

A Product Stewardship Plan For Unwanted Medicine from Households

Skagit County, Washington August 20, 2018

Table of Contents

l.	Intr	odu	ction	5		
II.	Cor	ntac	t Information	5		
III.	Pla	n De	efinitions	5		
IV.	Unv	wan	ted Medicine	7		
V.	Col	lect	on of Unwanted Medicine	8		
	A.	Unwanted Medicine Collection Program Implementation				
		1.	Outreach			
		2.	Implementation	9		
		3.	Convenience	9		
		4.	Services	9		
	B.	Kio	sk Drop-Off Sites	10		
		1.	Kiosk Drop-Off Site Locations	10		
		2.	Drop-Off Site Kiosk Placement	10		
		3.	Kiosk Specifications	10		
		4.	Kiosk Collection	11		
			a. Technician-Assisted Collection	12		
			b. Host-Assisted Collection	12		
	C.	Tak	re-Back Events	13		
		1.	Method	13		
		2.	Procedures	13		
	D.	Dis	posal of Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events	14		
	E.	Ma	il-Back Services for Unwanted Medicine	14		
		1.	Standard Mail-Back Services for Unwanted Medicine, Excluding Inhalers, Pre-Filled Injector			
			Products, and Iodine-Containing Medications	14		
		2.	Standard Mail-Back Services for Iodine-Containing Medications	15		
		3.	Injector Mail-Back Services	15		
		4.	Inhaler Mail-Back Services	15		
		5.	Mail-Back Package Availability	16		
		6.	Mail-Back Package Collection and Disposal	16		
VI.	Pla	n an	d Collection Goals	17		
VII.	Pat	ient	Privacy	18		
VIII	. Cal	l Ce	nter	18		
IX.			orter and Disposal Facility Information			
	A.	Ve	ndors	19		
	B.	Tra	nsporters and Shippers	19		
	C.		nsfer Facility			
	D.	Rev	verse Distributor Facilities	. 23		
	E.	Au	oclave Facility	. 24		
	F.	Dis	posal Facilities	. 24		
X.			ted Medicine Educational and Outreach Programming			
	A.	Ov	erview	27		
	B.		diences			
	C.		ssages			
	D.	Too	ols/Communications Channels			
		1.	Phones			
		2.	MED-Project Website			
		3.	Materials	. 29		

	4. Media Outreach	
	5. Broadcast Outreach	29
E.	Collaboration with County Officials and Community Organizations	29
F.	Disclaimer	30
XI. Su	irvey	
	ıckaging	
	ompliance with Applicable Laws, Regulations, and Other Legal Requirements	
	DEA Controlled Substances Act and Implementing Regulations	
Λ.	DEA Registration Modification	
В		
В.		
C.	Washington State Pharmacy Quality Assurance Commission (WSPQAC)	
D.	State of Washington Waste Management Program	
	eporting	
	ıdix A	
	ED-Project Participants	
	dix B	
	osk Drop-Off Sites with Expressions of Interest	
	dix C	
	otential Additional Kiosk Drop-Off Sites	
Appen	ldix D	37
Kid	osk Prototype and Proposed Signage	37
Pr	oposed Kiosk Signage	38
Pr	oposed Kiosk Signage	39
Pr	oposed Kiosk Signage	40
Pre	oposed Kiosk Drop-Off Site Signage	41
Pre	oposed Mail-Back Distribution Location Signage	42
Appen	dix E	43
M	ED-Project Request for Approval of Disposal Process for Host-Assisted Collection Kiosk I	Orop-Off
	Sites	
Appen	dix F	
	Sample Standard Mail-Back Package	
В.	•	
C.		
D.		
	idix G	
	ED-Project Request for Approval of Standard Mail-Back Package Disposal Process	
	idix H	
	ED-Project Request for Approval to Autoclave Pre-Filled Injector Products	
	dix I	
	ED-Project Request for Approval of Inhaler Mail-Back Package Disposal Process	
	dix J	
	ochure Mockup	
	dix K	
	ED-Project Website	
	dix L	
	mple Media List	
	dix M	
	mple Contact List for Outreach and Education to the Community	
Appen	dix N	84

Sample Template: Education and Outreach Call Script [1-844-MED-PROJ]	84
Appendix O	.87
Sample Digital and Local Social Networks	.87

I. Introduction

MED-Project LLC ("MED-Project"), on behalf of the participating companies as described in <u>Appendix A</u>, submits this Product Stewardship Plan ("Plan") for Unwanted Medicine in compliance with Skagit County Code Chapter 12.20, Secure Medicine Return Ordinance ("Ordinance"). The Ordinance requires pharmaceutical Producers¹ to develop a Product Stewardship Program to finance and manage the collection, transportation, and disposal of Unwanted Medicine from Skagit County households. MED-Project is requesting standard 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

III. Plan Definitions

Call Center is the MED-Project call center for Residents, which can be reached by callers at the toll-free number of 1-844-MED-PROJECT or 1-844-633-7765.

Carrier is United Parcel Service, Inc. ("UPS").

County is Skagit County, Washington.

DEA is the U.S. Drug Enforcement Administration.

DEA Rule is the DEA Final Rule, "Disposal of Controlled Substances," 79 Fed. Reg. 53520 *et seq.*, adopted on September 9, 2014.

DOT is the U.S. Department of Transportation.

FDA is the U.S. Food and Drug Administration.

Help Desk is the MED-Project call center and email-in database for Kiosk Drop-Off Sites, Mail-Back Distribution Locations and other non-Residents, which can be reached by callers at the toll-free number of 1-844-677-6532 or 1-844-6-PROJECT and/or by email at skagitcounty@med-project.org.

Host-Assisted Collection Kiosk Drop-Off Site is a location hosting a MED-Project kiosk for the collection of Unwanted Medicine that is accessible to the public where boxes and inner liners will be removed from kiosks, sealed, and packaged by the Host-Assisted Collection Kiosk Drop-Off Site employees and transported to a disposal facility by Carrier.

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

Inhaler Mail-Back Services is the provision of pre-paid, pre-addressed packages for the collection and disposal of inhalers ("**Inhaler Mail-Back Packages**") by Vendor.

¹ All capitalized terms used but not otherwise defined herein shall have their respective meanings set forth in the Ordinance.

Injector Mail-Back Services is the provision of pre-paid, pre-addressed, FDA-cleared sharps containers for the collection and disposal of Pre-filled Injector Products ("**Injector Mail-Back Packages**") by Vendor.

Kiosk Drop-Off Site is a location hosting a MED-Project kiosk for the collection of Unwanted Medicine, including Host-Assisted Collection Kiosk Drop-Off Sites and Technician-Assisted Collection Kiosk Drop-Off Sites, that is accessible to the public.

Kiosk Drop-Off Site Host is the designated contact person or persons at the Kiosk Drop-Off Site, including Host-Assisted Collection Kiosk Drop-Off Site Hosts and Technician-Assisted Collection Kiosk Drop-Off Site Hosts.

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

Mail-Back Distribution Location is a site that is accessible to the public, such as a fire station or library, which provides MED-Project Standard Mail-Back Packages to Residents.

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

MED-Project Website is the Internet website located at www.med-project.org or www

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

Pre-filled Injector Products are pre-filled injector products with a retractable or otherwise securely covered needle where medicine cannot be removed from them or where they contain more than trace amounts of Covered Drugs.

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

Public Health is the Skagit County Public Health Department.

Required Languages are English, Spanish, Russian, Tagalog (Filipino), Chinese, and Korean.

Residents or Covered Entities means residents of Skagit County, including individuals living in single and multiple family residences and other residential settings, and including other non-business sources of Unwanted Medicine that is unused, unwanted, disposed of, or abandoned by residents as identified by Public Health. "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 Convenience Goal is established in Ordinance § 12.20.070(4)(d).

Service Technicians are personnel trained to service Program kiosks.

Shipper is United States Postal Service ("USPS").

Standard Mail-Back Services is the provision of pre-paid, pre-addressed envelopes for the collection and disposal of Unwanted Medicine ("**Standard Mail-Back Packages**") by Vendor.

Take-Back Event is a one-day event at a location accessible to the public, conducted by MED-Project, for the collection of Unwanted Medicine from Residents.

Technician-Assisted Collection Kiosk Drop-Off Site is a location hosting a MED-Project kiosk for the collection of Unwanted Medicine that is accessible to the public where boxes and inner liners will be removed from kiosks, sealed, and packaged by the Service Technicians and transported to a disposal facility by Carrier.

Technician-Assisted Collection Kiosk Drop-Off Site Host is the designated contact person or persons at the Technician-Assisted Collection Kiosk Drop-Off Site.

Unwanted Medicine is defined in Section IV of this Plan.

Vendor is any vendor retained by MED-Project to carry out its obligations under the Program.

IV. Unwanted Medicine²

For the purposes of the Plan, "Unwanted Medicine" includes all materials identified as "Covered drug[s]" under Ordinance § 12.20.040(2) that qualify as "Unwanted covered drug[s]" under Ordinance § 12.20.040(24). Per the Ordinance, 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 prefilled inhaler devices and prefilled injector devices with a retractable or otherwise securely covered needle." § 12.20.040(2). 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, batteries, mercury containing thermometers;
- 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 unless they are disposed of by the patient;
- 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);
- xi. Drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of the Ordinance if the Producer already provides a pharmaceutical product stewardship or takeback program;
- xii. Injector products and medical devices or their component parts or accessories that have been emptied or contain no more than trace residual amounts of Unwanted Medicine;
- xiii. Used, empty containers, vials, and pouches;
- xiv. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other similar products;
- xv. Schedule I or other illicit drugs; and
- xvi. Any other items excluded pursuant to the Ordinance.

See Section XIII.A for collection limitations imposed by the DEA Rule.

² Unwanted Medicine collected at Kiosk Drop-Off Sites and/or in Standard Mail-Back Packages does not include inhalers, Pre-filled Injector Products, or iodine-containing medications. If the Washington State Pharmacy Quality Assurance Commission Guidance Document dated March 19, 2018 ("WSPQAC Guidance Document") is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project may accept inhalers and/or iodine-containing medications at Kiosk Drop-Off Sites, and iodine-containing medications may be accepted in Standard Mail-Back Packages with Unwanted Medicine. MED-Project will continue to offer separate Mail-Back Services for inhalers.

V. Collection of Unwanted Medicine

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

A. Unwanted Medicine Collection Program Implementation

1. Outreach

Per Ordinance § 12.20.050(4)(b), MED-Project initially notified 24 sites with a licensed pharmacy, 10 LEAs, 11 Narcotic Treatment Programs, and five Long Term Care facilities located in the County of the opportunity to participate as a Kiosk Drop-Off Site Host. MED-Project also performed outreach to several locations through calls and emails with the goal of establishing Kiosk Drop-Off Sites in accordance with the Service Convenience Goal. 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.

Of the locations contacted, eight pharmacies and four LEAs expressed interest in participating in the Program. These interested sites are identified in Appendix B.

A map of the interested and potential Kiosk Drop-Off Site Host locations is below.

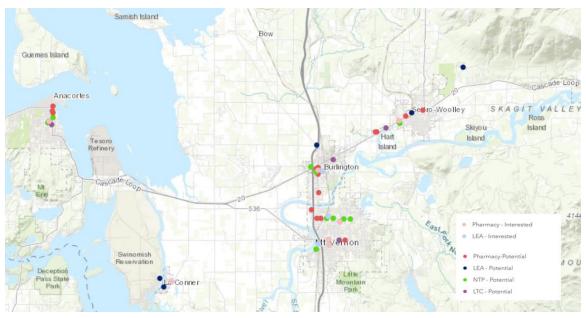


Figure 1: Interested and Potential Kiosk Drop-Off Site Hosts

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 <u>Appendix C</u>.

Locations currently serving as a drop-off site may participate in the Program by executing an agreement with MED-Project and modifying their DEA registration, if required. The process for modifying DEA registrations is outlined in Section XIII.A.1. MED-Project will work with the potential Kiosk Drop-Off Site Host to transition to the Program and Vendor.

2. Implementation

MED-Project has begun work with LEAs and pharmacies identified during outreach (see Section V.A.1.) to obtain signed Kiosk Drop-Off Site Host agreements. Upon Plan approval, MED-Project will work to satisfy the Service Convenience Goal through signed agreements with Kiosk Drop-Off Site Hosts. Participation in the Program is contingent upon compliance with all applicable laws, regulations, and other legal requirements and following the MED-Project collection processes provided in Section V.B.4, including the use of Vendor.

As required under Ordinance § 12.20.070(4)(a), within 90 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 as long as the site has an executed agreement with MED-Project, kiosks have been installed, sites have been trained, and, in the case of pharmacies, all requirements of the DEA and Washington State Pharmacy Quality Assurance Commission ("WSPQAC") have been met. Per Ordinance § 12.20.050(4)(d)(1), within 90 days of Plan approval, MED-Project will provide written documentation to Public Health confirming that all pharmacy Kiosk Drop-Off Site Hosts participating in the Program have amended their registrations with the DEA.

Mail-Back Services shall be available upon request for all Residents and to persons providing home care services to Residents, including hospice services, thereby offering more opportunities to dispose of Unwanted Medicine.

3. Convenience

Per 12.20.070(4)(d), MED-Project will establish two Kiosk Drop-Off Sites in each city in the County and an additional Kiosk Drop-Off Site for each additional 20,000 Residents in any city with a population greater than 40,000. MED-Project will establish a Kiosk Drop-Off Site in each town in the County. Kiosk Drop-Off Sites will be geographically distributed to provide reasonably convenient and equitable access to Residents. MED-Project will use the annual population estimate provided by the 2010 United States Census to define the population of cities, towns and unincorporated areas of Skagit County.

If a Kiosk Drop-Off Site cannot be established in a city or town, MED-Project will satisfy the Service Convenience Goal via a Mail-Back Distribution Location³ in a fire station, library or a municipal building, until the Service Convenience Goal has been met through a Kiosk Drop-Off Site. Take-Back Events may also be held annually in each city and town in which the Service Convenience Goal has not been achieved via Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations.

See Sections V.C.1 and V.E.4 for details of how the Program will satisfy the Service Convenience Goal.

4. Services

MED-Project will 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 <u>Appendices B</u> and <u>C</u>.

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites. and Mail-Back Services. Take-Back Events will be offered if the Service Convenience Goal is not met via Kiosk Drop-Off Sites, Mail-Back Distribution Locations, and/or Mail-Back Services. Over the course of implementation, additional Kiosk Drop-Off Sites will be established to the

³ Mail-Back Distribution Locations offer additional convenience to Residents at locations available to the public, year-round, by issuing Standard Mail-Back Packaged to Residents upon request, in contrast to one-day Take-Back Events, held in varying locations.

extent that (1) additional eligible LEAs and/or DEA-registered pharmacies agree to participate, and (2) contracts can be executed with such entities.

Mail-Back Services for Pre-filled Injector Products, inhalers, and iodine-containing medications will be available through the Call Center and MED-Project Website as an alternative collection method per Ordinance § 12.20.070(6). The WSPQAC Guidance Document suggests that Residents should not dispose of sharps, asthma inhalers, or iodine-containing medications in collection receptacles or mail-back packages containing controlled substances. If the WSPQAC Guidance Document is modified to allow for the commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project may accept inhalers and/or iodine-containing medications at Kiosk Drop-Off Sites, and iodine-containing medications may also be accepted in Standard Mail-Back Packages with Unwanted Medicine. MED-Project will continue to offer separate Mail-Back Services for inhalers.

B. Kiosk Drop-Off Sites

Kiosk Drop-Off Sites will be located within the County to best meet the Service Convenience Goal. This network will provide Residents the ability to participate in the Program. All Kiosk Drop-Off Sites shall provide Residents with access to Program kiosks during regular business hours.

1. Kiosk Drop-Off Site Locations

As required under Ordinance § 12.20.070(4)(a), within 90 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 that has an executed agreement with MED-Project and is able to meet all applicable laws, regulations, and other legal requirements. MED-Project will notify Public Health at least 15 days prior to making planned changes to the network of Kiosk Drop-Off Sites to the extent possible. MED-Project may not be able to provide 15-days notice in some cases, including those where a Kiosk Drop-Off Site closes down and provides notice to MED-Project following such closure.

2. Drop-Off Site Kiosk Placement

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 compliant 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 DEA Rule § 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. DEA Rule § 1317.75(d)(2)(i). Costs associated with installation and maintenance will be paid by MED-Project per the agreements with the Kiosk Drop-Off Site Hosts.

3. Kiosk Specifications

A kiosk will be offered to eligible host locations. Pursuant to DEA Rule § 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 (<u>Appendix D</u>) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the tamper-resistant drop-slot; and commercial hinges.⁴ 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 overflow 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.⁵ Kiosk signage will provide information about what is and is not accepted in the kiosk.

Additionally, under DEA Rule § 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 identifier 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 DEA Rule § 1317.05(c)(2)(iv), pharmacy Kiosk Drop-Off Site Hosts must dispose of sealed inner liners and their contents either on-site; through common or contract carrier delivery to, or pick-up by, a reverse distributor or distributor; or with DEA assistance.

Section 1317.75(c) of the DEA Rule prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, DEA Rule § 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 DEA Rule § 1317.60(b), (c). Section 1317.75(g) of the DEA Rule 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 DEA Rule§ 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 LEA's recordkeeping requirements for illicit controlled substances evidence pursuant to DEA Rule § 1317.35. LEAs will record the unique identifier and size of the sealed inner liner transferred to Vendor. *See* DEA Rule § 1317.35. Additionally, any Unwanted Medicine will be stored in a manner to prevent the diversion of controlled

-

⁴ MED-Project will develop clear, standardized instructions for Residents who use kiosks. <u>Appendix D</u> provides the kiosk design and signage MED-Project expects to propose when coordinating with other Product Stewardship Plans. ⁵ Specifically, as required under DEA Rule § 1317.75(e)(4), all kiosks will prominently display a sign stating that: "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, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk."

substances and consistent with the LEA's standard procedures for storing illicit controlled substances. *See* DEA Rule § 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* DEA Rule § 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 Program will keep all records required under the DEA Rule, including those required under DEA Rule §§ 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.

A Kiosk Drop-Off Site may elect to participate in the program via either the technician-assisted collection method or host-assisted collection method. If a Kiosk Drop-Off Site elects to participate via the technician-assisted collection method, a Service Technician will regularly come to the Technician-Assisted Collection Kiosk Drop-Off Site to help prepare the inner liner for shipment and disposal. If a Kiosk Drop-Off Site elects to participate via the host-assisted collection method, the Host-Assisted Collection Kiosk Drop-Off Site employees will prepare the inner liner for shipment.

a. Technician-Assisted Collection

For Kiosk Drop-Off Sites that opt to participate via the technician-assisted collection method, pick-up of Unwanted Medicine collected at Technician-Assisted Kiosk Drop-Off Sites will be scheduled year-round based on their regular business hours and volume collected.

The inner liner and box will be securely removed from the kiosk by a Service Technician and Technician-Assisted Collection Kiosk Drop-Off Site employees following procedures meeting all DEA requirements. Specifically, two Technician-Assisted Collection 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. 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 Technician-Assisted Collection Kiosk Drop-Off Site employees, the Service Technician will seal the liner for packaging and transport. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The Service Technician will schedule a pick-up by Carrier to be completed within a few business days and leave the packaged, sealed inner liner with the Technician-Assisted Collection Kiosk Drop-Off Site Host for storage in compliance with all applicable laws, regulations, and other legal requirements until Carrier pick-up.

Vendor will prepare the materials for shipment and perform applicable pre-transportation functions to comply with DOT Hazardous Materials Regulations ("HMR").

Any collection of controlled substances by LEA will be consistent with the LEA's standard procedures for transferring illicit controlled substances. See DEA Rule § 1317.35.

b. Host-Assisted Collection

Host-assisted collection will enable a Host-Assisted Collection Kiosk Drop-Off Site Host to directly control the timing for servicing the kiosk by allowing the Host-Assisted Collection Kiosk Drop-Off Site Host employees to seal the inner liner and prepare the package for transport at a time of their choosing. This method will allow Host-Assisted Collection Kiosk Drop-Off Site Hosts to avoid disruptions to operations that may result from Vendor-scheduled visits or storage limitations.

Unwanted Medicine will be securely removed from the kiosk by Host-Assisted Collection Kiosk Drop-Off Site employees following procedures meeting all DEA requirements. Specifically, two Host-Assisted Collection 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. 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.

Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site employees will seal the inner liner and prepare the package for transport. Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site Host employees will prepare the materials for shipment and perform applicable pre-transportation functions to comply with DOT HMR. The unique identifier on the inner liner will be matched to the tracking number on the shipping label. The two Host-Assisted Collection Kiosk Drop-Off Site employees will either schedule a pick-up by Carrier to be completed within a few business days or offer the package containing the sealed inner liner for pick-up during a routine Carrier service to the Host-Assisted Collection Kiosk Drop-Off Site. If the package containing the sealed inner liner is prepared prior to pick-up, the Host-Assisted Collection Kiosk Drop-Off Site Host will store the inner liner in compliance with all applicable laws, regulations, and other legal requirements until Carrier pick-up. Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site Host employees will replace the removed inner liner and box with a replenishment inner liner and box provided by Vendor. Each inner liner and box provided by Vendor will be pre-paid and pre-addressed for transport and disposal.

Any collection of controlled substances by LEA will be consistent with the LEA's standard procedures for transferring illicit controlled substances. See DEA Rule § 1317.35.

C. Take-Back Events

Ninety (90) days after Plan approval, MED-Project will schedule an annual take-back event in any city or town where the Service Convenience Goal not been achieved through signed Kiosk Drop-Off Site Host agreements and/or Mail-Back Distribution Locations. Due to the dynamic schedule of Take-Back Events, the list of dates and locations will be maintained on the MED-Project Website as events are scheduled and confirmed.

1. Method

The conducting of Take-Back Events by MED-Project is contingent upon participation and oversight by LEAs. 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. Events will be promoted and communicated to the public through targeted outreach in the communities served.

2. Procedures

MED-Project will partner with LEAs to ensure that at least one law enforcement officer oversees collection at every Take-Back Event 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 DEA Rule § 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. No other person will handle controlled substances at Take-Back Events under DEA Rule § 1317.65(e); however, Vendor may assist LEAs in the collection of Unwanted Medicine at Take-Back Events. *See* 79 Fed. Reg. 53,539.

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 published expectations of the planned event. Vendor will work in conjunction with 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 collection, storage, and destruction of the collected Unwanted Medicine in a manner consistent with the LEA's recordkeeping requirements for illicit controlled substances evidence pursuant to DEA Rule § 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 DEA Rule §§ 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 materials 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 pick-up by Carrier from the LEA facility to take place within a few business days of the event.

D. Disposal of Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events

Vendor and Carrier shall handle Unwanted Medicine from Technician-Assisted Collection Kiosk Drop-Off Sites, Host-Assisted Collection 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 all Kiosk Drop-Off Sites and Take-Back Events to the reverse distributor facility identified in Section IX.D. MED-Project's request for approval to incinerate materials collected at Host-Assisted Kiosk Drop-Off Sites at a municipal solid waste combustor is included in Appendix E.

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

E. Mail-Back Services for Unwanted Medicine

MED-Project will provide four types of Mail-Back Services that will be available to Residents through the Call Center and MED-Project Website:

- Standard Mail-Back Services as described in Section V.E.1;
- Standard Mail-Back Services for the collection of iodine-containing medications as described in Section V.E.2;
- Injector Mail-Back Services for the collection of Pre-filled Injector Products as described in Section V.E.3; and
- Inhaler Mail-Back Services for the collection of inhalers as described in Section V.E.4.

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, Excluding Inhalers, Pre-Filled Injector Products, and Iodine-Containing Medications

MED-Project will provide Standard Mail-Back Services via the Call Center and MED-Project Website. Standard Mail-Back Packages may also be available at municipal buildings, fire stations, or public libraries as Mail-Back Distribution Locations where the Service Convenience Goal cannot be met via Kiosk Drop-Off Sites. The pre-paid shipping label will direct the Standard Mail-Back Package to the facility identified in

Section IX. Standard Mail-Back Packages for Unwanted Medicine shall comply with all applicable laws, regulations, and other legal requirements.

Pursuant to DEA Rule § 1317.70(c), the Standard Mail-Back Packages for the collection of Unwanted Medicine, not including inhalers, Pre-filled Injector Products, or iodine-containing medications 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 identifier enabling tracking; and
- Provided with instructions indicating the process for mailing back the packages, accepted substances, instructions not to commingle inhalers, iodine-containing medication, and pre-filled injector products 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 DEA Rule § 1317.70(d). As required under DEA Rule § 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 DEA Rule § 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 DEA Rule § 1317.70(f). Vendor and MED-Project will keep all records required under the DEA Rule, including those identified in DEA Rule § 1304.22(f).

See Appendix F for a sample package and package specifications.

2. Standard Mail-Back Services for Iodine-Containing Medications

For iodine-containing medications, MED-Project will offer Residents Standard Mail-Back Services via the call center and MED-Project website. The pre-paid shipping label will direct the Standard Mail-Back Package to the facility identified in Section IX. If the WSPQAC Guidance Document is modified to allow for the commingling of iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in collection receptacles and will discontinue Mail-Back Services for iodine-containing medications.

3. Injector Mail-Back Services

MED-Project will offer Residents Injector Mail-Back Services via the Call Center and MED-Project Website. The pre-paid shipping label will direct the Injector Mail-Back Package to an approved facility identified in Section IX. An instruction sheet describing how to properly dispose of Pre-filled Injector Products that explains what materials may be placed in the sharps container, how to use the sharps container, and how to return the Injector Mail-Back Package will be included with the Injector Mail-Back Package.

See Appendix F for a sample package and package specifications.

4. Inhaler Mail-Back Services

MED-Project will offer Residents Inhaler Mail-Back Services via the Call Center and MED-Project Website. The pre-paid shipping label will direct the Inhaler Mail-Back Packages to an approved facility identified in Section IX. An instruction sheet will be included with the Inhaler Mail-Back Package that describes how to

properly dispose of inhalers, explains what materials may be placed in the Inhaler Mail-Back Package, and how to return the Inhaler Mail-Back Package.

See Appendix F for sample package specifications.

5. Mail-Back Package Availability

Residents may request Standard Mail-Back Packages for Unwanted Medicine, Standard Mail-Back Packages for iodine-containing medications, Injector Mail-Back Packages for Pre-filled Injector Products, and Inhaler Mail-Back Packages for inhalers by calling the Call Center or through a link on the MED-Project Website. Upon such request, Residents will be provided Standard Mail-Back Packages complying with all applicable laws, regulations, and other legal requirements. Mail-Back Services will also be made available to persons providing home care services to residents, including hospice services.

All Mail-Back Packages will contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine.

6. Mail-Back Package Collection and Disposal

The following general procedures will be applied to the processing of Mail-Back Packages:

- Requests by Residents made via the Call Center or MED-Project Website and are verified and logged;
- 2. Requests by Residents are processed, and tracking numbers are logged;
- 3. Mail-Back Packages are sent to requesting Residents;
- 4. Residents place Unwanted Medicine in Mail-Back Packages per instructions;
- 5. Residents mail the mail-back packages to the preaddressed location via the USPS or UPS depending on the type of Mail-Back Package;
- 6. Mail-Back Packages are received by facilities identified in Section IX, and a unique identifier on each returned Mail-Back Package is logged as "returned";
- 7. Mail-Back Packages are disposed of; and
- 8. Information on returned Mail-Back Packages are reconciled with the log of Mail-Back Packages shipped to Residents to verify type and average weight of Mail-Back Packages.

As described above, Residents may also obtain Standard Mail-Back Packages at Mail-Back Distribution Locations. All Mail-Back Services will supply packages that contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine. Residents will be directed to follow the instructions provided in the Mail-Back Package. 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 Standard Mail-Back Packages shall be scanned for receipt verification and then incinerated at the permitted Hospital, Medical, and Infectious Waste Incinerator (HMIWI) facility listed in Section IX. MED-Project's request for approval to incinerate Standard Mail-Back Packages at an HMIWI facility is included as <u>Appendix G</u>. Any storage of returned Standard Mail-Back Packages by Vendor will comply with the applicable security requirements of DEA Rule Section 1317, including the requirement that Unwanted Medicine be 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 Injector 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 facility identified in Section IX. MED-Project's request to use an autoclave and municipal waste landfill to treat and dispose of Pre-filled Injector Products is included as Appendix H.

This Plan proposes to incinerate inhalers collected through Inhaler Mail-Back Packages. The incinerator facilities are included in Section IX. MED-Project's request for approval to incinerate Inhaler Mail-Back Packages at a municipal solid waste combustor or medical waste incinerator is included in Appendix I.

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.

Once all Kiosk Drop-Off Sites 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 9 Kiosk Drop-Off Sites are operational for a full year, MED-Project anticipates collecting approximately 3,240 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2020. *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 Distribution Locations and/or Take-Back Events.

MED-Project Standard Mail-Back Packages have a capacity of 8 oz. per package. As MED-Project continues to capture collection data from current MED-Project Programs, MED-Project's estimated collection totals in 2019 could vary based on actual usage. Collection in 2019 will be used to adjust subsequent years' collection goals.

Based on Take-Back Event collection totals in other jurisdictions, MED-Project anticipates collection of approximately 140 pounds of Unwanted Medicine at Take-Back Events.

Data from 2019 will be utilized to establish baseline collection statistics and estimate collection goals for future years.

Short- and Long-Term Goals:

Goal Area	Short-Term	Long-Term
Collection	Approximately 2,500 pounds of Unwanted Medicine collected in 2019 through Kiosk Drop-Off Sites and Take-Back Events.	By year 5, collect approximately 3,300 pounds of Unwanted Medicine per year through Kiosk Drop-Off Sites and Mail-Back Services.
		Increase reliance on established Kiosk Drop-Off Sites and limited or no collection via Take-Back Events.
Education & Public Awareness	Develop baseline number of MED-Project 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 used.	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. Results of the survey will be published on the MED-Project Website.

VII. Patient Privacy

Instructions at each Kiosk Drop-Off Site will inform Residents 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 Residents 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 material are available in Appendix D and Appendix K. As added protection, inner liners and Standard Mail-Back Packages 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.

VIII. Call Center

MED-Project will operate a Call Center for Residents in the Required Languages. Questions from Residents will be managed through the Call Center with the support of an agent. All agents are trained to respond based on the requirements set by MED-Project.

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

- 1. Items that can be disposed of;
- 2. Disposal options; and
- 3. Direction to the MED-Project Website for additional information.
- 4. Information about Mail-Back Services.

Because the list of Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations is subject to change, Residents will be directed to the MED-Project Website or to an agent for detailed information about locations and contact information.

MED-Project kiosk signage will provide information on a 24/7 Call Center to answer questions and monitor comments from Residents.

Per Ordinance § 12.20.080(2), MED-Project will operate a call center and website jointly with all other Stewardship Programs should other Stewardship Plans be approved by the County.

IX. Transporter and Disposal Facility Information

A. Vendors

Name	Address	Phone	Website	Description
Stericycle Specialty Waste Solutions, Inc.	2850 100th Court NE Blaine, MN 55449	(612) 285-9865	www.stericycleenvironment al.com	 Services Technician- Assisted Collection Kiosk Drop-Off Sites May also service Take- Back Events. Provides Standard Mail- Back Packages. May also provide Inhaler Mail-Back Packages
Covanta Environmental Solutions, LLC	7326 E. Evans Road Suite B, Scottsdale, AZ 85620	(855) 269-1750	www.covantaes.com	Provides boxes and inner liners for Host-Assisted Collection Kiosk Drop-Off Sites.
PureWay Compliance Inc.	20501 Katy Freeway, Suite 206 Katy TX 77450	(877) 765-3030	http://pureway.com/	 Provides Injector Mail- Back Packages. May also provide Inhaler Mail-Back Packages.

B. Transporters and Shippers

Name	Address	Phone	Website	Туре	Description
United Parcel Service,	55 Glenlake Parkway	(800) PICK-UPS	www.UPS.com	Common Carrier	Transports
Inc.	NE				Unwanted Medicine
	Atlanta, GA, 30328				from Technician-
					Assisted Collection
					Kiosk Drop-Off Sites
					to the Stericycle ,

Name	Address	Phone	Website	Туре	Description
					Inc., Indianapolis, Indiana Facility. Transports Unwanted Medicine from Host-Assisted Collection Kiosk Drop-Off Sites to the Covanta Environmental Services, LLC Scottsdale, AZ Facility. May also transport Unwanted Medicine from Take-Back Events to the Stericycle, Inc., Indianapolis, Indiana Facility.
United States Postal Service	475 L'Enfant Plaza, S.W. Washington, DC 20260	(202) 268-2000	www.USPS.com/	Common Carrier	Transports Standard Mail Back Packages to the Stericycle, Inc. Warren Ohio facility. Transports Injector Mail Back Packages to Medsharps. Transports Inhaler Mail-Back Packages to Daniels Sharpsmart, Inc. May transport Inhaler Mail Back Packages to the

Name	Address	Phone	Website	Туре	Description
					Stericycle, Inc. Warren Ohio facility.
Heritage Transport	1626 Research Way Indianapolis, IN 46231	(317) 486-2973	http://www.heritage- enviro.com/	Contract Carrier	Transports Unwanted Medicine collected at Technician-Assisted Collection Kiosk Drop-Off Sites from the Stericycle, Inc., Indianapolis, Indiana Facility to Heritage Thermal Services — Ohio. May also transport Unwanted Medicine collected at Take- Back Events from the Stericycle, Inc., Indianapolis, Indiana Facility to Heritage Thermal Services — Ohio.
Stericycle Specialty Waste Solutions, Inc.	2850 100th Court NE Blaine, MN 55449	(612) 285-9865	www.stericycleenviron mental.com	Contract Carrier	May transport Unwanted Medicine collected at Technician-Assisted Collection Kiosk Drop-Off Sites from the Stericycle, Inc., Indianapolis, Indiana Facility to Veolia- Port Arthur.

Name	Address	Phone	Website	Туре	Description
					May transport Unwanted Medicine collected at Take- Back Events from the Stericycle, Inc., Indianapolis, Indiana Facility to Veolia- Port Arthur.
Transchem Environmental, LLC	542 East 27 th Street, Tucson, AZ 85713	(602) 344-4536	www.tcenv.com	Contract Carrier	Transports Unwanted Medicine from the Covanta Environmental Solutions, LLC, Scottsdale, AZ to Covanta Long Beach Municipal Solid Waste Combustor.
Medsharps LLC	17340 Bell North Drive Schertz, TX 78154	(844) 800-6981	www.medsharps.com	Private Carrier	Transports non- infectious waste from Medsharps to the Tessman Road Landfill.
Lula Logistics Inc.	8268 Nelson Ridge Ln Las Vegas NV 89178	(352)346-6219	lulalogistics@yahoo.co m	Contract Carrier	Transports Inhaler Mail- Back Packages received from Daniels Sharpsmart, Inc.
GPB Logistics Inc.	2115 W Farwell Ave #103 Chicago, IL 60645	(773) 968-7210	www.gpblogistics.com	Contract Carrier	Transports Inhaler Mail- Back Packages received from Daniels Sharpsmart, Inc.

C. Transfer Facility

Name	Address	Phone	Website	Туре	Description
Daniels Sharpsmart,	4144 East Therese	(559) 834-6252	http://danielsinternatio	Medical Waste	Receives Inhaler Mail-
Inc.	Avenue Fresno, CA 93725		nal.com/	Treatment Facility	Back Packages from the United States Postal Service.

D. Reverse Distributor Facilities

Name	Address	Phone	Website	Туре	Description
Stericycle, Inc., Indianapolis, Indiana Facility	2670 Executive Drive, Suite A Indianapolis, IN 46241- 9901	(317) 860-1200	www.stericycle.com	DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA) Treatment, Storage, and/or Disposal Facility	Receives Unwanted Medicine collected at Technician-Assisted Collection Kiosk Drop-Off Sites from the United Parcel Service, Inc. May also receive Unwanted Medicine collected at Take-Back Events from the United Parcel Service, Inc.
Covanta Environmental Solutions, LLC Scottsdale, AZ,	7326 E. Evans Road Suite B, Scottsdale, AZ 85620	(855) 269-1750	www.covantaes.com	DEA Registered Collector and Reverse Distributor	Receives Unwanted Medicine collected at Host-Assisted Collection Kiosk Drop- Off Sites from the United Parcel Service, Inc.

Stericycle, Inc., Warren,	1901 Pine Avenue, S.E.	(330) 393-0370	www.stericycle.com/se	DEA Registered	Receives Standard
Ohio	Warren, OH 44483		rvice-	Collector and Reverse	Mail-Back Packages
			locations/ohio/warren	Distributor & Permitted	from United States
				Hospital, Medical, and	Postal Service.
				Infectious Waste	 May receive Inhaler
				Incinerator (HMIWI)	Mail-Back Packages
				Facility	from United States
					Postal Service.

E. Autoclave Facility

Name	Address	Phone	Website	Туре	Description
Medsharps	17340 Bell N Dr. Schertz, TX 78154	(844) 800-6981	www.medsharps.com	Medical Waste Processing Facility	Receives Injector Mail- Back Packages from United States Postal Service and renders them non-infectious.

F. Disposal Facilities

Name	Address	Phone	Website	Туре	Description
Heritage Thermal	1250 Saint George	(800) 545-7655	http://www.heritage-	Hazardous Waste	• Incinerates
Services – Ohio	Street		thermal.com/	Incinerator	Unwanted Medicine
	East Liverpool, Ohio,				collected at
	43920				Technician-Assisted
					Collection Kiosk
					Drop-Off Sites
					received from the
					Stericycle, Inc.,
					Indianapolis, Indiana
					Facility.
					May incinerate
					Unwanted Medicine

Name	Address	Phone	Website	Туре	Description
					collected at Take- Back Events received from the Stericycle, Inc., Indianapolis, Indiana Facility.
Veolia-Port Arthur	7665 Texas Highway 73 Beaumont, TX 77705	(409) 736-2821	www.veolianorthameric a.com	Permitted Hazardous Waste Incinerator	 Incinerates Unwanted Medicine collected at Technician-Assisted Collection Kiosk Drop-Off Sites received from the Stericycle, Inc., Indianapolis, Indiana Facility that cannot be processed by Heritage Thermal Services-Ohio. May incinerate Unwanted Medicine collected at Take- Back Events received from the Stericycle, Inc., Indianapolis, Indiana Facility that cannot be processed by Heritage Thermal Services-Ohio.

Name	Address	Phone	Website	Туре	Description
Tessman Road Landfill	7000 E IH 10 San Antonio TX 78219	(210) 661-7558	https://www.republicse rvices.com/customer- support/facilities	Municipal Solid Waste Landfill	Receives and disposes of non-infectious waste from Medsharps .
Covanta Huntsville, Inc.	5251 Triana Blvd SW Huntsville, AL 35805	(256) 882-1019	https://www.covanta.co m/Our- Facilities/Covanta- Huntsville	Municipal Waste Combustor	Incinerates Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.
Covanta Marion, Inc.	4850 Brook Lake Rd. NE Brooks, OR 97305	(503) 393-0890	http://www.covanta.co m/facilities/facility-by- location/marion.aspx	Municipal Waste Combustor	Incinerates Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.
Stericycle, Inc., Warren, Ohio	1901 Pine Avenue, S.E. Warren, OH 44483	(330) 393-0370	www.stericycle.com/se rvice- locations/ohio/warren	DEA Registered Collector and Reverse Distributor & Hospital, Medical, and Infectious Waste Incinerator (HMIWI) Facility	 Incinerates Standard Mail-Back Packages from the United States Postal Service. May incinerate inhaler Mail-Back Packages from the United States Postal Service.

X. 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 and key stakeholders 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 jurisdictions to the extent possible.

As required by Ordinance § 12.20.080(2), MED-Project will seek to coordinate its promotional activities with other stewardship programs that are approved by the County.

B. Audiences

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

- Residents
- Pharmacies and Retailers of Covered Drugs
- Health care providers
- Veterinary providers
- Public health facilities
- Law enforcement agencies
- County Agencies
- Solid waste management facilities

This Plan details Program efforts to reach the varied cultural, linguistic, geographic, and age demographics, through outreach to local media (Appendix L); outreach to community organizations serving a broad range of audiences (Appendix M); availability of alternate language phone lines (Section X.D.1.); and availability of educational information through a broad range of channels, including the Call Center, broadcast media, digital media and/or the MED-Project Website.

Efforts to ensure that materials are appropriately targeted and available to these populations will be pursued with associations, agencies, and organizations that can be viewed in Appendix M.

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,
- Educating Residents about Mail-Back Services available, and;
- Providing Residents with clear steps to properly manage the disposal of their Unwanted Medicine, iodine-containing medications, inhalers, and/or Pre-filled Injector Products, including following instructions found on the medicine label and packaging, use of Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations, and use of available Mail-Back Services.

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 and/or Mail-Back Distribution Locations;
- 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).

D. Tools/Communications Channels

The Program will include several components designed to reach Residents 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. Phones

MED-Project will provide a Call Center for Residents to obtain information about Kiosk Drop-Off Sites, Mail-Back Distribution Locations, Take-Back Events, Mail-Back Services, educational materials, and other aspects of the Program. The toll-free number will provide:

- Basic information about the Program in the Required Languages, such as where to obtain more
 information (e.g., the MED-Project Website) and an option to talk with an agent to find or utilize
 Kiosk Drop-Off Sites, Mail-Back Distribution Locations, Mail-Back Services, and/or Take-Back
 Events, if applicable, in the caller's zip code or local area.
- A call script directing callers with medical emergencies to call 911 and directing callers with medication-related questions to contact their health care provider(s).

MED-Project kiosk signage will provide information on a 24/7 Call Center to answer questions and monitor comments from Residents.

See Appendix N for a sample template of the Call Center script.

2. MED-Project Website

MED-Project is developing a mobile-friendly website in the Required Languages. Information available to Residents on the MED-Project Website will include locations of Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations, educational materials, frequently asked questions and responses, Mail-Back Services information, and Take-Back Event dates and locations, if applicable

- The Plan includes a sample mockup of the MED-Project Website and its supporting pages. Appendix K provides a proof of concept for each page.
- The MED-Project Website will also include access to a public relations toolkit in a downloadable format (see Section X.D.3) and contact information for Residents. A toolkit available on the MED-Project Website includes a brochure (See Appendix J).
- 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 medications, inhalers, and Pre-filled Injector Products will be available through the MED-Project Website, through potential third-party partners, community organizations, and at Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations. 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.

The Plan includes a sample of the educational brochure (<u>Appendix J</u>). Educational materials use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency and will be available in the Required Languages.

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. The following materials support the Unwanted Medicine educational and outreach programming:

- See Appendix N for a sample education and outreach Call Center script with the toolkit, including flyers in Appendix J and MED-Project Website information included in Appendix K.
- See Appendix L for a sample list of key media outlets.
- See Appendix O for a sample list of social media outlets.

5. Broadcast Outreach

MED-Project may utilize local television outlets to conduct outreach to Residents. Outreach will be conducted through local print, online, television, and/or radio outlets as well as through outlets specifically targeting the diverse demographic communities within the County. Please *see* Appendix L 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:
 - o MED-Project will provide access to Educational and Outreach Programming materials, including the sample brochure (Appendix J), 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 <u>Appendix M</u> with the toolkit, which includes the brochure in <u>Appendix J</u>.
- Briefing Materials Provided to Support Collaboration with Persons Providing Home Care Services.
 - MED-Project will collaborate with persons providing home care services to Residents, including hospice services, to promote the use of Mail-Back Services by differentiallyabled and home bound Residents. MED-Project will provide persons providing home care services to Residents with the toolkit included in Appendix J.

F. Disclaimer

The written and verbal educational materials and public outreach tools required by the Ordinance and disseminated under this Product Stewardship Plan will include a disclaimer similar to the following: "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."

XI. Survey

Per Ordinance § 12.20.080(1)(f), MED-Project will conduct a survey of Residents and of health care providers including but not limited to pharmacists, health professionals, and/or veterinarians in the County who interact with Residents prior to the start of Program operations, after the first 12 months of plan operations, after 24 months of plan operations, and biennially thereafter, until such time that Public Health designates a less frequent schedule.

Survey questions will be designed to measure percent awareness of the Program, whether Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and knowledge and attitudes about risks of abuse, poisonings, and overdoses from prescription and nonprescription drugs used in the home. The survey conducted prior to the start of Program operations shall measure awareness of existing drop-off sites and other collection methods and assess knowledge and attitudes about the risks of abuse, poisoning and overdoses from prescription and nonprescription drugs used in the home. As required by Ordinance § 12.20.080(1)(f)(iii), draft survey questions will be submitted to Public Health for review and comment 30 days prior to initiation of the survey. Results of the survey will be reported to Public Health and made public within 90 days of the end of the survey period on the MED-Project Website. The privacy of all survey respondents will be maintained.

XII. Packaging

The Ordinance requires 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." Ordinance §§ 12.20.060(8)(b) and 12.20.060(8(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: 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 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
- 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.

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

The Ordinance requires that a Product Stewardship Plan describe how all entities participating in the Program will "operate under" all applicable laws, regulations, and other legal requirements. *See* Ordinance § 12.20.060(4). As described in more detail below, the Plan is designed so 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)⁶; 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* DEA Rule § 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 Program, including Vendor, are individually responsible to comply with their respective compliance obligations under the DEA Rule. Vendor will ensure that the transportation of Unwanted Medicine collected from Kiosk Drop-Off Sites, including controlled substances, complies with all DEA requirements, including those in DEA Rule § 1317.

31

⁶ 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." DEA Rule § 1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Standard Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent's property. See DEA Rule §§ 1317.65(d); 1317.70(b).

Controlled substances collected pursuant to the Plan 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* DEA Rule §§ 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 DEA Rule § 1301.51(b), pharmacies may modify their registrations to become authorized collectors by submitting a request to the DEA or online at www.DEAdiversion.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 DEA Rule § 1301.13(j).

See DEA Rule § 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

When preparing Unwanted Medicine for transport and transporting Unwanted Medicine, Vendor or the Host-Assisted Collection Kiosk Drop Off-Site will ensure compliance with the DOT HMR.

C. Washington State Pharmacy Quality Assurance Commission (WSPQAC)

The Ordinance requires that a Plan describe "how any pharmacy drop-off site will operate under applicable regulations and guidance of the Washington State Pharmacy Quality Assurance Commission." Ordinance § 12.20.060(4). On March 3, 2016, WSPQAC published "Pharmacy Quality Assurance Commission Guidance Document: Secure and Responsible Drug Disposal Program" and subsequently released an update published on March 19, 2018.⁷

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.

XIV. Reporting

Within 90 days after each calendar quarter of Program operation, MED-Project will submit a quarterly report to Public Health that states the total amount, by weight, of Unwanted Medicine collected during the previous calendar quarter, for each collection method used. Ordinance § 12.20.110(1). Within 90 days after the end of the first 12-month period of Program operations and annually thereafter, MED-Project will submit an annual report to Public Health describing the Program's activities during the previous calendar year. Ordinance § 12.20.110(2).

MED-Project annual reports will include the information required in Ordinance § 12.20.110(2) *et seq* and § 12.20.080(1)(g). For Mail-Back Services, MED-Project will include the number of Mail-Back Packages provided to Residents by type of Mail-Back Service and the number of mail-back packages that were returned.

⁷ https://www.doh.wa.gov/portals/1/Documents/Pubs/690294.pdf

Appendix A

MED-Project Participants

The list of participating Producers in MED-Project's Program in Skagit County is provided to the County on a regular basis.

Appendix B

Kiosk Drop-Off Sites with Expressions of Interest

Below is a list of locations that have expressed interest in participating as a Kiosk Drop-Off Site Host. The pharmacy and LEA responses below reflect information provided by the sites surveyed as of August 19, 2018. 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 reach out and work within the corporate structure where applicable.

SITE NAME	ADDRESS	CITY	TYPE
Anacortes Police Department	1218 24th Street	Anacortes	LEA
Burlington Police Department	311 Cedar Street, Suite B	Burlington	LEA
Family Pharmacy	1213 24th St Ste 400	Anacortes	PHY
Highway 20 Hometown Pharmacy	640 State Route 20 # A	Sedro-Woolley	PHY
Hilltop Pharmacy LLC	1223 E Division St	Mount Vernon	PHY
La Conner Drug #1146	708 E Morris St	La Conner	PHY
Makers Compounding Pharmacy	839 S Burlington Blvd	Burlington	PHY
Mount Vernon Police Department	1805 Continental Place	Mount Vernon	LEA
Sea Mar Community Health Center Pharmacy	7438 S D Ave Ste C	Concrete	PHY
Sea Mar Community Health Center Pharmacy	1400 N Laventure Rd	Mount Vernon	PHY
Skagit County Sheriff's Office	600 South Third	Mount Vernon	LEA
Skagit Valley Hospital Pharmacy	1415 E Kincaid St	Mount Vernon	PHY

Appendix C

Potential Additional Kiosk Drop-Off Sites

SITE NAME	ADDRESS	CITY	TYPE
Catholic Community Services Recovery Center	614 Peterson Road	Burlington	NTP
Compass Health	1100 S. 2nd Street	Mount Vernon	NTP
Costco Pharmacy #662	1725 S Burlington Blvd	Burlington	PHY
Fidalgo Care Center	1105 27th Street	Anacortes	LTC
Fred Meyer Pharmacy 24	920 S Burlington Blvd	Burlington	PHY
Haggen Pharmacy #3436	757 Haggen Dr	Burlington	PHY
Haggen Pharmacy #3450	2601 E Division St	Mount Vernon	PHY
Island Hospital Behavioral Health	2511 M Avenue, Suite B	Anacortes	NTP
Island Hospital Pharmacy	1211 24th St	Anacortes	PHY
Life Care Center of Mount Vernon	2120 East Division Street	Mount Vernon	LTC
Life Care Center of Skagit Valley	1462 West State Route 20	Sedro-Woolley	LTC
Mira Vista Care Center	300 South 18th Street	Mount Vernon	LTC
PeaceHealth United General Medical Center Pharmacy	2000 Hospital Dr	Sedro-Woolley	PHY
Phoenix Recovery Services	1601 East College Way	Mount Vernon	NTP
Prestige Care & Rehabilitation	1036 East Victoria Avenue	Burlington	LTC
Rite Aid #5245	412 E College Way	Mount Vernon	PHY
Rite Aid Pharmacy #5234	1517 Commercial Ave	Anacortes	PHY
Rite Aid Pharmacy #5248	851 Moore St	Sedro-Woolley	PHY
Safeway Pharmacy #0593	911 11th St	Anacortes	PHY
Safeway Pharmacy #1472	315 E College Way	Mount Vernon	PHY
San Juan Rehab and Care Center	911 21st Street	Anacortes	NTP
Schaffner Pharmacy	1990 Hospital Dr Ste 120	Sedro-Woolley	PHY
Sea Mar Behavioral Health Clinic	1010 E College Way	Mount Vernon	NTP
Sedro-Woolley Police Department	325 Metcalf Street	Sedro-Woolley	LEA
Skagit County Crisis Center	201 Lila Lane	Burlington	NTP
Skagit County Sheriff La Connor Detachment	204 Douglas S	La Conner	LEA
Skagit Reach Center	1413 E College Way	Mount Vernon	NTP
Sunrise Services	2500 East College Way	Mount Vernon	NTP
Swinomish Tribal Police Department	17353 Reservation Road	La Conner	LEA
· · · · · · · · · · · · · · · · · · ·			

United Northwest Recovery Center	605 B Sunset Park Land	Sedro-Woolley	NTP
Upper Skagit Tribal Police Department	25944 Community Plaza Way	Sedro Woolley	LEA
VA Community-Based Outpatient Clinic Services	307 S 13th St Ste 200	Mount Vernon	NTP
Wal Mart Pharmacy 10-2596	2301 Freeway Dr	Mount Vernon	PHY
Walgreens #07131	909 17th St	Anacortes	PHY
Walgreens #11300	623 S Burlington Blvd	Burlington	PHY
Walgreens Pharmacy 10994	320 Harrison St	Sedro-Woolley	PHY
Washington State Patrol	10945 Chuckanut Dr	Burlington	LEA
Washington State Patrol Department	236 I-5	Bow	LEA

Appendix D

Kiosk Prototype and Proposed Signage



Proposed Kiosk Signage

Front Panel Kiosk Art



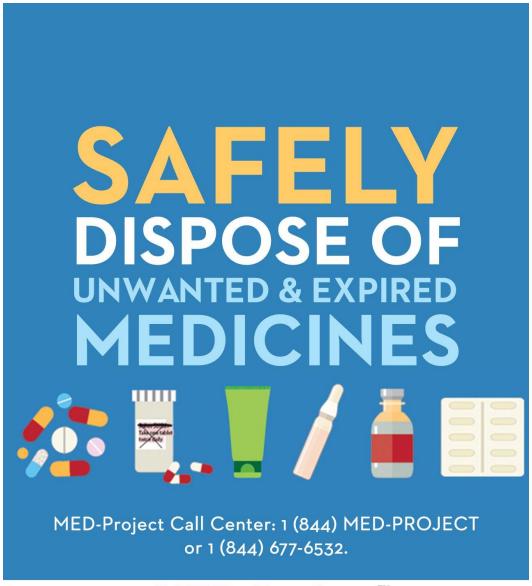
ONLY SCHEDULE II-V CONTROLLED AND NON-CONTROLLED SUBSTANCES THAT ARE LAWFULLY POSSESSED BY THE ULTIMATE USER ARE ACCEPTABLE TO BE PLACED IN THE KIOSK. SCHEDULE I CONTROLLED SUBSTANCES, ILLICIT OR DANGEROUS SUBSTANCES, AND ANY CONTROLLED SUBSTANCES NOT LAWFULLY POSSESSED BY THE ULTIMATE USER MAY NOT BE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

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



Proposed Kiosk Signage

Side Panel Kiosk Art





Proposed Kiosk Signage

Drop-Slot Kiosk Art





MED-Project[™]
Medication Education & Disposal





Appendix E

MED-Project Request for Approval of Disposal Process for Host-Assisted Collection Kiosk Drop-Off Sites

MED-PROJECT REQUEST FOR APPROVAL OF DISPOSAL PROCESS FOR HOST-ASSISTED COLLECTION KIOSK DROP-OFF SITES



August 20, 2018

MED-PROJECT REQUEST FOR APPROVAL DISPOSAL PROCESS FOR HOST-ASSISTED COLLECTION KIOSK DROP-OFF SITES

Pursuant to §§ 12.20.090(2) and 12.20.130(7) of the Secure Medicine Return Ordinance adopted by that Skagit County Board of Health enacting Skagit County Code 12.20 ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Skagit County Health Officer (the "Health Officer") to use a municipal waste combustor for the disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, cost, logistics, and other considerations make disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites not feasible at a permitted hazardous waste incinerator at this time, so the Health Officer should approve disposal of such materials at a municipal waste combustor in accordance with Ordinance § 12.20.090(2). Additionally, exercising discretion to allow for the disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites at a municipal waste combustor would achieve the objectives of the Ordinance in accordance with § 12.20.130(7) of the Ordinance.

I. THE PROCESS FOR THE DISPOSAL OF MATERIALS FROM HOST-ASSISTED COLLECTION KIOSK DROP-OFF SITES AT COVANTA LONG BEACH

MED-Project is proposing that materials collected at Host-Assisted Collection Kiosk Drop-Off Sites be delivered by the United Parcel Service, Inc. to the Covanta Environmental, LLC, facility in Scottsdale, Arizona. From there, the materials will be transported to the Covanta Long Beach Renewable Energy¹ facility in Long Beach, California ("Covanta Long Beach")² for destruction via incineration.

Covanta Long Beach is a municipal waste combustor. Covanta Long Beach is a waste-to-energy facility that processes up to 1,380 tons of municipal solid waste per day, generating up to 36 megawatts of electricity. Covanta Long Beach also has a Clean Air Act Title V permit, which establishes air emissions limits for particulate matter, carbon monoxide, sulfur dioxide, nitrogen oxides, lead, mercury, and fluorides, among other chemicals. To control air pollution, Covanta Long Beach employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, activated carbon filter units, and a continuous emissions monitoring system.

II. STANDARDS FOR THE HEALTH OFFICER TO APPROVE THE USE OF COVANTA LONG BEACH FOR THE DISPOSAL OF MATERIALS FROM HOST-ASSISTED COLLECTION KIOSK DROP-OFF SITES

Under Ordinance § 12.20.090(2), the Health Officer may grant approval for a producer or group of producers 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 C.F.R. parts 60 and 62, if use of a permitted hazardous waste disposal facility is not feasible for the stewardship plan based on cost, logistics or other considerations.

Additionally, in approving a plan, the Health Officer has discretion to waive strict compliance with the requirements of the Ordinance under § 12.20.130(7) in order to achieve the objectives of the Ordinance, which include protecting the public health and preventing unwanted drugs from being disposed of in a manner that can adversely affect the environment. *See* Ordinance § 12.20.010(1).

_

¹ The Southeast Resource Recovery Facility is operating as Covanta Long Beach Renewable Energy. See Covanta, Covanta Long Beach, https://www.covanta.com/Our-Facilities/Covanta-Long-Beach (last visited Aug. 19, 2018).

² Covanta Long Beach's mailing address is 118 pier S Avenue, Long Beach, CA 90802.

III. THE USE OF COVANTA LONG BEACH TO DISPOSE OF MATERIALS FROM HOST-ASSISTED COLLECTION KIOSK DROP-OFF SITES SHOULD BE APPROVED UNDER ORDINANCE §§ 12.20.090(2) AND 12.20.130(7) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Health Officer should approve incineration of materials from Host-Assisted Collection Kiosk Drop-Off Sites at Covanta Long Beach since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations, consistent with the intent of Ordinance § 12.20.090(2).

Additionally, the Health Officer should exercise its discretion and approve the use of Covanta Long Beach for disposal of materials from Host-Assisted Collection Kiosk Drop-Off Sites under Ordinance § 12.20.130(7) because disposal at Covanta Long Beach would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment, in furtherance of the objectives of the Ordinance.

A. <u>It is Not Feasible to Dispose of Materials Collected at Host-Assisted Collection Kiosk Drop-Off Sites at a Permitted Hazardous Waste Facility.</u>

MED-Project requests approval under Ordinance § 12.20.090(2) to use Covanta Long Beach because disposal of materials from Host-Assisted Collection Kiosk Drop-Off Sites at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, the cost to dispose of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites at a hazardous waste disposal facility would be much greater than the cost to dispose of such packages at Covanta Long Beach. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than municipal waste combustors to dispose of the same quantity of waste.

Second, disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites at Covanta Long Beach would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment. Municipal waste combustors, like Covanta Long Beach, are subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. Covanta Long Beach is subject to a Clean Air Act Title V permit for air emissions, and the facility has extensive air pollution controls in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, activated carbon filter units, and a continuous emissions monitoring system.

For the above reasons, the use of Covanta Long Beach to dispose of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites meets the standard at Ordinance § 12.20.090(2), under which the Health Officer can approve disposal at a municipal waste combustor. Accordingly, MED-Project requests that the Health Officer approve disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites at Covanta Long Beach.

B. <u>Disposal at Covanta Long Beach would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment.</u>

Disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites at Covanta Long Beach would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment. Municipal Waste Combustors, like Covanta Long Beach, are subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. Covanta Long Beach is subject to a Clean Air Act Title V permit for air emissions, and the facility has extensive air pollution controls in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, activated carbon filter units, and a continuous emissions monitoring system.

The permits and other requirements that apply to Covanta Long Beach protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment. Accordingly, the

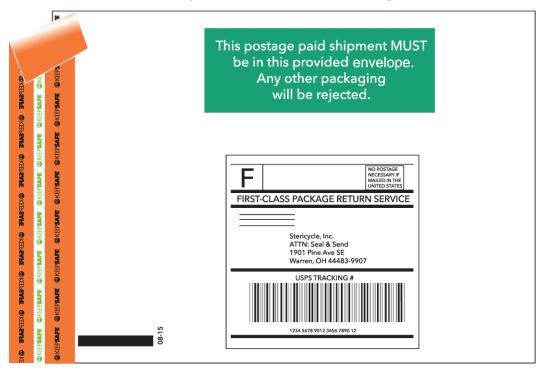
Health Officer should exercise its discretion under Ordinance § 12.20.130(7) to approve Covanta Long Beach as a disposal site for materials collected at Host-Assisted Collection Kiosk Drop-Off Sites.

IV. CONCLUSION

Accordingly, the Health Officer should approve the disposal of materials collected at Host-Assisted Collection Kiosk Drop-Off Sites via incineration at Covanta Long Beach as proposed by MED-Project under Ordinance § 12.20.090(2) and § 12.20.130(7).

Appendix F

A. Sample Standard Mail-Back Package³



Description:

Plastic envelope with return label and instructional flyer.

Package Size:

Outer dimensions: 8.25" x 12"

Inner dimensions: 7.375" x 10.375"

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to requirements in the Ordinance.

³ If the WSPQAC Guidance Document is modified to allow for commingling of iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in kiosks at Kiosk Drop-Off Sites and in Standard Mail-Back Packages for Unwanted Medicine.

B. Sample Injector Mail-Back Package





Description:

Injector Mail-Back Package including FDA-cleared sharps container with mail-back packaging, return label, instructional flyer, and unique identifier enabling tracking from collection through final disposal.

Package Sizes:

1.4-quart mail-back system

PureWay mail-back solutions are an example of complete, turnkey systems to provide for the safe return of Pre-filled Injector Products via Shipper.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to the requirements in the Ordinance.

C. Sample PureWay Inhaler Mail-Back Package Specifications

Description:

Inhaler Mail-Back Package including container with mail-back packaging, return label, and instructional flyer.

Package Sizes:

2.5-gallon mail-back system

Mail-back solutions are an example of complete, turnkey systems to provide for the safe return of inhaler waste through Carrier.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to the requirements in the Ordinance.

D. Sample Stericycle Inhaler Mail-Back Package is postage paid shipment MUST be in this provided envelope. Any other packaging will be rejected. ORM-D 8.75" 11.25

Description:

Inhaler Mail-Back Package including container with mail-back packaging, return label, and instructional flyer.

Package Sizes:

Outer dimensions: 8.75"x 11.25"x 3"

Mail-back solutions are an example of complete, turnkey systems to provide for the safe return of inhaler waste through Shipper.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to the requirements in the Ordinance.

Appendix G

MED-Project Request for Approval of Standard Mail-Back Package Disposal Process

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



August 20, 2018

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

Pursuant to §§ 12.20.130(7) and 12.20.090(2) of the Secure Medicine Return Ordinance adopted by that Skagit County Board of Health enacting Skagit County Code 12.20 ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Skagit County Health Officer (the "Health Officer") to use a permitted medical waste incinerator for the disposal of Standard Mail-Back Packages for Unwanted Medicine (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, exercising discretion to allow for the disposal of Standard Mail-Back Packages at a permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 12.20.130(7) of the Ordinance. Further, because cost, logistics, and other considerations make disposal of Standard Mail-Back Packages at a permitted hazardous waste facility not feasible at this time, approving the disposal of Standard Mail-Back Packages at a permitted medical waste incinerator would be consistent with the intent of Ordinance § 12.20.090(2).

V. THE PROCESS FOR THE DISPOSAL OF STANDARD MAIL-BACK PACKAGES AT THE WARREN INCINERATOR

MED-Project is proposing to provide Standard Mail-Back Packages that are pre-addressed and pre-paid for delivery to the Stericycle, Inc. ("Stericycle") incinerator in Warren, Ohio (the "Warren Incinerator")¹ for destruction via incineration. The Warren Incinerator will scan the unique identifier on each Standard Mail-Back Package to record receipt of the package before incinerating it and will confirm the materials have been properly incinerated.

The Warren Incinerator is a permitted hospital, medical, and infectious waste incinerator. The incinerator's primary chamber has a minimum exit gas temperature of 1400 °F, and the incinerator's secondary chamber is operated at over 1,830.5 °F. The Warren Incinerator also has a Clean Air Act Title V permit, which establishes air emissions limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury, among other chemicals. To control air pollution, the Warren Incinerator employs a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system, among other controls. The incinerator stack must be designed to minimize the impact of emissions on employees, residents, visitors, and nearby residences.

The Warren Incinerator is a United States Drug Enforcement Administration ("DEA") registered collector facility and destroys Standard Mail-Back Packages from MED-Project and other Stericycle clients in compliance with DEA requirements.

VI. STANDARDS FOR THE HEALTH OFFICER TO APPROVE THE USE OF THE WARREN INCINERATOR FOR THE DISPOSAL OF STANDARD MAIL-BACK PACKAGES

In approving a plan, the Health Officer has discretion to waive strict compliance with the requirements of the Ordinance under § 12.20.130(7) in order to achieve the objectives of the Ordinance, which include protecting the public health and preventing unwanted drugs from being disposed of in a manner that can adversely affect the environment. *See* Ordinance § 12.20.010(1).

Additionally, under Ordinance § 12.20.090(2), the Health Officer may grant approval for a producer or group of producers to dispose of some or all collected covered drugs, including those collected in Standard Mail-Back Packages, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a permitted hazardous waste disposal facility is not feasible for the stewardship plan based on cost, logistics or other considerations.

¹ The Warren Facility's mailing address is 1901 Pine Ave SE, Warren, OH 44483.

VII. THE USE OF THE WARREN INCINERATOR TO DISPOSE OF STANDARD MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE §§ 12.20.130(7) AND 12.20.090(2) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Health Officer should exercise its discretion and approve the use of the Warren Incinerator for disposal of Standard Mail-Back Packages under Ordinance § 12.20.130(7) because disposal at the Warren Incinerator would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment, in furtherance of the objectives of the Ordinance.

Furthermore, the Health Officer should also exercise its discretion to approve incineration of Standard Mail-Back Packages at the Warren Incinerator since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations, consistent with the intent of Ordinance § 12.20.090(2).

C. <u>Disposal at the Warren Incinerator would protect the public health and prevent unwanted drugs from being</u> disposed of in a manner that could adversely affect the environment.

Disposal of Standard Mail-Back Packages at the Warren Incinerator would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment. Medical waste incinerators, like the Warren Incinerator, are subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The Warren Incinerator is subject to environmental permits, including a Clean Air Act Title V permit for air emissions and a state solid waste management permit, and the facility has extensive air pollution controls in place, including a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system. The Warren Incinerator's Clean Air Act Title V air permit cites to federal standards and emissions limits that are specific to incinerators for hospital, medical, and infectious waste. Additionally, facilities that handle medical waste, like the Warren Incinerator, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

As these applicable requirements protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment, the Health Officer should exercise its discretion under Ordinance § 12.20.130(7) to approve the Warren Incinerator as a disposal site for Standard Mail-Back Packages. Such approval would be consistent with the intent of Ordinance § 12.20.090(2) to allow other disposal options should the use of a hazardous waste disposal facility prove not feasible.

D. Disposal of Standard Mail-Back Packages at a Permitted Hazardous Waste Facility is Not Feasible.

MED-Project requests approval to use the Warren Incinerator because disposal of Standard Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project's vendor for Standard Mail-Back Packages, Stericycle, only offers disposal at the Warren Incinerator for the Standard Mail-Back Packages distributed by MED-Project. MED-Project is considering alternative disposal options, but the use of a hazardous waste disposal facility for Standard Mail-Back Packages is not logistically feasible at present given the information MED-Project has received from its vendor about the vendor's access to disposal facilities.

Second, the cost to dispose of Standard Mail-Back Packages at a hazardous waste disposal facility, if any DEA registered collector hazardous waste disposal facilities exist, would be much greater than the cost to dispose of such packages at the Warren Incinerator. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than medical waste incinerators to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing and able to accept Standard Mail-Back Packages, if any such facilities exist, would cause delay in service to the public and increase MED-Project's costs, further supporting the

conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Standard Mail-Back Packages at a hazardous waste incinerator.

Third, there are no other laws or requirements, outside of this Ordinance, that would require MED-Project to dispose of Standard Mail-Back Packages at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a permitted medical waste incinerator like the Warren Incinerator. Any unwanted medicines collected via Standard Mail-Back Packages under this Plan are not regulated under Washington's dangerous waste regulations, and therefore are not required to be treated as dangerous waste.

For the above reasons, the use of the Warren Incinerator to dispose of Standard Mail-Back Packages would meet the standard at Ordinance § 12.20.090(2), under which the Health Officer can approve disposal at a municipal waste combustor. Disposal at the Warren Incinerator is at least as protective of the environment and human health as compared to a municipal waste combustor. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 12.20.090(2), but not at a medical waste incinerator (i.e., the Warren Incinerator) that is permitted to receive this waste and would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment. Accordingly, MED-Project requests that the Health Officer approve disposal of Standard Mail-Back Packages at the Warren Incinerator.

VIII. CONCLUSION

Accordingly, the Health Officer should approve the disposal of Standard Mail-Back Packages via incineration at the Warren Incinerator as proposed by MED-Project under Ordinance § 12.20.130(7) and consistent with the intent of Ordinance § 12.20.090(2).

Appendix H

MED-Project Request for Approval to Autoclave Pre-Filled Injector Products

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS

MED-Project Medication Education & Disposal

August 20, 2018

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS

Pursuant to § 12.20.090(3) and § 12.20.130(7) of the Secure Medicine Return Ordinance adopted by that Skagit County Board of Health enacting Skagit County Code 12.20 ("Ordinance"), MED-Project, LLC ("MED-Project") requests approval from the Skagit County Health Officer (the "Health Officer") to autoclave Pre-filled Injector Products (as defined in MED-Project Product Stewardship Plan ("Plan") § III) collected through MED-Project's Product Stewardship Program (the "Program"). As described below, exercising discretion to allow for the treatment of Pre-filled Injector Products at an autoclave facility permitted to accept such waste would further the objectives of the Ordinance in accordance with § 12.20.130(7). Further, autoclaving Pre-filled Injector Products would provide superior environmental and human health protection than incineration at lower cost, and therefore should be approved under the alternative final disposal technology provision in Ordinance § 12.20.090(3).

I. THE AUTOCLAVE TREATMENT PROCESS FOR PRE-FILLED INJECTOR PRODUCTS

MED-Project is proposing that mail-back packages containing Pre-Filled Injector Products would be delivered to the Daniels Sharpsmart facility in Fresno, California for transport to the MedSharps LLC facility (the "MedSharps Facility") for treatment via autoclave. The MedSharps Facility is permitted to accept and treat regulated medical waste, which includes sharps, and outdated/off-specification pharmaceuticals. Therefore, the facility can accept Pre-filled Injector Products that are required to be collected by the Ordinance.

The MedSharps Facility relies on autoclaving as the principal treatment method for medical waste. Autoclaves operate at high 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. After the materials are sterilized via autoclave at the MedSharps Facility, they are transferred to self-contained compactors that compact the waste in roll-off containers before being transported to the municipal waste landfill for disposal.

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 Pre-filled Injector Products collected by MED-Project in Skagit County are not dangerous waste and would not require disposal at a permitted hazardous waste facility, if not for these Ordinance. Washington state law regulates sharps as "biomedical waste." Washington state law does not prohibit the use of autoclaving to treat sharps or the 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,

¹ HEALTH CARE WITHOUT Harm, Non-Incineration Medical Waste Treatment Technologies 23 (Aug. 2001), available at https://noharm.org/sites/default/files/lib/downloads/waste/Non-Incineration_Technologies.pdf.

² U.N. G.A. Human Rights Council, Report of the Special Rapporteur on the adverse effects of the movement and dumping of toxic and dangerous products and wastes on the enjoyment of human rights, U.N. Doc. A/HRC/18/31 (July 4, 2011), available at https://documents-dds-ny.un.org/doc/UNDOC/GEN/G11/144/22/PDF/G1114422.pdf?OpenElement.

³ Impact on carbon footprint: a life cycle assessment of disposable versus reusable sharps containers in a large US hospital (2012), *available at* http://journals.sagepub.com/doi/pdf/10.1177/0734242X12450602.

⁴ See Pharmaceutical Waste Frequently Asked Questions, DEPARTMENT OF ECOLOGY, http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/faqs.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).

⁶ See R.C.W. 70.95K.030(1).

⁷ See W.A.C. 173-303-071(3)(c).

nothing in the Washington dangerous waste regulations would prohibit or otherwise restrict the treatment and disposal of Pre-filled Injector Products in the manner proposed by MED-Project.

II. STANDARDS FOR THE HEALTH OFFICER TO APPROVE THE USE OF THE PROPOSED AUTOCLAVE FOR THE TREATMENT OF PRE-FILLED INJECTOR PRODUCTS

In approving a plan, the Health Officer may exercise its discretion to approve a proposed plan and waive strict compliance with the requirements of the Ordinance to achieve the objectives of the Ordinance, which include protecting the public health and preventing unwanted drugs from being disposed of in a manner that can adversely affect the environment. *See* Ordinance § 12.20.010(1). Therefore, Ordinance § 12.20.130(7) grants the Health Officer discretion to waive strict compliance with Ordinance § 12.20.090 requiring that Pre-Filled Injector Products be disposed of at a permitted hazardous waste disposal facility or 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. As discussed in more detail below, autoclaving would allow for the proper treatment and disposal of Pre-filled Injector Products in a manner that protects the public health and prevents unwanted drugs from being disposed of in a manner that can adversely affect the environment, in furtherance of the Ordinance's objectives.

In addition, the Health Officer has discretion to approve alternative final disposal technologies under Ordinance § 12.20.090(3). A producer or group of producers participating in a stewardship plan may petition the Health Officer for approval to use alternative final disposal technologies that provide superior environmental and human health protection than permitted hazardous waste disposal facilities or municipal waste combustors, or equivalent protection at lesser cost. Ordinance § 12.20.090(3). Autoclaving would allow for the treatment and disposal of Prefilled Injector Products in a manner that is protective of the environment and human health, and it provides superior or equivalent protection regarding the criteria listed in § 12.20.090(3) of the Ordinance at lesser cost. 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 Ordinance § 12.20.090(3).

III. THE HEALTH OFFICER SHOULD APPROVE THE USE OF AUTOCLAVING TO TREAT PRE-FILLED INJECTOR PRODUCTS

MED-Project is requesting and petitioning for approval to use an autoclave to treat Pre-filled Injector Products, pursuant to Ordinance § 12.20.130(7) and § 12.20.090(3). The Health Officer should approve MED-Project's proposed treatment 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 set forth below.

A. The Health Officer Should Exercise its Discretion to Waive Strict Compliance with the Ordinance Under § 12.20.130(7) and Approve the Use of Autoclaving to Treat Pre-Filled Injector Products.

The Health Officer should exercise its discretion under Ordinance § 12.20.130(7) to approve MED-Project's Plan and waive strict compliance with the disposal provisions of the Ordinance in order to achieve the Ordinance's goal of protecting the public health and preventing unwanted drugs from being disposed of in a manner that can adversely affect the environment. *See* Ordinance §§ 12.20.010(1).

MED-Project's proposal to autoclave Pre-filled Injector Products meets the objectives of the Ordinance. MED-Project's proposal would protect the public health and prevent unwanted drugs from being disposed of in a manner that can adversely affect the environment 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 the public health against the improper handling and treatment 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 treatment and disposal process also adequately protects public health and the environment because all Pre-filled Injector Products collected by MED-Project are contained throughout the collection, transportation, autoclaving, and disposal process, dramatically reducing the chance that any workers or members of the public could be exposed to Pre-filled Injector Products. Accordingly, the use of an autoclave to treat Pre-filled Injector Products collected by MED-Project furthers the objectives of the Ordinance.

B. The Health Officer Should Approve the Use of Autoclaving to Treat Pre-Filled Injector Products Under the Standard for Alternative Final Disposal Technologies at Ordinance § 12.20.090(3).

The Health Officer should approve MED-Project's petition under Ordinance § 12.20.090(3) to autoclave Pre-filled Injector Products. Under Ordinance § 12.20.090(3), MED-Project may petition the Health Officer for approval to use alternative final disposal technologies that provide environmental and human health protection than permitted hazardous waste disposal facilities or municipal waste combustors, or equivalent protection at lesser cost. Ordinance § 12.20.090(3).

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

- 1) Overall impact on 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 Ordinance § 12.20.090(3)(a)–(d). Additionally, autoclaving is less expensive than incinerating these materials at a hazardous waste disposal facility or large municipal waste combustor.

1. Autoclaving provides superior or equivalent protection related to the overall impact on the environment and human health.

Autoclaving Pre-Filled Injector Products at the MedSharps Facility would provide superior or equivalent protection related to the overall impact on the environment and human health as compared to that provided by disposal at a permitted hazardous waste disposal facility or municipal waste combustor, satisfying this criterion under Ordinance § 12.20.090(3)(d).

As compared to incinerators, autoclaves generate few air emissions.^{8,9} In addition, autoclaves use far less energy to treat sharps than incineration,¹⁰ and therefore minimize the environmental impacts associated with energy production, including greenhouse gas emissions.

Autoclave facilities must comply with federal and state laws. For instance, the MedSharps Facility must comply with Texas' regulations regarding the treatment and disposal of medical waste and operates as a Type V Medical

⁸ State of California, Department of Health Services, Transforming Medical Waste Disposal Practices to Protect Public Health: Worker Health and Safety and the Implementation of Large-Scale, Off-Site Steam Autoclaves 14 (Feb. 2006) (citing J. Emmanuel, Health Care Without Harm, Non-Incineration Medical Waste Treatment Technologies: A Resource for Hospital Administrators, Facility Managers, Health Care Professionals, Environmental Advocates, and Community Members (Aug. 2001), available at https://noharm.org/sites/default/files/lib/downloads/waste/Non-Incineration Technologies.pdf).

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.

¹⁰ Incineration or Autoclave? A Comparative Study in Isfahan Hospitals Waste Management System, 25 Materia Socio Medica 48-51 (2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3633376/pdf/MSM-25-48.pdf (reporting that autoclaving costs half as much as incineration with regard to energy consumption on water, gas, and electricity).

Waste Processing Facility under a medical waste 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 MedSharps 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 or equivalent worker health and safety protections.

Autoclaving Pre-filled Injector Products at the MedSharps Facility provides superior or equivalent worker health and safety protections by minimizing worker exposure to any potential air contaminants and sharps. The MedSharps Facility 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 of Transportation ("DOT") Hazardous Materials Regulations. For instance, the MedSharps Facility and 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 MedSharps Facility receive extensive training. For example, all employees at the 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 MedSharps 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. 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 MedSharps 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 emissions from the autoclave. These operational controls protect workers and limit potential exposure to the sharps and any emissions generated during the autoclave process. As further evidence of the protection of worker health and safety against any potential emissions, 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.

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 such 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

https://noharm.org/sites/default/files/lib/downloads/waste/Non-Incineration_Technologies.pdf).

_

¹¹ State of California, Department of Health Services, Transforming Medical Waste Disposal Practices to Protect Public Health: Worker Health and Safety and the Implementation of Large-Scale, Off-Site Steam Autoclaves 14 (Feb. 2006) (citing J. Emmanuel, Health Care Without Harm, Non-Incineration Medical Waste Treatment Technologies: A Resource for Hospital Administrators, Facility Managers, Health Care Professionals, Environmental Advocates, and Community Members (Aug. 2001), *available at*

municipal waste landfill, where they are deposited into a designated space and covered. This ensures the waste is contained from collection through treatment and 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 at the MedSharps Facility provides superior worker health and safety protections per Ordinance § 12.20.090(3)(b).

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

Autoclaves, including the MedSharps Facility, 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 appropriately returned, transported, treated, and disposed of. The MedSharps Facility will confirm the autoclaved materials have been treated and sent to the landfill. No other waste monitoring is required. Thus, the MedSharps Facility provides equivalent compliance with all established requirements for emissions and waste monitoring.

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

Autoclaving produces minimal air emissions.¹² 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. Also, according to a California Air Resources Board technical assessment, water effluent from the autoclaving process is negligible provided facilities properly segregate their waste.¹³

All materials that have been rendered noninfectious through autoclave treatment will 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.

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.

_

¹² 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.

¹⁵ 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.

IV. CONCLUSION

Based on the foregoing reasons, MED-Project respectfully requests that the Health Officer exercise its discretion and authorize the use of an autoclave for treating Pre-filled Injector Products collected from residents of Skagit County in accordance with § 12.20.090(3) and § 12.20.130(7) of the Ordinance.

Appendix I

MED-Project Request for Approval of Inhaler Mail-Back Package Disposal Process

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



August 20, 2018

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

Pursuant to § 12.20.090(2) and § 12.20.130(7) of the Secure Medicine Return Ordinance adopted by the Skagit County Board of Health enacting Skagit County Code 12.20 ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Skagit County Health Officer (the "Health Officer") to use permitted municipal waste combustors for the disposal of Inhaler Mail-Back Packages (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, cost, logistics, and other considerations make disposal of Inhaler Mail-Back Packages at permitted hazardous waste facilities not feasible at this time. Further, exercising discretion to allow for the disposal of Inhaler Mail-Back Packages at a permitted municipal waste combustor or permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 12.20.130(7) of the Ordinance.

I. THE PROCESSES FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES AT THE PROPOSED INCINERATORS

MED-Project has identified two vendors that it may use to provide and dispose of Inhaler Mail-Back Packages. The two vendors are PureWay Compliance, Inc. ("PureWay") and Stericycle, Inc. ("Stericycle"). Each vendor has a slightly different disposal process, as laid out below.

A. Pureway's Process

MED-Project is proposing that one vendor for Inhaler Mail-Back Packages will be PureWay. The Inhaler Mail-Back Packages provided by PureWay will be pre-addressed and pre-paid for delivery to the Daniels Sharpsmart facility in Fresno, California (the "Daniels Facility") for transport to one of two incinerators for disposal: the Covanta Huntsville, Inc. facility (the "Covanta Huntsville Facility")¹ or the Covanta Marion, Inc. facility (the "Covanta Marion Facility").² The Daniels Facility will scan the unique identifier on each Inhaler Mail-Back Package to record receipt of the package before sending it for incineration to one of these two facilities. These facilities will receive and dispose of the Inhaler Mail-Back Packages and provide confirmation that the materials have been properly incinerated and disposed of.

1. Covanta Huntsville Facility

The Covanta Huntsville Facility is a permitted large municipal waste combustor. The furnaces at the Covanta Huntsville Facility are operated at temperatures exceeding 1800 degrees Fahrenheit.³ As a "waste-to-energy" facility, the Covanta Huntsville Facility uses municipal solid waste, like Inhaler Mail-Back Packages, to generate steam used for the U.S. Army's nearby Redstone Arsenal's heating and air conditioning needs.⁴ To control air pollution, the Covanta Huntsville Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. Additionally, the Covanta Huntsville Facility has been designated as a Voluntary Protection Program ("VPP") Star facility by the U.S. Occupational Safety and Health Administration ("OSHA"), recognizing the facility's employer's and employees' exemplary achievement in the prevention and control of occupational safety and health hazards.⁵

¹ Covanta Huntsville's mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.

² Covanta Marion's mailing address is 4850 Brooklake Road, NE, Brooks, OR 97305.

³ See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, http://swdahsv.org/waste-to-energy/.

⁴ See Covanta, Covanta Huntsville, https://www.covanta.com/Our-Facilities/Covanta-Huntsville.

⁵ Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

2. Covanta Marion Facility

The Covanta Marion Facility is also a permitted large municipal waste combustor. The Covanta Marion Facility is a "waste-to-energy" facility that incinerates waste and generates 13.1 megawatts per day from a condensing steam turbine generator that provides energy to the local utility.⁶ Like the Covanta Huntsville Facility, the Covanta Marion Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system.⁷ The Covanta Marion Facility is a member of the Safety and Health Achievement Recognition Program ("SHARP"), Oregon's safety and health recognition program.⁸ The Covanta Marion Facility has also been designated as a VPP Star facility by OSHA.⁹

B. <u>Stericycle's Process</u>

MED-Project is proposing that the other vendor for Inhaler Mail-Back Packages will be Stericycle. The Inhaler Mail-Back Packages provided by Stericycle will be pre-addressed and pre-paid for delivery to the Stericycle incinerator in Warren, Ohio (the "Warren Incinerator")¹⁰ for incineration. The Warren incinerator will scan the unique identifier on each Inhaler Mail-Back Package to record receipt of the package and will confirm the materials have been properly incinerated and disposed of.

1. Warren Incinerator

The Warren Incinerator is a permitted hospital, medical, and infectious waste incinerator. The incinerator's primary chamber has a minimum exit gas temperature of 1400 °F, and the incinerator's secondary chamber is operated at over 1,830.5 °F. The Warren Incinerator has a Clean Air Act Title V permit, which establishes air emissions limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury, among other chemicals. To control air pollution, the Warren Incinerator employs a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system, among other controls. The incinerator stack must be designed to minimize the impact of emissions on employees, residents, visitors, and nearby residences.

II. STANDARDS FOR THE HEALTH OFFICER TO APPROVE THE USE OF THE PROPOSED INCINERATORS FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES

Under Ordinance § 12.20.090(2), the Health Officer may grant approval for a producer or group of producers to dispose of some or all of the collected covered drugs, including inhalers, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a permitted hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

Additionally, in approving a plan, the Health Officer has discretion to waive strict compliance with the requirements of Ordinance under § 12.20.130(7) in order to achieve the objectives of the Ordinance, which include protecting public health and preventing unwanted drugs from being disposed of in a manner that can adversely affect the environment. See Ordinance § 12.20.010(1). Therefore, Ordinance § 12.20.130(7) grants the Health Officer discretion to waive strict compliance with the disposal provisions at § 12.20.090(1) requiring that such materials be disposed of at a permitted hazardous waste disposal facility.

⁶ See Covanta, Covanta Marion, https://www.covanta.com/Our-Facilities/Covanta-Marion.

⁹ Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

¹⁰ The Warren Facility's mailing address is 1901 Pine Ave SE, Warren, OH 44483.

III. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 12.20.090(2) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project proposes to use the Covanta Huntsville Facility, the Covanta Marion Facility, and the Warren Incinerator because disposal of Inhaler Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project engaged multiple potential vendors to evaluate whether they could distribute, receive, and dispose of Inhaler Mail-Back Packages, but most vendors do not offer such services.

Second, the cost to dispose of Inhaler Mail-Back Packages at a hazardous waste disposal facility would be much greater than the cost to dispose of such packages at the proposed facilities. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than other facilities to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing to accept Inhaler Mail-Back Packages and ensuring that one of MED-Project's vendors is capable of delivering Inhaler Mail-Back Packages to that facility would cause delay in service to the public and increase MED-Project's costs, further supporting the conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Inhaler Mail-Back Packages at a hazardous waste incinerator.

Third, there are no other laws or requirements, outside of this Ordinance, that would require MED-Project to dispose of Inhaler Mail-Back Packages at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a municipal waste combustor or medical waste incinerator. Any inhalers collected by MED-Project under this Plan are not regulated under the state's dangerous waste regulations, and therefore are not required to be treated as dangerous waste.

For the above reasons, the Health Officer should approve MED-Project's request to use the Covanta Huntsville Facility and Covanta Marion Facility to dispose of Inhaler Mail-Back Packages under Ordinance § 12.20.090(2), which authorizes the Health Officer to approve disposal at a municipal waste combustor.

Similarly, the Health Officer should approve MED-Project's request to use the Warren Incinerator to dispose of Inhaler Mail-Back Packages because the use of the Warren Incinerator would meet the standard at Ordinance § 12.20.090(2) and the Health Officer has discretion to waive strict compliance with the Ordinance requirements.

IV. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 12.20.130(7) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Health Officer should exercise its discretion and approve the use of the proposed incinerators for disposal of Inhaler Mail-Back Packages under Ordinance § 12.20.130(7) because disposal at the proposed incinerators would protect public health and prevent unwanted drugs from being disposed of in a manner that can adversely affect the environment in furtherance of the objectives of the Ordinance.

A. Covanta Huntsville Facility and Covanta Marion Facility

The Covanta Huntsville Facility and the Covanta Marion Facility have extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. They have also been recognized for their workplace safety achievements, as evidenced by their status as VPP Star facilities. The use of these facilities would protect public health and prevent unwanted drugs from being disposed of in a manner that can adversely affect the environment in furtherance of the objectives of the Ordinance.

B. Warren Incinerator

The Health Officer should exercise its discretion to approve the use of the Warren Incinerator to dispose of Inhaler Mail-Back Packages. Disposal at the Warren Incinerator is at least as protective of the environment and human health as compared to a municipal waste combustor. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 12.20.090(2), but not at a medical waste incinerator (i.e., the Warren Incinerator) that would protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment.

The Warren Incinerator, as a medical waste incinerator, is subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The Warren Incinerator is subject to environmental permits, including a Clean Air Act Title V permit for air emissions and a state solid waste management permit, and the facility has extensive air pollution controls in place, including a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system. The Warren Incinerator's Clean Air Act Title V air permit cites to federal standards and emissions limits that are specific to incinerators for hospital, medical, and infectious waste. Additionally, facilities that handle medical waste, like the Warren Incinerator, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

As these applicable requirements protect the public health and prevent unwanted drugs from being disposed of in a manner that could adversely affect the environment, the Health Officer should exercise its discretion under Ordinance § 12.20.130(7) to approve the Warren Incinerator as a disposal site for Inhaler Mail-Back Packages. Such approval would be consistent with the intent of Ordinance § 12.20.090(2) to allow other disposal options since the use of a hazardous waste disposal facility is not feasible.

V. CONCLUSION

Accordingly, the Health Officer should approve the disposal of Inhaler Mail-Back Packages via incineration at the Covanta Huntsville Facility, the Covanta Marion Facility, and the Warren Incinerator, as proposed by MED-Project under Ordinance § 12.20.090(2) and § 12.20.130(7).

Appendix J

Brochure Mockup

Front of brochure

WHAT SHOULD YOU DO WITH YOUR UNWANTED OR EXPIRED MEDICINES?

MED-Project Medication Education & Disposal

SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

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-PROJECT

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)



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.









Unused, expired or contaminated pharmaceutical wastes are prohibited from disposal in the garbage system in Skagit County.

MED-Project

Medication Education & Disposal

www.med-project.org

Back of brochure

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 LOCATIONS



To find convenient kiosks in your area, visit www.med-project.org for more information. Mail-back distribution locations may also be available in your area.

What items can I dispose of at a kiosk?





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.



NOT ACCEPTED:

HERBAL REMEDIES, VITAMINS,
SUPPLEMENTS, COSMETICS, OTHER
PERSONAL CARE PRODUCTS, INHALERS,
MEDICAL DEVICES, PET PESTICIDE
PRODUCTS, BATTERIES, IODINE-CONTAINING
MEDICATIONS, MERCURY CONTAINING
THERMOMETERS, SHARPS, AND
ILLICIT DRUGS.

DISPOSAL OPTIONS



MAIL-BACK



Mail-Back Services for Unwanted Medicines, inhalers, pre-filled injector products, and iodine-containing medications may be available in your area. Visit the mail-back section of www.med-project.org to order a mail-back package.

4 TAKE-BACK EVENTS



Take-Back Services may be available in your area. Visit the take-back section of www.med-project.org to find events in your area.



To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

MAIL-BACK PACKAGE IS FOR UNWANTED OR EXPIRED MEDICATIONS



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

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

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials.

MAIL-BACK PACKAGE IS FOR IODINE-CONTAINING MEDICATIONS



ACCEPTED: lodine-containing medications in any dosage form, in their original container or sealed bag.*

NOT ACCEPTED: Unwanted medicines that are not iodine-containing medications, herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, medical devices, pet pesticide products, batteries, mercury-containing thermometers, sharps, and illicit drugs.

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials.

MAIL-BACK PACKAGE IS FOR

INHALERS

ACCEPTED: Inhalers



NOT ACCEPTED: Unwanted medicines that are not inhalers, herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, pet pesticide products, batteries, iodine-containing medications, mercury-containing thermometers, sharps, and illicit drugs. and iodine-containing medications.

Note: Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package, Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials.

PRE-FILLED INJECTOR PRODUCTS CONTAINING A SHARP AND AUTO INJECTORS

ACCEPTED: Pre-loaded products containing a sharp and auto injectors.

NOT ACCEPTED: Unwanted medicines that are not pre-loaded products containing a sharp or auto-injectors, herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, medical devices, pet pesticide products, batteries, iodine-containing medications, mercury containing thermometers, loose sharps, and illicit drugs.

Note: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot accept other types of items.

MED-Project

Medication Education & Disposal

DISPOSAL OPTIONS:

CHECK THE PACKAGE

If there are specific instructions for disposal on the label, package, or package insert, please follow those instructions.

2 CONVENIENT LOCATIONS

To find convenient locations in your area, visit www.med-project.org for more information. Mail-back distribution locations may also be available in your area.

MAIL-BACK

Mail-Back Services for Unwanted Medicines, inhalers, pre-filled injector products, and iodone-containing medications may be available in your area. Visit www.med-project.org to order a mail-back package.

TAKE-BACK EVENTS

Take-Back Services may by available in your area. Visit the take-back sections of www.med-project.org to find events in your area.

^{*}Unused, expired or contaminated pharmaceutical wastes are prohibited from disposal in the garbage system in Skagit County.

Appendix K

MED-Project Website













If there are any specific instructions for disposal on the label, package or package insert, please follow those instructions.

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

Source: U.S. Food and Drug Administration.



CHECK THE PACKAGE



CONVENIENT LOCATIONS



MAIL **BACK**



TAKE-BACK **EVENTS**











CONVENIENT LOCATIONS

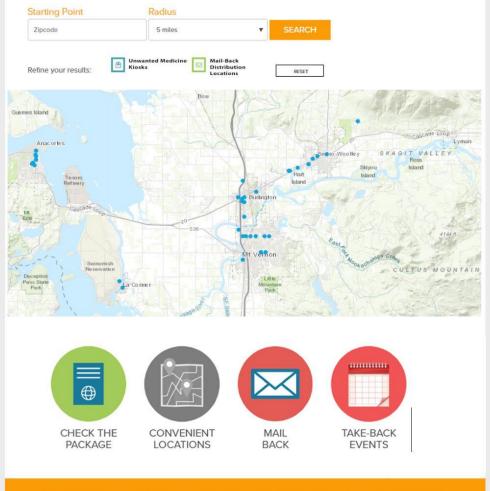
Community kiosk drop-off sites allow residents to bring expired or unwanted medicines to a convenient location for proper disposal.

 $\mbox{\bf ACCEPTED}$: 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.

NOT ACCEPTED: HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, INHALERS, MEDICAL DEVICES, BATTERIES, MERCURY-CONTAINING THERMOMETERS, SHARPS, PET-PESTICIDE PRODUCTS, IODINE-CONTAINING MEDICATIONS, AND ILLICIT DRUGS.

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













MAIL-BACK

Unwanted Medicine Mail-Back Services:

Mail-Back Services for Unwanted Medicine are available to Residents upon request. Medications in any dosage form in their original container or sealed bag are accepted.*

Note: The following items are not accepted in Unwanted Medicine Mail-Back Envelopes: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, medical devices, batteries, mercury-containing thermometers, sharps, pet pesticide products, iodinecontaining medications, and illicit drugs.

lodine-Containing Medication Mail-Back Services:Mail-Back Services for iodine-containing medications are available to Residents upon request.*

Note: Mail-Back Services for iodine-containing medications can only be used for iodinecontaining medications and cannot accept other types of items.

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

Inhaler Mail-Back Services:

Mail-Back Services for inhalers are available to Residents upon request.

Note: Only place undamaged Inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back PAckages can only be used for inhalers and cannot accept other types of items.

Injector Mail-Back Services:

Mail-Back Services for pre-filled injector products are available to Residents upon request.

Note: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot accept other types of items.

Mail-Back Services will also be made available to persons providing home care services to residents, including hospice services.

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

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.

Select your Package type		
		•
Contact Information		
First Name*		
Last Name*		
Emeil		
Address*		
Address 2		
City*		
California		•
Zip Code*		
SUBMIT REQUEST		





















TAKE-BACK EVENTS

Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. The local law enforcement 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.*

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

NOT ACCEPTED: HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, INHALERS, MEDICAL DEVICES, PET PESTICIDE PRODUCTS, BATTERIES, IODINE-CONTAINING MEDICATIONS, MERCURY CONTAINING THERMOMETERS, SHARPS, AND ILLICIT DRUGS.

CALENDAR OF LOCAL TAKE-BACK EVENTS

November

Friday, November 20, 2018

PUBLIC LIBRARY MEDICATION TAKE-BACK EVENT

20

Central Skagit Library 100 Main Street Skagit, WA Start time: 10:00 AM End time: 2:00 PM

December

22

Saturday, December 22, 2018
PUBLIC LIBRARY MEDICATION TAKE-BACK EVENT
Upper Skagit Library
123 Washington Street

Skagit, WA Start time: 10:00 AM End time: 2:00 PM



CHECK THE PACKAGE



CONVENIENT LOCATIONS



MAIL BACK



TAKE-BACK **EVENTS**









Contact

MEDinfo

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 and sharps 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:

English Español Tagalog 中文 Русский 한국어

Mall-Back Services Post-Card:

English Español Tagalog 中文 Русский 한국어

Frequently Asked Questions:

English Español Tagalog 中文 Русский 한국어

Video Public Service Announcement (PSA):

PLAY

Audio Public Service Announcement (PSA):

PLAY

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











- What is MED-Project?
- 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?
- 6) Where can I find information about the safe storage of medication?
- Where can I find more infomation about the Skagit County Household Hazardous Waste Program?
- 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?
- How do I dispose of my unwanted medicine?
- I am disabled and homebound and am unable to go to a kiosk or attend a take-back event. | I am disabled and homebound and an unique to go to | | 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?
- 6 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?
- 🙆 이 페이지를 한국어로보기
- Ver esta página en español
- Tingnan ang page na ito sa Tagalog
- 查看本页面(中文)
- Xem trang này bằng tiếng việt











If you are experiencing a medical emergency, please dial 911. If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 1 (800)-222-1222. If you have questions about your medication, please dial your health care provider.

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

Residents

If you are a resident of Skagit County and have questions about MED-Project, please contact: 1-(844)-MED-PROJECT or 1-(844) 633-7765

Pharmacies and Law Enforcement Offices

If you are a current kiosk drop-box host site, or a retail pharmacy, hospital/clinic pharmacy or law enforcement agency interested in hosting a drop-box,contact: Dr. Victoria Travis, PharmD, MS, MBA

National Program Director MED-Project LLC Phone: 1 (844) 677-6532

Fax: 1 (510) 686-8837 Email: skagitcounty@med-project.org

Drug Producers

If you are a drug producer interested in participating in a MED-Project stewardship plan, contact:

Phone: 1 (202) 495-3131

Email: compliance@med-project.org

Appendix L

Sample Media List

The following is a representative list of sample key media outlet options available to help educate Residents about proper disposal of Unwanted Medicine. The list includes local print, online, television, and radio outlets as well as outlets specifically targeting the diverse demographic communities within the County.

Print Outlets	City/Coverage Area	Website
Skagit Valley Herald	Skagit County	https://www.goskagit.com
The Seattle Times, Skagit Herald Insert	Skagit County	https://www.seattletimes.com/au thor/skagit-valley-herald/

Television Outlets	Network
KCPQ/Q13 (FOX)	Broadcast Skagit County
KING TV (NBC)	Broadcast Seattle Skagit County
KIRO-TV (CBS)	Broadcast Seattle Skagit County
KCTS-TV (PBS)	Broadcast Seattle – Skagit County

Radio Outlets	City/Coverage Area
KIRO Radio News 710 AM	CBS Regional
KOMO Radio 1000 AM	ABC Regional
KMWS 89.7 FM	Mount Vernon, WA
KTFJ 104.7 FM	Burlington, WA
KAPS-AM	Mount Vernon, WA
KBRC 1430 AM	Mount Vernon, WA
KPLK 88.9 FM	Sedro-Woolley, WA
KZGI 105.7 FM	Sedro-Woolley, WA
KZNW 103.3 FM	Oak Harbor, WA

Appendix M

Sample Contact List for Outreach and Education to the Community

The following are associations, agencies, and organizations that may be contacted for assistance with outreach to the community.

Health Systems & Clinics:

Island Hospital

Skagit Valley Hospital

Peacehealth United General Medical Center

Arthritis Foundation

Skagit Regional Clinics Women's Health

Skagit Pediatrics

HealthMed Centers

Skagit Family Health Clinic

Skagit Valley Kidney Center

Sea Mar Concrete Medical Clinic

La Conner Medical Center

Districts, Associations, Organizations, and Agencies:

Access to Baby and Child Dentistry

Alzheimer Society of Washington Support Center

Arthritis Foundation

Skagit County Public Health Department

Skagit County Public Environmental Health

National Council on Aging

Northwest Regional Council

Skagit County Department of Parks and

Recreation

Anacortes Department of Public Safety

Americans with Disabilities Committee -

Burlington

Public Safety Committee - Burlington

Wastewater Treatment Division – Sedro Woolley

Veterinary Services

Chuckanut Valley Veterinary

La Conner Veterinary Hospital

Skagit Animal Clinic

Mountain View Veterinary Clinic

North Cascade Veterinary Hospital

College Way Animal Hospital

Highland Veterinary Hospital

Mt. Vernon Veterinary Hospital

Parker Way Veterinary Clinic

Sedro Woolley Veterinary Care

Animal Care Center

Pet Emergency Center

Banfield Pet Hospital

Good Neighbor Vet

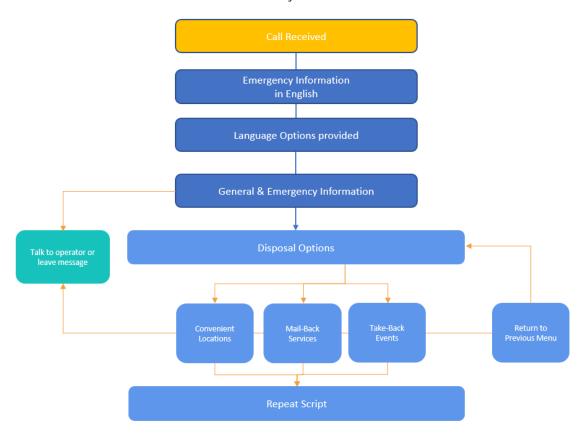
Puget Sound Veterinary Group

Appendix N

Sample Template: Education and Outreach Call Script [1-844-MED-PROJ]

MED-Project Medication Education & Disposal

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



Call Script:

- 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.
- Kiosks are located throughout the County and provide convenient options for returning expired or unwanted medicine. Press 3 for more information about convenient kiosks.
- Mail-back services are available to Residents. Press 4 for more information.
- Take-back events may be scheduled throughout the year and offer Residents a free and convenient way to dispose of expired or unwanted medicine. <u>Press 5</u> for more information.
- You may <u>press 0</u> 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 MEDproject.org or press 0 to talk to an operator.
- To hear this menu again, please press 1.
- Thank you for calling MED-Project.

Script for when 3 is selected:

- Kiosks to collect expired and unwanted medicine are located throughout your local area. To locate
 the kiosk site nearest you, or for precise information about kiosk site contact information, <u>press 0</u>
 to speak with an operator or visit <u>MEDProject.org</u> to search by your zip code. Mail-Back
 Distribution Locations may also be available in your area.
- Kiosks accept medications in any dosage form in their original container or sealed bag. For iodine-containing medications, inhalers or Pre-filled Injector Products, please <u>press 4</u> or talk to an operator. No herbal remedies, vitamins, supplements, cosmetics or other personal care products, compressed cylinders, medical devices, pet pesticide products, sharps, mercury containing thermometers, or illicit drugs 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 3.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

Mail-Back Services Script for when 4 is selected:

- Mail-Back Services are available to for Unwanted Medicine, iodine-containing medication, Pre-filled Injector Products, and inhalers.
- Mail-Back Distribution Locations may also be available near you.
- Mail-back packages for Unwanted Medicine 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, inhalers, medical devices, pet pesticide products,
 sharps, mercury containing thermometers, or illicit drugs will be accepted.
- To request a mail-back package, please press 0 to talk to the operator or visit MEDProject.org.
- 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.

Take-Back Event Script for when 5 is selected:

- MED-Project may be working with local law enforcement and other community organizations to
 offer regular expired and 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 MEDProject.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, medical devices, pet pesticide products, sharps, mercury containing thermometers, or illicit drugs 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 5.
- To return to the main menu, please <u>press 1</u>.
- Thank you for calling MED-Project.

Appendix O

Sample Digital and Local Social Networks

The following is a representative list of local organizations and their social media networks in the County.

Outlet	Facebook	Twitter
Anacortes Police	https://www.facebook.com/anacortespage/	@AnacortesPd
Skagit County Sheriff	https://www.facebook.com/SkagitCountySheriffsOffice/	@SkagitGov
City of Burlington	https://www.facebook.com/pg/visitburlingtonwa/about/?ref=page_internal	
Burlington PD	https://www.facebook.com/burlingtonwa.gov/	
City Mount Vernon	https://www.facebook.com/Tourismmvwa/	@TourismMV WA
Mount Vernon PD	https://www.facebook.com/Mount-Vernon-Police-Department-WA-6343331906/	
City of Sedro- Woolley	https://www.facebook.com/City-of-Sedro-Woolley-Washington-400779916663974/	
Sedro-Woolley PD	https://www.facebook.com/Sedro-Woolley-Police-Department- 448594781980107/	
La Conner CoC	https://www.facebook.com/LaConnerChamberofCommerce/	@LaConnerCh amber
Town of Lynman	https://www.facebook.com/Town-of-Lyman-WA- 258625284169327/	
Town of Big Lake	https://www.facebook.com/biglakewashington/	
Clear Lake Fire Dept	https://www.facebook.com/clearlakefireWA/	
Lake Cavanaugh Community	https://www.facebook.com/groups/282192631838163/	
Lake McMurray Fire Dept	https://www.facebook.com/Lake-Mcmurray-Fire-Department- SCFD-15-322854308499/	
Marblemount community Hall	https://www.facebook.com/Marblemount-Community-Hall- 216718881802153/	