to feeding any material into the mechanical process.

2c) Metallic Screening

i) A team member shall place the envelopes on the plastic table or desk.

ii) The team member will use a strong metal detector tool to screen each envelope for metal objects to protect employee safety and company equipment.

2d) Mechanical Process Loading

i) No medicine containers are removed from MailBack envelopes before destruction (and thus no medicines are removed from medicine containers before destruction).

ii) Envelopes will then be loaded into a small container, no larger than 30 gallons capacity, prior to loading into the mechanical process.

iii) Once the 30g container is full, it can be dumped into the chute of the mechanical process.

iv) Alternately, a conveyor belt shall be placed next to the mechanical process to allow envelopes to be placed onto it for conveyance up to the chute above the mechanical process, where they will be dropped by conveyor belt into the mechanical process.

v) Stericycle team members will monitor the end product material drum, the conveyor line, and monitor for fires. As the mechanical process is underway, if necessary, Stericycle team members will also use a manual agitator to mix the contents of the drum to ensure all product is in contact with the solvent. The end product of envelopes and their contents that go through the mechanical process is pea sized. Any medicine containers (whether containing drugs or not) that residents may have returned inside a MailBack envelope are also destroyed to a pea size.

vi) The mechanical process shall be stopped if the accumulation drum fills past 9/10ths full.

vii) Once mechanical process operations stop, the end product material drum contents are stirred to ensure that the solvent mixes with the pharmaceuticals and renders them ‘non retrievable’.

viii) Once the container is filled, mechanical process operations shall stop until the end product material drum is sealed and a replacement container is prepared, following the requirements in the site preparation section of this SOP.
2c) **Post-Destruction Process**

   i) Once all mechanical process activities have been completed for the shift, the remaining end product material drum shall be closed and sealed according to the container’s closure specifications as detailed by the container manufacturer.

   ii) This container shall be marked with a numerical seal and noted on a log present in the area to ensure the container is not reopened.

   iii) After all mechanical process operations are complete, the team members working the mechanical process shall ensure the working area is cleaned up and tidy, so that the next shift operating the mechanical process finds everything in clean and working order.

**Part 3 Post-Destruction Reporting**

3a) **Tracking**

   i) Date of destruction is recorded for each envelope in an internal system and linked to its original location by linking the unique tracking number
Appendix J

Request for Approval to Autoclave and Landfill Pre-filled Injector Products

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE TACOMA-PIERCE COUNTY SECURE MEDICINE RETURN REGULATIONS

September 29, 2017
MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE TACOMA-PIERCE COUNTY SECURE MEDICINE RETURN REGULATIONS

Pursuant to sections 9.C and 13.F of the Tacoma-Pierce County Board of Health Secure Medicine Return Regulations, Environmental Health Code Chapter 7 (the “Regulations”), MED-Project, LLC (“MED-Project”) respectfully requests approval from the Tacoma-Pierce County Health Department (“Health Department”) to autoclave and landfill pre-filled injector products collected through MED-Project’s Unused Medicine Stewardship Program (“MED-Project’s Program” or “Program”) in Tacoma-Pierce County (the “County”).

I. BASIS FOR MED-PROJECT’S REQUEST

“Covered drugs,” as defined in the Regulations, must be disposed of at a permitted hazardous waste disposal facility, or in the alternative at a permitted large municipal waste combustor if the use of a permitted hazardous waste disposal facility is infeasible based on costs, logistics, or other considerations. Regulations § 9.A–B. Both of those disposal options are commonly used for unwanted medicine, but there are other well-accepted treatment options for sharps, including pre-filled injector products covered by the Regulations. The health care industry has adopted autoclaving followed by landfilling as the preferred treatment and disposal option for sharps.

MED-Project will operate its Program through a vendor that has an established system to autoclave sharps, including pre-filled injector products, to render them noninfectious before final disposal. Requiring MED-Project to dispose of pre-filled injector products by incineration under MED-Project’s Program would be inconsistent with well-established industry practice for sharps, disrupt MED-Project’s established treatment and disposal system for sharps, and significantly increase costs. MED-Project is therefore requesting and petitioning for approval to use autoclaves to treat pre-filled injector products, pursuant to Regulations sections 9.C and 13.F.

A. Regulations Section 9.C

Under Regulations section 9.C, the Health Department has discretion to approve alternative final disposal technologies. Manufacturers of covered drugs participating in a stewardship plan may petition the Health Department for approval to use alternative final disposal technologies that provide superior environmental and human health protection than provided by disposal at permitted hazardous waste disposal facility or municipal waste combustors, or equivalent protection to these disposal options at lesser cost. Regulations § 9.C.

As set forth in more detail below, MED-Project believes its proposed treatment method meets this standard, contrary to the feedback received from the County in its July 31, 2017 letter. Autoclaving has clear environmental and human health advantages, particularly as compared to incineration. Autoclaving would allow disposal of pre-filled injector products in a manner that is protective of the environment and human health, and it provides equivalent or superior protection regarding the criteria listed in section 9.C of the Regulations. In addition, treating pre-filled injector products via autoclave is less expensive than incineration at a permitted hazardous waste disposal facility or municipal waste combustor. For these reasons, the use of an autoclave to treat pre-filled injector products collected under MED-Project’s Program should be approved.
under the petition process for alternative final disposal technologies under Regulations section 9.C.

B. Regulations Section 13.F

Under Regulations section 13.F, the Health Department may exercise its discretion to approve a proposed plan and “waive strict compliance with the requirements of this Chapter that apply to producers in order to achieve the objectives of this Chapter.” The Regulations were intended to “provide for and promote the health, safety, and welfare of the general public.” Regulations § 2.B. “The provisions of this Chapter shall be liberally construed for the accomplishment of its purposes.” Regulations § 2.B.

As discussed in more detail below, autoclaving would allow for the proper disposal of any pre-filled injector products collected under MED-Project’s Program in a manner that provides for and promotes the public health, safety, and welfare of the general public, in furtherance of the Regulations’ objectives. Accordingly, the Health Department should exercise the discretion granted in section 13.F of the Regulations and approve autoclaving as a treatment technology for pre-filled injector products.

II. AUTOCLAVING

Autoclaving is a treatment method for medical waste, including sharps, by which the waste is sterilized using heat, pressure, and steam. Autoclaves typically operate at temperatures between 120°C and 300°C, and pump saturated steam generated at elevated pressures in the chamber through the autoclave to kill microbes and completely sterilize the contents.\(^1\) After sharps are sterilized in an autoclave, the autoclaved materials are generally disposed of in solid waste landfills.

Autoclaving is the most common method for treating sharps around the world and in the United States, and represents industry best practice for treating these materials. Internationally, autoclaving is recommended by the United Nations General Assembly Human Rights Council for sharps treatment.\(^2\) In the United States, it is estimated that approximately 85% of sharps waste is sterilized, mostly through autoclaving, and only 10% of sharps waste is incinerated.\(^3\) Washington is no different; like the rest of the U.S., most sharps containers in Washington are autoclaved or microwaved and then landfilled.\(^4\)

The sharps collected by MED-Project in Pierce County are not hazardous waste and would not require disposal at a permitted hazardous waste facility, if not for these Regulations. Washington state law regulates sharps as “biomedical waste,” but does not prohibit the use of autoclaving to treat sharps or the


\(^4\) See Pharmaceutical Waste Frequently Asked Questions, DEPARTMENT OF ECOLOGY, http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/faq.html (“Most sharps containers in Washington are microwaved or autoclaved to sterilize the contents and then sent to solid waste landfills.”); Specific Waste: Dual Waste, DEPARTMENT OF ECOLOGY, http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/dualwaste.html (“most biomedical waste in Washington State is autoclaved and landfilled”). As these sources note, sharps and other biomedical wastes may need to be treated differently if they contain dangerous wastes, but the pre-filled injector products MED-Project would collect are excluded from regulation as dangerous wastes since they are household wastes.

\(^5\) See R.C.W. 70.95K.0101(1)(f).
disposal of autoclaved materials in a landfill. Under the Washington dangerous waste regulations, pre-filled injector products collected from residents would constitute excluded “household wastes.” Given this exclusion, nothing in the Washington dangerous waste regulations would prohibit or otherwise limit the disposal of pre-filled injector products in the manner proposed by MED-Project.

III. THE TACOMA-PIERCE COUNTY HEALTH DEPARTMENT SHOULD APPROVE THE USE OF AUTOCLAVING TO TREAT PRE-FILLED INJECTOR PRODUCTS.

Autoclaves are protective of the environment and human health, which supports MED-Project’s petition under Regulations section 9.C and request under Regulations section 13.F. The Health Department should approve MED-Project’s proposed disposal technology under each standard because autoclaving is a widely-used means to dispose of sharps, including pre-filled injector products; represents industry best practice; and is protective of the environment and human health, as explained further below.

A. The Health Department Should Approve the Use of Autoclaving to Treat Pre-Filled Injector Products under the Standard for Alternative Final Disposal Technologies at Regulations Section 9.C.

The Health Department should approve MED-Project’s petition under Regulations section 9.C to autoclave pre-filled injector products. Under Regulations section 9.C, MED-Project:

may petition the Health Department for approval to use alternative final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections A. and B. of this section, or equivalent protection at lesser cost.


MED-Project’s proposed technology would provide equivalent or superior protection in each of the following areas:

(1) Overall impact to the environment and human health;
(2) Worker health and safety;
(3) Monitoring of any emissions or waste; and
(4) Air, water or land emissions contributing to persistent, bio-accumulative, and toxic pollution.

See Regulations § 9.C. Additionally, autoclaving is less expensive than incinerating these materials at a hazardous waste disposal facility or large municipal waste combustor.

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6 See R.C.W. 70.95K.030(1).
7 See W.A.C. 173-303-071(3)(c).
1. **Autoclaving provides superior protection related to the overall impact to the environment and human health.**

Autoclaving would provide superior protection related to the overall impact to the environment and human health than provided by disposal at a permitted hazardous waste disposal facility or municipal waste combustor, satisfying this criterion under Regulations section 9.C.4.

As compared to incinerators, autoclaves generate few air emissions.\(^8\) In addition, autoclaves use far less energy to treat sharps than incineration,\(^9\) and therefore minimize the environmental impacts associated with energy production, including greenhouse gas emissions.

Autoclave facilities have environmental protections in place and release minimal pollution during the autoclaving process. In Washington, autoclaves are not even required to obtain air operating permits under Washington law because they are considered categorically exempt insignificant emissions units.\(^11\) The proposed autoclave facility is not subject to state air permitting requirements in Texas either.

Autoclave facilities must comply with federal and state laws. For instance, the proposed autoclave for use in MED-Project’s Program to treat pre-filled injector products complies with Texas’ regulations regarding the treatment and disposal of medical waste, and operates as a Type V Medical Waste Processing Facility under a medical waste registration permit issued by the Texas Commission on Environmental Quality. The facility is also certified to transport medical waste. The permit and certification serve to ensure that the autoclave is operated in a manner that is environmentally sound and protective of human health. The proposed autoclave facility has an exemplary compliance record, and has not had a single environmental or safety violation since it began operating in 2009.

2. **Autoclaving provides superior worker health and safety protections.**

Autoclaving provides superior worker health and safety protections by minimizing worker exposure to any potential air contaminants and sharps. The proposed autoclave facility for treating pre-filled injector products under the Program operates in a manner which ensures compliance with all applicable federal and state laws intended to protect workers, including the U.S. Occupational Safety and Health Administration (‘‘OSHA’’) Bloodborne Pathogens Standard, OSHA Hazard Communication Standard, and U.S. Department

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\(^9\) According to a California Air Resources Board technical assessment, in general, air emissions are not a concern from autoclaving as long as inappropriate medical waste, like chemotherapeutic waste, or hazardous chemicals are removed from the waste stream. California Air Resources Board, Technical Assessment Review of the Dioxins Airborne Toxic Control Measure for Medical Waste Incinerators (July 2003), Attachment B available at https://www.arb.ca.gov/toxics/dioxins/attachmentb.pdf; the main body of the Technical Assessment is available at https://www.arb.ca.gov/toxics/dioxins/medwastereview.pdf.


\(^11\) W.A.C. 173-401-532(119).
of Transportation ("DOT") Hazardous Materials Regulations. For instance, the autoclave facility and its employees that are involved in the handling and treatment of sharps waste operate under the facility’s Bloodborne Pathogen Exposure Control Plan.

Employees at the autoclave facility receive extensive and regular training. For example, all employees at the proposed autoclave facility that may be exposed to bloodborne pathogens must receive bloodborne pathogen training prior to their assignment and at least annually thereafter. And, all employees involved in packaging, loading, unloading, and transporting the waste receive DOT hazardous materials training. Employees also receive training in other areas, including: accident and injury reporting, compactor use, hazard communication, proper lifting, spill response, waste acceptance protocols, and access and exposure to medical records under the Health Insurance Portability and Accountability Act.

The autoclave facility has a standard operating procedure regarding personal protective equipment, general handling of waste received by the facility, engineering and work practice controls, spill procedures, and incident response. Autoclave employees are required to wear personal protective equipment, including puncture resistant gloves, steel-toe shoes, full coveralls, and appropriate eye protection. The autoclave facility employs operational controls and automated systems to protect workers from exposure to sharps. These include an automated autoclave and mechanical tippers for dumping the waste into the autoclave bins. The facility utilizes a vacuum autoclave that operates in a closed system and contains any air emissions during the autoclave process, which are ultimately vented outside. The facility also has ridge ventilators that provide for ventilation inside the building. Accordingly, workers should not be exposed to any fumes from the autoclave. These operational controls protect workers and limit potential exposure to the sharps and fumes during the autoclave process. As further evidence of the protection of worker health and safety against any potential fumes, a study by the California Department of Health Services measured air pollutants (including mercury, methanol, and total hydrocarbons) at an autoclave facility and found that none were detectable in autoclave workers’ personal air space.12

In addition, the pre-filled injector products collected by MED-Project will be securely contained throughout the process, limiting the risk of exposure to the waste materials at the autoclave and landfill. Pre-filled injector products collected by MED-Project will be contained in leak-proof, rigid, puncture resistant containers that are sealed during storage, handling, and transport, and appropriately labeled as biohazardous materials. MED-Project will provide sharps containers meeting these requirements as part of its mail-back packages and will only accept pre-filled injector products that are returned in the provided containers. Once the materials are treated in the autoclave, they are transferred to self-contained compactors that compact the waste in roll-off containers before being transported to the municipal waste landfill, where they are deposited into a designated hole and buried. This ensures the waste is contained from collection to ultimate disposal.

Given the training, use of personal protective equipment, operational controls, automated systems to protect workers from exposure to sharps, and containment requirements described above, autoclaving pre-filled injector products provides superior worker health and safety protections.

3. *Autoclaves must comply with all applicable emissions and waste monitoring laws and regulations.*

Autoclaves must comply with all applicable environmental and public health laws and regulations relating to emissions and waste monitoring at the federal, state, and local level. Autoclaving results in lower environmental impacts than treating waste at an incinerator or municipal waste combustor. Therefore, autoclaves need not comply with the more extensive regulatory and permit requirements imposed on incinerators and municipal waste combustors related to air emissions.

With respect to waste monitoring, MED-Project and its vendor will track all mail-back packages of pre-filled injector products using a unique identifier to ensure the collected materials are treated and disposed of. The autoclave will confirm the materials have been treated and sent to the landfill. No other waste monitoring is required. Thus, autoclaves provide equivalent compliance with all established requirements for emissions and waste monitoring.

4. *As opposed to incineration, autoclaving would provide equivalent or superior protection from air, water, or land emissions contributing to persistent, bio-accumulative, and toxic pollution.*

Autoclaving produces minimal air emissions.\(^{13}\) Furthermore, because autoclaves typically operate at temperatures between 120°C and 300°C, they consume far less energy than incinerators, and therefore produce less greenhouse gas emissions and toxic air pollution from energy production.

All materials that have been rendered noninfectious through autoclave treatment remain securely contained in a sharps container throughout the process as they are transported, handled, and treated at an autoclave facility. The autoclaved materials are then compacted in a sealed roll-off container, and disposed of in a permitted municipal solid waste landfill. The autoclaved materials are therefore contained after treatment, including when they are placed in the landfill.

Also, according to a California Air Resources Board technical assessment, water effluent from the autoclaving process is negligible provided facilities properly segregate their waste.\(^{14}\) With respect to MED-Project’s Program, the effluent from autoclaving pre-filled injector products should not contain hazardous materials.

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\(^{13}\) According to a California Air Resources Board technical assessment, in general, air emissions are not a concern from autoclaving as long as inappropriate medical waste, like chemotherapeutic waste, or hazardous chemicals are removed from the waste stream. California Air Resources Board, Technical Assessment Review of the Dioxins Airborne Toxic Control Measure for Medical Waste Incinerators (July 2003), Attachment B available at https://www.arb.ca.gov/toxics/dioxins/attachmentb.pdf; the main body of the Technical Assessment is available at https://www.arb.ca.gov/toxics/dioxins/medwastereview.pdf.

\(^{14}\) The technical assessment noted that “[s]taff at the Los Angeles County Sanitation District indicated that there were no adverse water discharge issues from autoclaves.” California Air Resources Board, Technical Assessment Review of the Dioxins Airborne Toxic Control Measure for Medical Waste Incinerators (July 2003), Attachment B available at https://www.arb.ca.gov/toxics/dioxins/attachmentb.pdf; the main body of the Technical Assessment is available at https://www.arb.ca.gov/toxics/dioxins/medwastereview.pdf.
5. **Autoclaving sharps would provide superior or equivalent protection at lesser cost.**

Autoclaving sharps is significantly less expensive than incinerating sharps at a permitted hazardous waste disposal facility or permitted large municipal waste combustor.

B. **The Health Department Should Exercise its Discretion to Waive Strict Compliance with the Regulations under Regulations Section 13.F and Approve the Use of Autoclaving to Treat Pre-Filled Injector Products.**

The Health Department should exercise its discretion under Regulations section 13.F to approve MED-Project’s Plan and waive strict compliance with the disposal provisions of the Regulations in order to achieve the Regulations’ goal to “provide for and promote the health, safety, and welfare of the general public...” Regulations § 2.B.

MED-Project’s proposal to autoclave pre-filled injector products and landfill the autoclaved materials meets the objectives of the Regulations, as evidenced by the information provided above. MED-Project’s proposal provides for and promotes public health, safety, and welfare because there are minimal, if any, air and water emissions from the autoclaving process. There are also reduced environmental impacts associated with energy production, as compared to incineration, because autoclaves use less energy to treat sharps. MED-Project’s use of the autoclave would also protect human health and safety against the improper handling and disposal of pre-filled injector products since the autoclave employs automated systems, operational controls, and robust worker health and safety protocols to protect workers from exposure to sharps and any potential emissions from the autoclave.

MED-Project’s proposed disposal process also protects public safety because all pre-filled injector products collected by MED-Project are containerized throughout the collection, transportation, autoclaving, and disposal process, dramatically reducing the chance that the public could be exposed to pre-filled injector products. Accordingly, any risk to the health, safety, and welfare of the public is minimized by the use of an autoclave to treat pre-filled injector products collected by MED-Project.

IV. **CONCLUSION**

Based on the foregoing reasons, MED-Project respectfully requests that the Health Department exercise its discretion and authorize the use of autoclaves for treating pre-filled injector products collected from Pierce County residents under MED-Project’s Program under sections 9.C and 13.F of the Regulations.
Sample Template: Education and Outreach Call Script [1-844-MED-PROJ]

MED-Project will expand the call script to be available in Khmer, Korean, Russian, Spanish, and Vietnamese.

Thank you for calling the information line for the Medication Education and Disposal Project, or MED-Project.

- If you are experiencing a medical emergency, please hang up and dial 9-1-1.
- If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Washington Poison Control at 800-222-1222.
- Unwanted Medicine Kiosks and Mail-Back Distribution Sites are located throughout your local area and provide convenient options for disposing of expired or Unwanted Medicines. Press 3 for more information about convenient kiosks or mail-back distribution sites.
- Take-back events are scheduled throughout the year and offer residents a free and convenient way to dispose of expired or Unwanted Medicines. Press 4 for more information.
- Mail-back services are available to Residents. Press 5 for more information.
- You may press 0 at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and consumer disposal.
• MED-Project reminds you that taking your medicine as directed by your health care provider is critically important to your health.
• If you have questions about your medication, please hang up and dial your health care provider.
• For additional questions about the proper disposal of expired or unwanted medications from households, please go to www.med-project.org or press 0 to talk to an operator.
• To hear this menu again, please press 1.
• Thank you for calling MED-Project.

Unwanted Medicine Kiosk or Mail-Back Distribution Site Script for when 3 is selected:

• Kiosks drop-off sites or mail-back distribution sites for Unwanted Medicine are located conveniently throughout your local area. To locate the site nearest you, or for precise information about hours of operation, press 0 to speak with an operator or visit med-project.org to search by your zip code. Kiosks accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; pet pesticide products; sharps; illicit drugs; or iodine-containing medications will be accepted.
• Mail-back distribution sites for Unwanted Medicine may also be available in your local area. To locate the site nearest you, or for precise information about hours of operation, press 0 to speak with an operator or visit med-project.org to search by your zip code.
• Mail-back distribution sites will contain mail-back packages with explicit instructions on the unwanted medicine that can be disposed of.
• If you do transfer your medications to a sealed bag before placing it into a kiosk, please be sure to recycle all remaining packaging.
• To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
• To repeat this information, press 3.
• To return to the main menu, please press 1.
• Thank you for calling MED-Project.

Take-back Script for when 4 is selected:

• MED-Project is working with local law enforcement and other community organizations to offer Unwanted Medicine take-back events in your area. For a complete list of take-back events, please press 0 to speak to the operator or visit: www.med-project.org.
• Take-back events accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; pet pesticide products; sharps; illicit drugs; or iodine-containing medications will be accepted.
• If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
• To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
• To repeat this information, press 4.
• To return to the main menu, please press 1.
• Thank you for calling MED-Project.
Mail-back Package Script for when 5 is selected:

- Mail-back services are available through the call center or website to residents who are differentially-abled or homebound. Home healthcare professionals providing services to differentially-abled or homebound residents may also request an envelope on behalf of differentially-abled or homebound residents.
- Mail-back services will be available for iodine containing medications and pre-filled injector products with a retractable or otherwise securely covered needle that contain more than trace residual amounts of unwanted medicine. Mail-back packages for pre-filled injector products cannot accept unwanted medicine, controlled substances, or shaving razors.
- To request a mail-back package, please press 0 to talk to the operator or visit www.med-project.org.
- Unwanted medicine mail-back packages accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; sharps; or illicit drugs will be accepted. Iodine-containing medication should not be commingled with other unwanted medicine.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 5.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.
Appendix L

MED-Project Website

Translations of the website pages will be available in Khmer, Korean, Russian, Spanish, and Vietnamese.
If there are any specific instructions for disposal on the label, package or package insert, please follow those instructions.

Pierce County discourages the disposal of unused, expired, or contaminated pharmaceutical wastes in the solid waste system per County Regulations.

To protect your privacy, consumers are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Source: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, last updated May 9, 2017.
CONVENIENT KIOSKS

Community kiosk drop-off sites allow residents to bring expired or unwanted medicines to a convenient, centralized location for proper disposal.

ACCEPTED: Medications in any dosage form, except for those listed below, in their original container or sealed bag.

NOT ACCEPTED: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, pet pesticide products, medical devices, sharps, illicit drugs, mercury containing thermometers and iodine-containing medications.

To find the nearest disposal locations for unwanted medicine or to locate a mail-back distribution site, enter your zip code below.

Enter your zip code

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.
Residents will have the opportunity to request up to two Mail-Back Packages.

Mail-Back Services for Unwanted Medicine are available to differentially-abled and homebound residents upon request.

Mail-Back Services for iodine-containing medications and Pre-filled Injector Products with a retractable or otherwise securely covered needle are available to all residents upon request. Please note that iodine-containing medications cannot be commingled with other Unwanted Medicine.

Mail-Back packages for pre-filled injector products cannot accept unwanted medicine, controlled substances, or shaving razors.

Please complete the below form to request a pre-paid, pre-addressed mail-back package. Instructions for disposal will be provided with all mail-back services.

Mail-Back Package Distribution Locations may also be available in your area.

[Form]

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.
Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. The local authorities and MED-Project may also sponsor drug take-back events in your area.

ACCEPTED: Medications in any dosage form, except for those listed below, in their original container or sealed bag.

NOT ACCEPTED: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, pet pesticide products, medical devices, sharps, illicit drugs, mercury containing thermometers and iodine-containing medications.

CALENDAR OF LOCAL TAKE-BACK EVENTS

Thursday, July 14, 2017
TAKE-BACK DAY
Tacoma Police Department
3701 S Pine Street
Tacoma, WA 98409
Start Time: 2:00 PM
End Time: 5:00 PM
Link to Website
Medicines help treat diseases, manage chronic conditions and improve health and well-being for millions of Americans. It's vitally important that patients take their medicines as prescribed by their health care provider and as indicated on the label or packaging. It's also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

There are a number of ways to dispose of expired or unwanted medicines. To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the available disposal options.

For additional information on the program, MED-Project has developed an educational toolkit, including:

- Brochure
- Frequently Asked Questions

If you would like any of these materials emailed to you, contact piercecounty@med-project.org.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.
MED-Project
Medication Education & Disposal

MEDfaq

What is the MED-Project?
MED-Project is the entity implementing the County Product Stewardship Plan, including the education and outreach programming.

What should I do if I am having a medical emergency?

What should I do if I think I have ingested something poisonous?

What should I do if my pet has ingested medication?

Whom should I call with a question about my medication?

Where can I find information about the safe storage of medication?

Can I flush my medication down the toilet?

Should I remove my personal information before disposing of my medication?

Where are the MED-Project disposal locations nearest me?

Will it cost me anything to dispose of my expired or unwanted medications?

What items can I dispose of in the MED-Project kiosks?

Will there be any take-back events in my area?

I am differently-abled or homebound and unable to go to a kiosk or attend a take-back event. How can I dispose of my expired or unwanted medicine?

Where else can I find information about the safe disposal of expired or unwanted medicines?

I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?

What is recommended for safe disposal of expired or unwanted medicine in my area?

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.
If you are experiencing a medical emergency, please dial 9-1-1. If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 800-222-1222. If you have questions about your medication, please dial your healthcare provider.

For answers to some frequently asked questions about MED-Project, click here.

Pharmacies and Law Enforcement Offices
If you are a retail pharmacy, hospital/clinic pharmacy, or law enforcement agency interested in hosting a drop-box, contact:
Dr. Victoria Travis, PharmD, MBA, MS
Program Director
MED-Project LLC
Phone: (844) 677-6532
Fax: (510) 686-8837
Email: piercecounty@med-project.org

Drug Producers
If you are a drug producer interested in participating in a MED-Project stewardship plan contact:
Phone: (202) 495-3131
Email: compliance@med-project.org

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.
Translations of the brochure will be available in Khmer, Korean, Russian, Spanish, and Vietnamese.

Front of brochure

**Appendix M**

**Brochure Mockup**

What items can I dispose of?

**DISPOSAL OPTIONS**

1. **CHECK THE PACKAGE**
   
   If there are specific instructions for disposal on the label, package or package insert, please follow those instructions.

2. **CONVENIENT KIOSKS**
   
   To find convenient kiosks in your area, visit www.med-project.org for more information. Mail-Back Package distribution locations may also be available in your area.

3. **MAIL-BACK**
   
   Mail-Back Services are available in your area. Visit the mail-back section of www.med-project.org to order a mail-back package.

4. **TAKE-BACK EVENTS**
   
   Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. Visit the take-back events section of www.med-project.org for information on events in your area.

**NOT ACCEPTED:**

- Herbal remedies, vitamins, supplements, cosmetics, other personal care products, compressed cylinders, aerosols, inhalers, pet pesticides, medical devices, sharps, illicit drugs and mercury containing thermometers.

**ACCEPTED:**

Medications in any dosage form, except for those listed below, in their original container or sealed bag.

If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.
There are a number of ways to dispose of expired or unwanted medicines.

For more information about the MED-Project program, go to www.med-project.org or call 1-844-MED-PROJ

What should you do with your expired or unwanted medicines?

Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It’s vitally important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It’s also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

If you have expired or unwanted medication, proper disposal is easy. To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the following disposal options.

(Source: U.S. Food and Drug Administration)
MAIL-BACK SERVICES AVAILABLE

MAIL-BACK SERVICES ARE AVAILABLE FOR:

- Unwanted or expired medications.*
- Pre-filled injector products with a retractable or otherwise securely covered needle.†
- Iodine-containing medications.‡

Mail-back packages will be pre-paid and pre-addressed.

HOW DO I ORDER A MAIL-BACK PACKAGE?

1. Call 1-844-MED-PROJ, or
2. Visit www.med-project.org

For more information about the MED-Project program, please go to www.med-project.org or call 1-844-MED-PROJ.

*For differentially-abled and home bound residents.

†Mail-back packages for pre-filled injector products cannot accept unwanted medicine, controlled substances, or shaving razors.

‡Iodine-containing medications should not be commingled with other unwanted medicine.
Translations of the FAQ will be available in Khmer, Korean, Russian, Spanish, and Vietnamese.

The following are suggested questions to be addressed by the “Frequently Asked Questions” section of the MED-Project website/public relations toolkit. All text is subject to change.

**What is the MED-Project?**
MED-Project is the entity implementing the Product Stewardship Plan, including the education and outreach programming.

**What should I do if I am having a medical emergency?**
If you are having a medical emergency, contact emergency medical services immediately by dialing 911.

**What should I do if I think I have ingested something poisonous?**
If you think you have ingested something poisonous, contact emergency services immediately. Please dial 911 or contact your local poison control center.

**What should I do if my pet has ingested medication?**
If you believe your pet may have ingested human or animal medication not intended for consumption by your pet, please contact your veterinarian or local animal poison control hotline.

**Whom should I call with a question about my medication?**
Please direct all questions about your medication to your health care provider.

**Where can I find information about the safe storage of medication?**
You should follow any storage instructions provided by your healthcare provider and any written instructions provided with your medication or listed on its packaging.

In addition, many government agencies provide information regarding safe storage of medication. Possible sources include the National Institutes of Health’s information page and the Center for Disease Control’s information page.

**Can I flush my medication down the toilet?**
Do not flush medications down the toilet unless the information on the label, package, or package insert specifically instructs you to do so.

**Should I remove my personal information before disposing of my medication?**
Please remove all personal and identifying information from your medication labels and/or its packaging before disposal.

**Where are the MED-Project disposal locations nearest me?**
MED-Project is providing disposal locations throughout the County. For more information about the location nearest to you, please visit the “Convenient Kiosks” portion of the MED-Project web site, or call the hotline at 1-844-MED-PROJ.

**Will it cost me anything to dispose of my expired or unwanted medications?**
There will be no fee for medication disposal charged at the point of collection.
What items can I dispose of in the MED-Project kiosks?
Kiosks accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; pet pesticide products; sharps; illicit drugs; or iodine-containing medications will be accepted.

If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.

Will there be a take-back event in my area?
Please visit the MED-Project website or dial the hotline at 1-844-MED-PROJ to learn about take-back events in your area.

I am differentially-abled or home bound and am unable to go to a kiosk or attend a take-back event. How can I dispose of my expired or unwanted medicine?
Please dial the hotline at 1-844-MED-PROJ or visit the mail-back page of the MED-Project website to request a pre-paid envelope to return your unwanted or expired medicine.

Where else can I find information about the safe disposal of expired or unwanted medicines?
Several government agencies provide information regarding safe disposal of medication. Please refer to the FDA’s website for more information “Consumer Updates: How to Dispose of Unused Medicines.”

I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?
For more information, please dial the hotline at 1-844-MED-PROJ.

What is recommended for safe disposal of expired or unwanted medicine?
The United States Food and Drug Administration developed the following guidelines to encourage the proper disposal of medicines and help reduce harm from accidental exposure or intentional misuse after they are no longer needed:¹

Check the Package: Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet unless this information specifically instructs you to do so.

Take-Back Events: Take advantage of programs that allow the public to take unused drugs to a central location for proper disposal. Call your local law enforcement agencies to see if they sponsor medicine take-back programs in your community. Contact your city’s or county government’s household trash and recycling service to learn about medication disposal options and guidelines for your area.

Convenient Kiosks: Transfer unused medicines to collectors registered with the Drug Enforcement Administration (DEA). Authorized sites may be retail, hospital or clinic pharmacies, and law enforcement locations. Some offer mail-back programs or collection receptacles (“kiosks”). Visit the DEA’s website or call 1-800-882-9539 for more information and to find an authorized collector in your community.

Mail-Back Packages: Mail-Back Services for unwanted medicine are available to residents upon request. Please dial the hotline at 1-844-MED-PROJ or visit the mail-back page of the MED-Project website to request a pre-paid envelope to return your unwanted or expired medicine. Home healthcare professionals providing services to differentially-abled or homebound residents may also request an envelope on behalf of differentially-abled or homebound residents.

¹ http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, page last updated May 9, 2017
Appendix N

Sample Template: Take-Back Event Media Advisory

MED-Project
Medication Education & Disposal

ADVISORY * * * ADVISORY * * * ADVISORY * * * ADVISORY * * * ADVISORY

MED-Project to Support Take-Back Event on [Date, 2017]

Residents are invited to bring expired or unwanted medications to [Location] from [x time] to [y time] for disposal

Tacoma-Pierce County, Washington, [Date] – The Medication Education & Disposal Project (MED-Project), a consumer education campaign dedicated to responsible medication use and disposal, announced today that it will be supporting a medication take-back event supervised by a local law enforcement agency for consumers in [town] on [date]. All County residents are invited to bring their expired or unwanted medications for disposal. The service is free. [Insert information for residents about what can be collected]. To protect privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials that are brought to this take-back event.

What: MED-Project Medication Take-Back Event – bring your expired or Unwanted Medicines for disposal

When: [Date], [Time]

Where: [Location]

For more information about disposal options for expired or Unwanted Medicine, visit www.med-project.org.

###

Contact:
MED-Project Public Affairs at (844) 677-6532 (844-6PROJECT)
Appendix O

Sample Digital and Local Social Networks

The following is a representative list of local organizations and their social media networks in Tacoma-Pierce County. MED-Project will reach out to relevant groups to help promote the Program.

<table>
<thead>
<tr>
<th>Outlet</th>
<th>Facebook</th>
<th>Twitter</th>
</tr>
</thead>
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<td></td>
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<td><a href="https://www.facebook.com/pages/Pierce-County-Washington/136891229664598">https://www.facebook.com/pages/Pierce-County-Washington/136891229664598</a></td>
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</tr>
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