



A Product Stewardship Plan For Unwanted Medicine from Households

Santa Barbara County, California
March 1, 2018

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I. Introduction

MED-Project LLC (“MED-Project”), on behalf of the participating companies as described in Appendix A, submits this Product Stewardship Plan (“Plan”) for Unwanted Medicine in compliance with Santa Barbara County Code Chapter 18C, Article II, Section 18C-12 through 18C-30, the Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs 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 Santa Barbara County households.

II. Contact Information

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

III. Plan Definitions

Board of Pharmacy is the California State Board of Pharmacy.

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-PROJ or 1-844-633-7765.

Carrier is United Parcel Service, Inc. (“UPS”), the common carrier used by Vendor to transport Unwanted Medicine from Kiosk Drop-Off Sites.

County means the county of Santa Barbara, California.

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.

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 PureWay Compliance Inc. (“PureWay”).

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 PureWay.

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

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

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

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

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

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

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

Plan or **Product Stewardship Plan** is the 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 Plan.

Required Languages are English and Spanish and other languages as determined by the Department.

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

Service Convenience Goals are the goals established in Ordinance § 18C-16(B)(1).

Service Technicians are personnel trained to service Program kiosks.

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 Stericycle Specialty Waste Solutions, Inc. (“Stericycle”).

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 § 18C-13(F) that qualify as “Unwanted Covered Drug[s]” under Ordinance § 18C-13(Y). Per the Ordinance, Covered Drug means “a drug sold or distributed in any form and used by County Residents, including prescription, nonprescription, brand name, generic drugs, and controlled substances.” § 18C-13(F). 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 and homeopathic remedies or products;
- vi. Compressed cylinders and 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;
- 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. Iodine-containing medications;
- xii. 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 take-back program;
- xiii. Medical devices or component parts or accessories;
- xiv. Used, empty containers, vials, and pouches;
- xv. Schedule I or other illicit drugs; and
- xvi. Any other items excluded pursuant to the Ordinance.

See Section XIVA for collection limitations imposed by the DEA Rule.

2 Unwanted Medicine collected at Kiosk Drop-Off Sites does not include inhalers and Pre-Filled Injector Products.

V. Collection of Unwanted Medicine

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

A. Unwanted Medicine Collection Program Implementation

1. Outreach

Per Ordinance § 18C-14(E)(2), MED-Project initially notified 72 sites with a licensed pharmacy and 14 LEA locations in the County of the opportunity to participate as a Kiosk Drop-Off Site. MED-Project continues to periodically perform outreach to these locations via calls, emails, and/or site visits, with the goal of establishing five (5) Kiosk Drop-Off Sites per Supervisorial District. As part of this outreach, MED-Project asks if the sites are interested in participating in the Program, whether the sites currently host a kiosk or provide other services for the disposal of Unwanted Medicine, whether pharmacies are DEA registrants, and if the sites would like more information regarding the Program.

Sites that hosted kiosks in the County prior to the Program may transition to the Program upon entering into an agreement with MED-Project.

2. Implementation

MED-Project continues to work to satisfy the Service Convenience Goals through executed agreements with Kiosk Drop-Off Site Hosts. MED-Project will satisfy the Service Convenience Goals in any Supervisorial District in which signed agreements have not been obtained for the minimum number of Kiosk Drop-Off Sites through Mail-Back Distribution Locations. See Section V for details on how the Program will satisfy the Service Convenience Goals.

Collection of Unwanted Medicine begins at Kiosk Drop-Off Sites once agreements have been executed with each location, kiosks have been installed, sites have been trained, and, in the case of pharmacies, all requirements of the DEA and Board of Pharmacy have been met.

3. Convenience

Per Ordinance § 18C-16(B)(1), MED-Project will strive to establish five (5) Kiosk Drop-Off Sites in each Supervisorial District. If the minimum number of Kiosk Drop-Off Sites cannot be established, Mail-Back Distribution Locations shall be established to supplement the disposal of Unwanted Medicine by Residents in those areas.

Mail-Back Services for Unwanted Medicine will be available through the MED-Project Website and Call Center to Residents and home healthcare professionals providing services to Residents.

4. Services

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites and Mail-Back Distribution Locations in underserved areas. Over the course of implementation, additional Kiosk Drop-Off Sites will be established to the extent that (1) additional eligible LEAs and/or DEA-registered collector pharmacies agree to participate, and (2) contracts can be executed with such entities. For every engagement with LEAs and pharmacies, contracts outlining the responsibilities of all involved parties will be drafted, reviewed by appropriate entities, and signed by all parties before MED-Project installs kiosks.

Mail-Back Distribution Locations shall supplement Kiosk Drop-Off Sites if the Service Convenience Goals are not met through executed agreements with Kiosk Drop-Off Site Hosts.

Although Kiosk Drop-Off Sites will not provide kiosk collection for Pre-filled Injector Products and inhalers, Mail-Back Services for Pre-filled Injector Products and inhalers will be available through the Call Center and MED-Project Website for all Residents. Under a current DEA General Public Fact Sheet dated October 21, 2016 (the “General Public Fact Sheet”), DEA suggests that Residents should not dispose of asthma inhalers in collection receptacles or mail-back packages containing controlled substances. If the General Public Fact Sheet is modified to allow for commingling of inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.

B. Kiosk Drop-Off Sites

Kiosk Drop-Off Sites will be strategically placed across the County in order to best meet the Service Convenience Goals. This network will provide Residents a number of different outlets to participate in the Program. All Kiosk Drop-Off Site Hosts shall provide Residents with access to Program kiosks during all regular business hours.

1. Kiosk Drop-Off Site Locations

MED-Project initially contacted 72 sites with a licensed pharmacy and 14 LEAs located in the County about the opportunity to serve as a Kiosk Drop-Off Site. Of the locations contacted, 22 pharmacies and 8 LEAs expressed interest in participating in the Program. Kiosk Drop-Off Sites and Mail-Back Distribution Locations that are interested in or currently participating in the Program are identified in [Appendix B](#).

MED-Project will continue outreach to potential Kiosk Drop-Off Sites that are not participating in the Program according to Ordinance Section 18C-14(E)(2), such as sites are listed in [Appendix C](#).

MED-Project will establish Mail-Back Distribution Locations in any Supervisorial District where there are fewer than the required number of Kiosk Drop-Off Sites. See Section V.D for more information on Mail-Back Services.

As required under Ordinance § 18C-16(B)(3), the Plan will include as a Kiosk Drop-Off Site any eligible Retail Pharmacy or LEA willing to serve voluntarily as a Kiosk Drop-Off Site for Unwanted Medicine and able to meet all applicable laws, regulations, and other legal requirements, within three months of their offer to participate (unless the collector requests a longer time-frame). Locations serving as a drop-off site prior to the Program may participate in the Program by signing an agreement with MED-Project and modifying their DEA registration if required. The process for modifying DEA registrations is outlined in Section XIV.A.1. MED-Project will work with the Kiosk Drop-Off Site Host to transition to the Program and Vendor.

2. Drop-Off Site Kiosk Placement and Maintenance Program

Kiosk installation shall take place within 90 days of a signed agreement and shall be the responsibility of MED-Project at LEA and pharmacy Kiosk Drop-Off Sites when 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 § 1317.75(d)(2). At a hospital or clinic with an on-site pharmacy, kiosks will be placed in an area regularly monitored by employees but not near areas of the facility where emergency or urgent care is provided. § 1317.75(d)(2)(i). Kiosk placement will also comply with any applicable Board of Pharmacy requirements. Costs associated with installation and maintenance will be paid by MED-Project per the agreements with the Kiosk Drop-Off Site Hosts.

The maintenance program will address items such as:

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

3. Kiosk Specifications

A kiosk will be offered to all eligible host locations and, in accordance with Ordinance § 18C-16(D).

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 ([Appendix D](#)) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the tamper-proof drop-slot; and commercial hinges. The design will increase the likelihood of consumer participation by providing easy access to wheelchair users. The locking mechanism on the drop-slot will prevent kiosk 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 personal information from any Unwanted Medicine and packaging before depositing them, and language required under the DEA Rule³ and by the Board of Pharmacy. Kiosk signage will provide information about what is and is not accepted in the kiosk.

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

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

³ Specifically, as required under § 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."

MED-Project kiosks and inner liners will also comply with Board of Pharmacy requirements.

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

4. Kiosk Collection

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

Section 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, § 1317.60 limits inner liner access to employees of the collector and requires two employees to immediately seal the inner liner upon its removal from the pharmacy kiosk's permanent outer container. See § 1317.60(b), (c). Section 1317.75(g) provides that pharmacy kiosk inner liner installation or removal shall be performed "by or under the supervision of at least two employees of the authorized collector." The pharmacy kiosk sealed inner liner must not be opened, x-rayed, analyzed, or otherwise penetrated. See § 1317.60(c).

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

MED-Project's Kiosk Drop-Off Site collection system complies with these DEA requirements for pharmacy and LEA Kiosk Drop-Off Sites. Vendor, pharmacies, and LEAs participating in the Program will keep all records required under the DEA Rule, including those required under §§ 1304 and 1317.35. Pharmacies participating in the Program will also keep all records required under Board of Pharmacy requirements.

Pharmacy kiosks will be located where an employee is present affording employees the opportunity to visually inspect Unwanted Medicine Residents attempt to deposit. See Section V.B.2. LEA kiosks will be located inside the LEA's physical location. See Section V.B.2. MED-Project's Kiosk Drop-Off Site collection system will also comply with all applicable Board of Pharmacy requirements.

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

Unwanted Medicine will be securely removed from the kiosk by Service Technicians and Kiosk Drop-Off Site employees following procedures meeting all DEA requirements. Specifically, two Kiosk Drop-Off Site employees will hold the two keys to unlock the kiosk. Once the kiosk is unlocked, the inner liner will be removed from the kiosk and immediately sealed. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Under the supervision of two Kiosk Drop-Off Site employees, the Service Technician will package the sealed inner liner for shipping. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The Service Technician will schedule a pick-up by the Carrier to be completed within a few business days and leave the packaged, sealed inner liner with the Kiosk Drop-Off Site Host for storage, in compliance with all applicable laws, regulations, and other legal requirements, until Carrier pick-up.

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

5. Frequency of Pick-Up

Initially, all Kiosk Drop-Off Site Hosts will be scheduled for a monthly pick-up from the kiosk. MED-Project will communicate with the Kiosk Drop-Off Site Host in the event the frequency of pick-up needs to be changed based on the volumes collected over time. Vendor will monitor volumes collected per service to ensure that all sites are receiving the appropriate service frequency. Vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Kiosk Drop-Off Site Host. Moreover, Vendor will monitor the weight of Unwanted Medicine collected at each participating Kiosk Drop-Off Site.

6. Procedures if a Kiosk is Full Prior to Scheduled Pick-Up

The Kiosk Drop-Off Site Host shall be instructed to lock the drop-slot to the kiosk and notify MED-Project of the need for service if prior to the scheduled service date.

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

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

7. Unplanned Event Preparedness

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

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

Along with major event preparedness, Vendor provides timely responses to events that may cause an inconvenience to the Kiosk Drop-Off Site. An example of this kind of event would be if the kiosk is giving off an odor prior to the scheduled service date. The Kiosk Drop-Off Site Host will contact MED-Project via the dedicated phone number and/or email address. Vendor is able to respond within two to three hours, in most cases, when notified of a need for an urgent response. If the request is an emergency that poses an immediate threat to the environment or health, the Kiosk Drop-Off Site Host is advised to call 911. If the request is not urgent or an emergency, Vendor will typically respond to a service location within two to three business days of the event.

In addition, personal items that a Resident deposits into a kiosk (i.e. dentistry, watch, keys, wallet, etc.) will not be retrieved.

C. Disposal of Unwanted Medicine

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

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

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.

D. Mail-Back Services for Unwanted Medicine

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

- Standard Mail-Back Services for all Residents as described in Section V.D.1;
- Injector Mail-Back Services for the collection of Pre-filled Injector Products for all Residents as described in Section V.D.2; and
- Inhaler Mail-Back Services for the collection of inhalers for all Residents as described in Section V.D.3.

If the General Public Fact Sheet is modified to allow for commingling of inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.

1. Standard Mail-Back Services

MED-Project will provide Standard Mail-Back Services at no cost to all Residents via the Call Center and/or MED-Project Website. Standard Mail-Back Packages will also be available at Mail-Back Distribution Locations for all Residents until the Service Convenience Goals are met via Kiosk Drop-Off Sites. The pre-paid shipping label will direct the Standard Mail-Back Package to the facility identified in Section X. 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 and Pre-filled Injector Products 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, a list of accepted substances, , 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 Packages to dispose of Unwanted Medicine. See § 1317.70(d). As required under § 1317.70(e), Vendor will only accept Standard Mail-Back Packages it made available (or packages lawfully forwarded under DEA requirements). Within three business days of receipt, Vendor will notify the DEA if it receives Standard Mail-Back Packages likely containing controlled substances that Vendor did not make available or did not agree to receive pursuant to DEA requirements. In accordance with § 1317.70(f), when Standard Mail-Back Packages are received, only employees of Vendor will handle the Standard Mail-Back Packages. Standard Mail-Back Packages will not be opened, x-rayed, analyzed, or otherwise penetrated upon receipt by Vendor. See § 1317.70(f). Vendor and MED-Project will keep all records required under the DEA Rule, including those identified in § 1304.22(f).

See [Appendix E](#) for a sample package and package specifications.

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

For Pre-filled Injector Products, MED-Project will offer all Residents Injector Mail-Back Services and Injector Mail-Back Packages, via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Injector Mail-Back Package to the facility identified in Section X. An instruction sheet describing how to properly dispose of Pre-filled Injector Products that explains what materials may be placed in a 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 E](#) for a sample package and package specifications.

3. Inhaler Mail-Back Services for Inhalers

For inhalers, MED-Project will offer all Residents Inhaler Mail-Back Services and Inhaler Mail-Back Packages, via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Inhaler Mail-Back Packages to the facility identified in Section X. 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. If the General Public Fact Sheet is modified to allow for commingling inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.

See [Appendix G](#) for a sample package and package specifications.

4. Mail-Back Package Availability

Residents and home healthcare professionals providing services to Residents may request Standard Mail-Back Packages 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 DEA requirements.

In Supervisorial Districts where fewer than five agreements have been obtained from Kiosk Drop-Off Site Hosts, MED-Project will supplement Kiosk Drop-Off Sites by establishing Mail-Back Distribution Locations for the dissemination of Standard Mail-Back Packages. MED-Project will work with sites, such as fire stations and/or libraries, to ensure that Mail-Back Package Distribution Locations are centrally located.

As noted above, if the General Public Fact Sheet is modified to allow for commingling of inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.

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 in the Required Languages.

5. Mail-Back Package Collection and Disposal

Residents will be directed to follow the instructions provided via Mail-Back Services. The USPS estimates up to three business days for delivery of First Class Mail. Mail-Back Services shall direct packages to an approved facility in accordance with their contents and packages will be handled in compliance with all applicable laws.

For Standard Mail-Back Packages, upon arriving at the destruction facility, they shall be scanned for receipt verification and then rendered non-retrievable.⁴ After this destruction, any remaining Standard Mail-Back Package materials shall be incinerated at the disposal facility listed in Section X. Any storage of Standard Mail-Back Packages received by Vendor will comply with the applicable security requirements of DEA Rule Section 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances. All Unwanted Medicine will be destroyed promptly.

This Plan proposes to treat 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 facilities identified in Section X. MED-Project's request for approval to autoclave Injector Mail-Back Packages is included in [Appendix H](#).

Inhaler Mail-Back Packages containing inhalers will be tracked using a unique identifier to a disposal facility for incineration. The incinerator facility for the disposal of inhalers is included in Section X. MED-Project's request for approval to incinerate Inhaler Mail-Back Packages containing inhalers at a municipal solid waste combustor is included in [Appendix I](#).

4 The Director approved MED-Project's Standard Mail-Back Package disposal process on August 24, 2017.

VI. Plan and Collection Goals

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

MED-Project anticipates that once 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 25 Kiosk Drop-Off Sites are operational for a full year, MED-Project anticipates collecting approximately 9,000 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2019. See Section V.B for more information about Kiosk Drop-Off Site collection.

Until the Service Convenience Goals are met, MED-Project anticipates supplementing Kiosk Drop-Off Sites with Mail-Back Distribution Locations. Standard Mail-Back Packages have a capacity of 8 oz. per package. Due to the lack of information available from current MED-Project Programs, MED-Project’s estimated collection totals in 2018 could vary based on actual usage. Collection in 2018 will be used to adjust subsequent years’ collection goal.

Goal Area	Short-Term	Long-Term
Collection	<p>Within 90 days of Plan approval, implement Mail-Back Services for inhalers and Pre-filled Injector Products via the MED-Project Website and Call Center.</p> <p>Continue to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations.</p>	<p>Increase retail chain pharmacy participation to satisfy the Service Convenience Goals via established Kiosk Drop-Off Sites in a minimum of four (4) of the five (5) Supervisorial Districts. Reduce or eliminate the number of Mail-Back Distribution Locations.</p> <p>If the General Public Fact Sheet is modified to allow for commingling of inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.</p>
Education & Public Outreach	<p>Develop baseline number of MED-Project Website page views or unique visitors.</p> <p>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.</p> <p>Establish a baseline number of media outlets receiving press advisory, with a minimum of five outlets.</p> <p>Establish a baseline number of messages returned by MED-Project within predetermined timeframe.</p>	<p>On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan.</p> <p>MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the Program, assess to what extent Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Results of the review will be published on the MED-Project Website established under Ordinance requirements.</p>
Collector Outreach	<p>Outreach to all potential eligible Kiosk Drop-Off Site Hosts according to requirements as outlined in Ordinance.</p>	<p>Ongoing communication with pharmacies. Evaluation of Kiosk Drop-Off Sites against the Service Convenience Goals.</p>

VII. Patient Privacy

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

In addition to kiosk signage, all MED-Project instructional, promotional, and educational materials encourage Residents to protect their information by ensuring that personally identifiable information is not present when utilizing Mail-Back Services or depositing containers into kiosks.

Vendor has additional protections available for keeping personally identifiable information safe and secure. Service Technicians are trained in managing items containing sensitive patient information. Privacy training is part of a Service Technician's prerequisite for field services. As added protection, containers, packages, and envelopes used for Mail-Back Services will be opaque rather than clear. In addition, inner liners used at Kiosk Drop-Off Sites 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

Questions from Residents will be managed by a Call Center with an interactive voice response ("IVR") system and the support of an operator available during business hours. If the operator is unavailable, a Resident will be able to leave a message to which the operator will respond within one business day. All operators are trained to respond based on the requirements set by MED-Project. IVR support will be made available in the Required Languages.

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

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

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

IX. Training

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

The support hotline will support two general communication functions:

1. Answer questions and monitor comments from participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations; and
2. Support and direct service requests from participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations.

Messages received from Kiosk Drop-Off Sites and Mail-Back Distribution Locations will be returned within one business day.

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

- Onboarding & on-truck observation of job functions;
- United States Department of Transportation ("DOT") Training;
- DEA Training;
- United States Environmental Protection Agency ("EPA") Waste Characterization;
- Occupational Safety and Health Administration ("OSHA") Training;
- Waste Handling Demo;
- Truck Operation;
- DEA Handling Demo;
- Health Insurance Portability and Accountability Act ("HIPAA") requirements;
- OSHA Bloodborne Pathogens Standard;
- Review & Written Test; and
- Perform work under supervision to demonstrate proficiency prior to certification to service client accounts.

A. Service Technician Training

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

- DOT hazardous materials requirements;
- EPA waste characterization requirements;
- Resource Conservation and Recovery Act ("RCRA") hazardous waste requirements;
- DEA controlled substances transfer protocols;
- OSHA requirements; and
- HIPAA requirements.

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

X. Vendor, Transporter, and Disposal Facility Information

Kiosk Collection Services

A. Vendor for Kiosk Drop-Off Sites

- Name: **Stericycle Specialty Waste Solutions, Inc.** will service Kiosk Drop-Off Sites. Stericycle Specialty Waste Solutions, Inc. may also be used to transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Veolia-Port Arthur.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleeenvironmental.com

B. Carrier for Kiosk Drop-Off Sites

- Name: **United Parcel Service, Inc.** will transport Unwanted Medicine from Kiosk Drop-Off Sites to the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA, 30328
- Phone: (800) PICK-UPS
- Website: www.UPS.com/

C. Reverse Distributor Facility & Transporter for Kiosk Drop-Off Sites

1. Reverse Distributor Facility

- Name: **Stericycle, Inc., Indianapolis, Indiana Facility** will receive Unwanted Medicine from Carrier.
- Address: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: (317) 275-7530
- Website: www.stericycleeenvironmental.com
- Type: DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA) Treatment, Storage, and/or Disposal Facility

2. Transporter

- Name: **Heritage Transport** will transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Heritage Thermal Services – Ohio.
- Address: 1626 Research Way, Indianapolis, IN 46231
- Phone: (317) 486-2973
- Website: <http://www.heritage-enviro.com/>

D. Disposal Facility for Kiosk Drop-Off Sites

1. Disposal Facility

- Name: **Heritage Thermal Services – Ohio** will incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility by Heritage Transport.
- Address: 1250 Saint George Street, East Liverpool, Ohio, 43920
- Phone: (800) 545-7655
- Website: <http://www.heritage-thermal.com/>
- Type: Permitted Hazardous Waste Incinerator

2. Secondary Disposal Facility

- Name: **Veolia – Port Arthur** will incinerate Unwanted Medicine that cannot be processed by Heritage Thermal Services- Ohio.
- Addresses: 7665 Texas Highway 73, Beaumont, TX 77705.
- Phone: (409) 736-2821
- Website: www.veolianorthamerica.com
- Type: Permitted Hazardous Waste Incinerator

Standard Mail-Back Services

E. Vendor for Standard Mail-Back Packages

- Name: **Stericycle Specialty Waste Solutions, Inc.** will provide Standard Mail-Back Packages.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com

F. Shipper of Standard Mail-Back Packages

- Name: **United States Postal Service** will ship Standard Mail-Back Packages to the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: www.USPS.com/

G. Destruction and Disposal Facilities for Standard Mail-Back Packages

1. Destruction Facility

- **Stericycle, Inc., Indianapolis, Indiana Facility** will render Standard Mail-Back Packages, and the controlled substances therein, non-retrievable.
- Address: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: (317) 275-7530
- Website: www.stericycleenvironmental.com
- Type: DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA) Treatment, Storage, and/or Disposal Facility

2. Disposal Facility

- Name: **Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility** will incinerate non-retrievable materials from the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 2320 S. Harding St., Indianapolis, IN 46221.
- Phone Number: (317) 634-7367
- Website: <http://www.covanta.com/facilities/facility-by-location/indianapolis.aspx>
- Type: Municipal Waste Combustor

Injector Mail-Back Services

H. Vendor for Injector Mail-Back Packages

- Name: **PureWay Compliance Inc.** will provide Injector Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy TX 77450
- Phone: (877) 765-3030
- Website: <http://pureway.com/>

I. Shipper of Injector Mail-Back Packages

- Name: **United States Postal Service** will transport Injector Mail Back Packages to Medsharps.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: www.USPS.com/

J. Treatment and Disposal Facilities for Injector Mail-Back Packages

1. Autoclave Facility

- Name: **Medsharps** will receive Injector Mail-Back Packages from United States Postal Service and render them non-infectious.
- Addresses: 17340 Bell N Dr., Schertz, TX 78154
- Phone: (844) 800.6981
- Website: www.medsharps.com
- Type: Medical Waste Processing Facility

2. Disposal Facility

- Name: **Tessman Road Landfill** will receive non-infectious waste from Medsharps and dispose of this waste.
- Address: 7000 E IH 10, San Antonio TX 78219
- Phone Number: (210) 661-7558
- Website: <https://www.republicservices.com/customer-support/facilities>
- Type: Municipal Solid Waste Landfill

Inhaler Mail-Back Services

K. Vendor for Inhaler Mail-Back Packages

- Name: **PureWay Compliance Inc.** will provide Inhaler Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy TX 77450
- Phone: (877) 765-3030
- Website: <http://pureway.com/>

L. Shipper of Inhaler Mail-Back Packages

- Name: **United States Postal Service** will transport Inhaler Mail-Back Packages to Daniels Sharpsmart Inc.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: www.USPS.com/

M. Transfer Facility for Inhaler Mail-Back Packages

- Name: **Daniels Sharpsmart Inc.** will be utilized to receive Inhaler Mail-Back Packages and provide for transport to Covanta Huntsville, Inc.
- Address: 4144 East Therese Avenue, Fresno, CA 93725
- Phone Number: (559) 834-6252
- Website: <http://danielsinternational.com/>
- Type: Medical Waste Treatment Facility

N. Disposal Facility for Inhaler Mail-Back Packages

1. Disposal Facility

- Name: **Covanta Huntsville, Inc.** will incinerate Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.
- Address: 5251 Triana Blvd SW, Huntsville, AL 35805
- Phone Number: (256) 882-1019
- Website: <https://www.covanta.com/Our-Facilities/Covanta-Huntsville>
- Type: Municipal Waste Combustor

2. Disposal Facility

- Name: **Covanta Marion, Inc.** will incinerate Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.
- Address: 4850 Brook Lake Rd. NE, Brooks, OR 97305
- Phone Number: (503) 393-0890
- Website: <http://www.covanta.com/facilities/facility-by-location/marion.aspx>
- Type: Municipal Waste Combustor

XI. Unwanted Medicine Educational and Outreach Programming

A. Overview

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

B. Audiences

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

- General public;
- Pharmacies and Retailers of Covered Drugs;
- Healthcare providers and their patients;
- Veterinary providers and animal owners;
- Public health facilities; and/or
- Law enforcement agencies.

This Program will include efforts to reach the varied cultural, linguistic, geographic, and age demographics through outreach to local media; (outreach to community organizations serving a broad range of

audiences; availability of phone lines (Section XI.D.1); and availability of educational information through a broad range of media platforms.

Demographic information, including race, ethnicity, language, age, and geographic data, will be analyzed to appropriately direct outreach and create educational materials to best serve the unique needs of all identified demographics.

C. Messages

MED-Project anticipates that messaging will:

- Educate Residents about the appropriate use, storage, and disposal of Unwanted Medicine;
- Educate Residents about Mail-Back Services available; and
- Provide Residents with information about available Kiosk Drop-Off Sites and Mail-Back Distribution Locations in their area that offer disposal of Unwanted Medicine.

Key points of emphasis might include:

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

D. Tools/Communications Channels

The Program will include several components designed to reach Residents and provide consistent access to timely and relevant information. Materials will be distributed to LEAs, pharmacies, health care providers and systems, health associations, local government agencies, and other community organizations and will be reviewed for effectiveness. Tools and communication channels will include:

1. Phone

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

- IVR support in the Required Languages. The Call Center will also provide an option for callers to be transferred to an operator.
- Basic information about how the Program works, where to obtain more information (e.g., the MED-Project Website), and an option to talk with an operator to find a Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations, if applicable, in the Resident's zip code or local area.
- A recorded call script directing Residents with medical emergencies to call 911. Residents with medication-related questions will be directed to contact their health care provider(s).

Please see [Appendix J](#) for a sample call script.

2. MED-Project Website

MED-Project is developing a mobile-friendly MED-Project Website with translations in the Required Languages. MED-Project expects information available to users will include pages to help Residents find locations of Kiosk Drop-Off Sites and Mail-Back Distribution Locations, educational materials, frequently asked questions and responses, and results of the most recent survey of Program awareness.

- The Plan includes a sample web pages for the MED-Project Website. [Appendix K](#) provides a proof of concept example for a possible MED-Project Website with subpages.
- The MED-Project Website will also include access to a public relations toolkit in a downloadable format (see Section XI.D.3) and contact information for Residents. A toolkit could include items such as a flyer/brochure (See [Appendix L](#), for an example) and a frequently asked questions (FAQ) document. Translations of the brochure and FAQ will be available in the Required Languages.
- 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 how to properly dispose of Unwanted Medicine, Pre-filled Injector Products, and inhalers will be available through the MED-Project Website, through potential third-party partners, community organizations, at Kiosk Drop-Off Sites, and will be provided to pharmacies, health care facilities, veterinary facilities and other interested parties.

This Plan includes a sample of the informational and educational brochure ([Appendix L](#)) that will be provided to Kiosk Drop-Off Sites. Educational materials use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency.

4. Media Outreach

The Program will conduct public outreach through mediums such as traditional and social media, posting of educational signage, and at community events. MED-Project will encourage media outlets and third-party groups to download and use the toolkit. The following will support the Unwanted Medicine educational and outreach programming:

- See [Appendix J](#) for a sample call script with the toolkit including flyers in [Appendix L](#) and the sample MED-Project Website information included in [Appendix K](#).
- See [Appendix M](#) for a sample list of key media outlets.
- See [Appendix N](#) for a sample contact list for outreach and education to the community.
- See [Appendix O](#) for a sample list of social media outlets.

E. Collaboration with County Officials and Community Organizations

MED-Project expects that the Program 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.

The Program will perform the following activities:

- *Briefing Materials Provided to Support Coordination with County Officials:*
 - ◊ MED-Project will provide access to educational and outreach materials, including the sample brochure (see [Appendix L](#)), to relevant departments and officials.

- *Outreach through Community Organizations:*
 - ◊ The Program will engage relevant stakeholders and community organizations by providing selected community organizations identified in [Appendix N](#) with the toolkit included in [Appendix L](#).

F. Disclaimer

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

XII. Survey

MED-Project will conduct a biennial survey of Residents, pharmacists, veterinarians, and health care professionals who interact with members of the community, according to requirements in the Ordinance. Survey questions will be designed to measure, at a minimum, (1) percent awareness of the Programs, (2) whether Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and (3) knowledge and attitudes about risks of abuse, poisonings, and overdoses from prescription and nonprescription drugs used in the home. As required by Ordinance § 18C-17(A)(5), draft survey questions will be submitted to the Director for review and comment at least thirty (30) days prior to distribution. The biennial survey will be conducted in the Required Languages as determined by the Department.

Results of the survey will be reported to the Director and made public within 90 days of the end of the survey period on the MED-Project Website described under Section XI.D.2. The privacy of all survey respondents will be maintained.

XIII. Packaging

The Ordinance requires that a Plan consider “[s]eparating Unwanted Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and [r]ecycling of Unwanted Covered Drugs packaging to the extent feasible.” Ordinance §§ 18C-15(H)(2) and 18C-15(H)(3).

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, including 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 and/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 for releases and leakage of Unwanted Medicine; and
3. Separating and recycling drug packaging could increase diversion risks by adding additional steps to the collection process and, because drug packaging is often used in drug counterfeiting, could be a diversion target itself.

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

MED-Project education and outreach materials instruct Residents to return Unwanted Medicine at a Kiosk Drop-Off Site or via Mail-Back Services, in its original container or in a sealed bag. These materials encourage Residents who transfer their Unwanted Medicine in a sealed bag to recycle all remaining packaging.

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

The Ordinance requires that a Plan describe how all entities participating in the Program will “operate under” all applicable laws, regulations, and other legal requirements. Ordinance § 18C-15(D). As described in more detail below, the Plan is designed such that all entities participating in the Program shall comply with all applicable laws, regulations, and other legal requirements.

A. DEA Controlled Substances Act and Implementing Regulations

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

Under the DEA Rule, collection of controlled substances is limited to Schedule II, III, IV, or V controlled substances that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent’s property. *See* DEA Rule §§ 1317.75(b) (Kiosk Drop-Off Sites)⁵; 1317.70(b) (Standard 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 of their own inventory or stock through the Program. *See also* § 1317.05.

The DEA Rule provides that LEAs can continue to accept controlled substances for disposal. However, the DEA Rule also provides that pharmacies, reverse distributors, hospitals/clinics with on-site pharmacies,

⁵ For Kiosk Drop-Off Site collection, only certain substances “that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected.” §1317.75(b). This language is similar to, but slightly different than, provisions limiting collection through Standard Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent’s property. *See* § 1317.70(b).

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 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 for complying with their respective compliance obligations under the DEA Rule. Vendor will ensure that the collection, transportation, and disposal of Unwanted Medicines collected from Kiosk Drop-Off Sites and via Standard Mail-Back Services, including controlled substances, complies with all DEA requirements, including those in § 1317.

Controlled substances collected pursuant to the Plan may be commingled with non-controlled substances at Kiosk Drop-Off Sites and through Standard Mail-Back Services per the DEA Rule. *See* §§ 1317.75(b) (Kiosk Drop-Off Sites); 1317.70(b) (Standard Mail-Back Services).

1. DEA Registration Modification

Pursuant to 21 C.F.R. § 1301.51(b), pharmacies may modify their registrations to become authorized collectors by submitting a written 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 § 1301.13(j).

See § 1301.51(b). MED-Project will consult with participating pharmacies, as requested, regarding how to modify DEA registrations to become authorized collectors.

B. United States Department of Transportation (DOT)

When transporting Unwanted Medicine, Vendor will ensure compliance with the DOT Hazardous Materials Regulations (HMR).

C. California State Board of Pharmacy

On June 8, 2017, the Board of Pharmacy adopted the Board of Pharmacy Regulations, Article 9.1 of Division 17 of Title 16 of the California Code of Regulations. Largely based on the DEA Rule, the Board of Pharmacy Regulations establish requirements applicable to pharmacies, hospitals/clinics with on-site pharmacies, distributors, and reverse distributors conducting certain drug take-back services. Among other things, the Board of Pharmacy Regulations provide:

- That California-licensed pharmacies and hospitals/clinics with on-site pharmacies must be in good standing with, and notify, the Board of Pharmacy to host a drug kiosk. *See* 16 CCR §§ 1776, 1776.1(i).
- That pharmacies must “know and adhere” to all applicable “federal, state, and local requirements governing the collection and destruction of dangerous drugs” when operating a drug take-back program. *See* 16 CCR § 1776.1(b).
- Drug kiosk placement and monitoring requirements. *See* 16 CCR §§ 1776.3(b)-(d).
- Drug kiosk inner liner, container, and signage requirements. *See* 16 CCR §§ 1776.3(f), (h), (m).
- Inner liner handling, storage, and destruction requirements for drug kiosks. *See, e.g.,* 16 CCR §§ 1776.3(h)-(j), 1776.5(a)-(c).
- Pharmacy and reverse distributor recordkeeping requirements. *See* 16 CCR §§ 1776.5(e)-(f), 1776.6.
- Pharmacy drug mail-back program requirements. *See* 16 CCR § 1776.2.

The Plan is designed such that all entities that are part of the Plan, including Vendor, are individually responsible for complying with their respective compliance obligations under the Board of Pharmacy Regulations.

XV. Annual Report

An annual report will be provided to the Director within six months after the end of the first twelve-month period of operation and annually thereafter. Ordinance § 18C-21(A).

For the reporting period, the report will include:

- A list of producers participating in the Plan;
- The amount, by weight, of Unwanted Medicine collected from Kiosk Drop-Off Sites. For Mail-Back Services, MED-Project will identify the number of mail-back packages destroyed;
- A list of Kiosk Drop-Off Sites and Mail-Back Distribution Locations;
- The number of mailers provided;
- The transporters, treatment, and disposal facilities used;
- Whether any safety or security problems occurred during collection, transportation, treatment, or disposal of Unwanted Medicine and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to remedy the problem and improve safety and security;
- A description of public education, outreach, and evaluation activities implemented, including the results of the biennial survey, if applicable;
- A summary of the Plan’s goals, the degree of success meeting these goals in the past year, and how these goals will be achieved in the next year if they were not met;
- The Plan’s total expenditures; and
- An executive summary.

Appendix A

MED-Project Participants

The list of participating Producers in MED-Project's Program in the County is provided to the County on a routine basis to satisfy Ordinance requirements.

Appendix B

Interested Sites and Participating Kiosk Drop-Off Sites

MED-Project will provide the County with a list of participating Kiosk Drop-Off Site, as required under the Ordinance.

Site Name	Address	City	State	Zip Code
COUNTY GOVERNMENT PROBATION DEPARTMENT	117 E CARRILLO STREET	SANTA BARBARA	CA	93101
COUNTY OF SANTA BARBARA COM HLTH	345 CAMINO DEL REMEDIO	SANTA BARBARA	CA	93110
CVS PHARMACY #9737	189 S TURNPIKE RD	GOLETA	CA	93111
CVS PHARMACY #9750	1830 NORTH BROADWAY	SANTA MARIA	CA	93454
CVS PHARMACY #9860	222 W CARRILLO ST	SANTA BARBARA	CA	93101
CVS/PHARMACY # 16105	223 E BETTERAVIA RD	SANTA MARIA	CA	93454
CVS/PHARMACY #09392	1109 STATE ST	SANTA BARBARA	CA	93101
CVS/PHARMACY #09394	4852 S BRADLEY RD	SANTA MARIA	CA	93455
CVS/PHARMACY #09567	1835 CLIFF DR	SANTA BARBARA	CA	93109
CVS/PHARMACY #09821	2116 S BROADWAY	SANTA MARIA	CA	93454
CVS/PHARMACY #09824	2973 STATE ST	SANTA BARBARA	CA	93105
CVS/PHARMACY #09871	1317 NO H ST	LOMPOC	CA	93436
CVS/PHARMACY #09970	218 E HIGHWAY 246 BLDG 3	BUELLTON	CA	93427
CVS/PHARMACY #3153	733 E MAIN ST	SANTA MARIA	CA	93454
CVS/PHARMACY #9156	5875 CALLE REAL	GOLETA	CA	93117
CVS/PHARMACY #9235	1036 CASITAS PASS RD	CARPINTERIA	CA	93013
CVS/PHARMACY #9333	1282 COAST VILLAGE RD	SANTA BARBARA	CA	93108
CVS/PHARMACY #9335	3939 STATE ST	SANTA BARBARA	CA	93105
FEDERAL DRUG	3327 STATE STREET	SANTA BARBARA	CA	93105
GUADALUPE POLICE DEPARTMENT	110 E GUTIERREZ STREET	SANTA BARBARA	CA	93101
GUADALUPE POLICE DEPARTMENT	4490 10TH STREET	GUADALUPE	CA	93434
HOMETOWN MEDICAL PHARMACY	1482 S. BROADWAY SUITE A	SANTA MARIA	CA	93454
LA JOYA PHARMACY	1115 WEST MAIN ST STE E1	SANTA MARIA	CA	93458
LOMPOC POLICE DEPARTMENT	107 CIVIC CENTER PLZ	LOMPOC	CA	93436
MEDICINE SHOPPE NO 793	3605 STATE ST	SANTA BARBARA	CA	93105
PUBLIC HEALTH PHARMACY - SANTA MARIA	2115 S CENTERPOINTE PARKWAY	SANTA MARIA	CA	93455
PUBLIC HEALTH PHARMACY-LOMPOC	301 NORTH R ST	LOMPOC	CA	93436
SAN YSIDRO PHARMACY INC	1498 E VALLEY RD	SANTA BARBARA	CA	93108
SANTA BARBARA COUNTY SHERIFF	4434 CALLE REAL	SANTA BARBARA	CA	93110
SANTA BARBARA COUNTY SHERIFF	5775 CARPINTERIA AVENUE	CARPINTERIA	CA	93013
SANTA BARBARA COUNTY SHERIFF	7042 MARKET PLACE DRIVE	GOLETA	CA	93117
SANTA BARBARA COUNTY SHERIFF	3500 HARRIS GRADE	LOMPOC	CA	93436
SANTA BARBARA COUNTY SHERIFF	812 W FOSTER ROAD A	SANTA MARIA	CA	93455

Site Name	Address	City	State	Zip Code
SANTA BARBARA COUNTY SHERIFF	140 WEST HIGHWAY 264	BUELLTON	CA	93427
SANTA BARBARA COUNTY SHERIFF	6504 TRIGO ROAD	ISLA VISTA	CA	93117
SANTA BARBARA COUNTY SHERIFF	1745 MISSION DRIVE	SOLVANG	CA	93463
SANTA BARBARA COUNTY SHERIFF	70 NEWSOME STREET	CUYAMA	CA	93254
SANTA BARBARA POLICE DEPARTMENT	215 EAST FIGUEROA STREET	SANTA BARBARA	CA	93101
SANTA BARBARA POLICE DEPARTMENT	735 ANACAPA STREET	SANTA BARBARA	CA	93101
SANTA MARIA POLICE DEPARTMENT	1111 W BETTERAVIA ROAD	SANTA MARIA	CA	93455
STAR DRUG CO	3576 MADERA ST	SANTA YNEZ	CA	93460
STARS PHARMACY	830 GUADALUPE STREET	GUADALUPE	CA	93434

Appendix C

Potential Additional Kiosk Drop-Off Sites

Site Name	Address	City	State	Zip Code
COSTCO PHARMACY 24	1335 SOUTH BRADLEY	SANTA MARIA	CA	93454
COSTCO PHARMACY NO 474	7095 MARKET PLACE DRIVE	GOLETA	CA	93117
GARFIELD BEACH CVS LLC D/B/A CVS/PHARMACY #10913	336 N MILPAS ST	SANTA BARBARA	CA	93103
JDX PHARMACY	1504 S BROADWAY	SANTA MARIA	CA	93454
KMART PHARMACY #7195	6865 HOLLISTER AVENUE	GOLETA	CA	93117
MARIAN MEDICAL CENTER	1400 E CHURCH ST	SANTA MARIA	CA	93454
MISSION HOPE INFUSION CENTER	1325 E CHURCH ST	SANTA MARIA	CA	93454
PAIN MANAGEMENT PHARMACY INC	2003 S MILLER ST	SANTA MARIA	CA	93454
PRESCRIPTION PHARMACY	215 PESETAS LANE P.O. BOX 1200	SANTA BARBARA	CA	93110
PRESCRIPTION PHARMACY	317 W PUEBLO ST	SANTA BARBARA	CA	93105
RALPHS PHARMACY 70300680	100 W CARRILLO ST	SANTA BARBARA	CA	93101
RITE AID 5776	801 LINDEN AVENUE	CARPINTERIA	CA	93013
RITE AID 5788	35 S MILPAS STREET	SANTA BARBARA	CA	93103
RITE AID 5789	825 STATE STREET	SANTA BARBARA	CA	93101
RITE AID 5790	1976 CLIFF DRIVE	SANTA BARBARA	CA	93109
RITE AID 5791	199 NORTH FAIRVIEW AVENUE	GOLETA	CA	93117
RITE AID 5835	345 TOWN CENTER WEST	SANTA MARIA	CA	93458
RITE AID 5836	2405 S BROADWAY	SANTA MARIA	CA	93454
RITE AID 6185	616 ALAMO PINTADO ROAD	SOLVANG	CA	93463
SAV-ON PHARMACY # 6348	2320 S BROADWAY	SANTA MARIA	CA	93454
SAV-ON PHARMACY # 6355	1018 CASITAS PASS RD	CARPINTERIA	CA	93013
SAV-ON PHARMACY # 6394	1120 E CLARK AVE	ORCUTT	CA	93455
SAV-ON PHARMACY #3171	1500 NORTH H STREET	LOMPOC	CA	93436
VONS PHARMACY #1738	729 N H ST	LOMPOC	CA	93436
VONS PHARMACY #2101	1046 COAST VILLAGE RD SUITE B	MONTECITO	CA	93108
WAL MART PHARMACY 10 1989	701 WEST CENTRAL AVENUE	LOMPOC	CA	93436
WAL-MART PHARMACY 10-5658	2240 S BRADLEY RD	SANTA MARIA	CA	93454
WAL-MART PHARMACY 10-5659	500 S BLOSSER RD	SANTA MARIA	CA	93454
WALGREENS #06287	2399 S BROADWAY	SANTA MARIA	CA	93454
WALGREENS #06288	707 N BROADWAY	SANTA MARIA	CA	93454
WALGREENS #06289	5900 CALLE REAL	GOLETA	CA	93117
WALGREENS #06290	937 NORTH H STREET	LOMPOC	CA	93436
WALMART PHARMACY NO 10 2507	2220 SOUTH BRADLEY	SANTA MARIA	CA	93455

Appendix D⁶

Kiosk Prototype and Proposed Signage

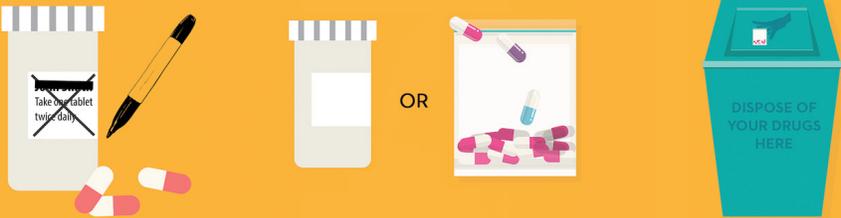


6 If the General Public Fact Sheet is modified to allow for commingling of inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles and modify signage accordingly.

Proposed Kiosk Signage

Front Panel Kiosk Art

SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES



1 Cross out or remove personal identifying information from the medicine bottle.

2 Leave the product in its original container or place solid medicines in a sealed plastic bag.

3 Put medicine in the kiosk.

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

ACCEPTED: MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER OR SEALED BAG.

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

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

PROP 65 WARNING: *Entering this area, or coming into contact with items or materials in this kiosk, may expose you to chemicals known to the State of California to cause cancer, birth defects, reproductive toxicity and/or other reproductive harm.*

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

MED-Project
Medication Education & Disposal

Proposed Kiosk Signage

Side Panel Kiosk Art



MED-ProjectTM

Medication Education & Disposal

Proposed Kiosk Signage

Drop-Slot Kiosk Art



ACCEPTED: MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER OR SEALED BAG.



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

Name: 123 Pharmacy

Contact: (555) 555-5555

Appendix E

Sample Standard Mail-Back Package



Description:

Plastic envelope with return label and instructional flyer, and unique identifier enabling tracking from collection through final disposal

Package Size:

Outer dimensions: 8.25" x 12"; inner dimensions: 7.375" x 10.375"; 2" flap with tamper-evident hot melt tape,

Return label: 4" x 4"

Instructional sheet: 5" x 7"

Paper Stock:

Package: 4mil white/ silver poly mailer with sequential identifier

Return label: 60# uncoated label stock

Instructional sheet: 80# gloss text

Color:

Package: 5/3 print (silver, white, white, + 2 PMS on clear web; silver + 2 PMS on white web)

Return label: K/O no bleeds (personalized identifier)

Instructional sheet: K/K

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

Appendix F

Sample Injector Mail-Back Package



Description:

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

Package Sizes:

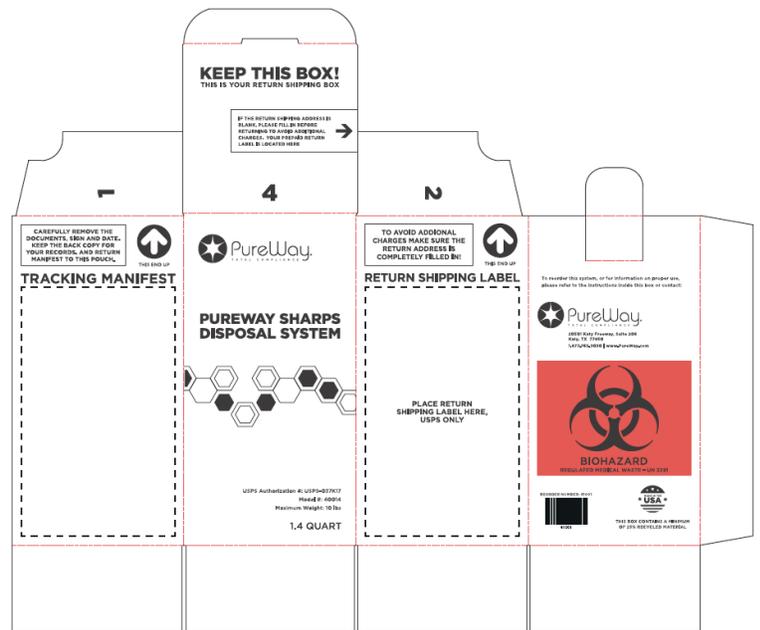
1.4 quart mail-back system

PureWay mail-back solutions are an example of complete, turnkey systems to provide for the safe return of Pre-filled Injector Products through the United States Postal Service. All PureWay solutions are tested and permitted to USPS specifications as outlined in USPS Publication 52.

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

Appendix G⁷

Sample Inhaler Mail-Back Package



Description:

Inhaler Mail-Back Package including container with mail-back package, return label, and 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 inhaler waste through the United States Postal Service. All PureWay solutions are tested and permitted to USPS specifications as outlined in USPS Publication 52.

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

7 If the General Public Fact Sheet is modified to allow for commingling inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers.

Appendix H

Request for Approval to Autoclave Pre-filled Injector Products

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE SANTA BARBARA COUNTY EXTENDED PRODUCER RESPONSIBILITY STEWARDSHIP FOR THE COLLECTION AND DISPOSAL OF UNWANTED COVERED DRUGS ORDINANCE



January 31, 2018

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE SANTA BARBARA COUNTY EXTENDED PRODUCER RESPONSIBILITY STEWARDSHIP FOR THE COLLECTION AND DISPOSAL OF UNWANTED COVERED DRUGS ORDINANCE

Pursuant to section 18C-19(C) of the Santa Barbara County Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs Ordinance (the “Ordinance”), MED-Project, LLC (“MED-Project”) respectfully requests approval from the Director of the Santa Barbara County Public Health Department (“Director”) to autoclave and landfill Pre-filled Injector Products (as defined in MED-Project Product Stewardship Plan (“Plan”) § III) that are required to be collected through MED-Project’s Unwanted Medicine Stewardship Program (“MED-Project’s Program”) in Santa Barbara County (the “County”).

I. BASIS FOR MED-PROJECT’S REQUEST

“Covered drugs,” as defined in the Ordinance, must be disposed of at a permitted hazardous waste disposal facility, or in the alternative, at a permitted large municipal waste combustor if the use of a permitted hazardous waste disposal facility is infeasible based on costs, logistics, or other considerations. Ordinance § 18C-19(A)-(B). Both of those disposal options are commonly used for unwanted medicine, but there are other well-accepted treatment options for sharps, including Pre-filled Injector Products covered by the Ordinance. The health care industry has adopted autoclaving followed by landfilling as the preferred treatment and disposal option for sharps.

MED-Project will operate its Program through a vendor that has an established system to autoclave sharps, including Pre-filled Injector Products, to render them noninfectious before final disposal. Requiring MED-Project to dispose of Pre-filled Injector Products by incineration under MED-Project’s Program would be inconsistent with well-established industry practice for sharps, disrupt MED-Project’s established treatment and disposal system for sharps, and significantly increase costs. MED-Project is therefore petitioning for approval to use autoclaves to treat Pre-filled Injector Products, pursuant to Ordinance section 18C-19(C).

Under Ordinance section 18C-19(C), the Director has discretion to approve alternative final disposal technologies. Manufacturers of covered drugs participating in a stewardship plan may petition the Director for approval to use alternative final disposal technologies that provide superior environmental and human health protection than provided by disposal at a permitted hazardous waste disposal facility or municipal waste combustor, or equivalent protection to these disposal options at lesser cost. Ordinance § 18C-19(C).

As set forth in more detail below, autoclaving has clear environmental and human health advantages, particularly as compared to incineration. Autoclaving would allow disposal of Pre-filled Injector Products in a manner that is protective of the environment and human health, and it provides equivalent or superior protection regarding the criteria listed in section 18C-19(C) of the

Ordinance. In addition, treating Pre-filled Injector Products via autoclave is less expensive than incineration at a permitted hazardous waste disposal facility or municipal waste combustor.

As discussed in more detail below, autoclaving would allow for the proper disposal of any Pre-filled Injector Products collected under MED-Project's Program in a manner that protects the environment and human health, in furtherance of the Ordinance's objectives. Accordingly, the Director should exercise its discretion and approve autoclaving as a treatment technology for Pre-filled Injector Products under the petition process for alternative final disposal technologies under Ordinance section 18C-19(C).

II. AUTOCLAVING

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

Autoclaving is the most common method for treating sharps around the world and in the United States, and represents industry best practice for treating these materials. Internationally, autoclaving is recommended by the United Nations General Assembly Human Rights Council for sharps treatment.² In the United States, it is estimated that approximately 85% of sharps waste is sterilized, mostly through autoclaving, and only 10% of sharps waste is incinerated.³ In California, in particular, autoclaving is used lawfully by hospitals, pharmacies, and even local governments. In fact, a California State Auditor found that home-generated sharps waste in California is generally treated through the use of autoclaving before being disposed of in a landfill as solid waste, and 16 of the 17 medical waste facilities that treat sharps waste in California use the autoclaving process.⁴

MED-Project proposes to use an autoclave facility that is permitted as a medical waste treatment facility and accepts home-generated sharps, in accordance with the California Medical Waste Management Act. Cal. Health & Safety Code § 117600 et seq. The law requires that sharps waste be treated at a permitted medical waste treatment facility. Cal. Health & Safety Code §§ 117903. Autoclaving is expressly identified as a lawful treatment option for sharps under the

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 California State Auditor's Report on Home-Generated Sharps and Pharmaceutical Waste, pg. 31 (May 2017), available at <https://www.auditor.ca.gov/pdfs/reports/2016-127.pdf>.

California Medical Waste Management Act. Cal. Health & Safety Code § 118225(a).⁵ Sharps that are treated and rendered noninfectious are considered solid waste, and may be disposed of in a solid waste landfill. Cal. Health & Safety Code §§ 118225(b), 117695. Therefore, nothing under California law would prohibit or otherwise limit the disposal of Pre-filled Injector Products in the manner proposed by MED-Project.

III. SANTA BARBARA COUNTY SHOULD APPROVE THE USE OF AUTOCLAVING TO TREAT PRE-FILLED INJECTOR PRODUCTS.

Autoclaves are protective of the environment and human health, which supports MED-Project's petition under Ordinance section 18C-19(C). The Director should approve MED-Project's proposed disposal technology under this standard because autoclaving is a widely-used means to dispose of sharps, including Pre-filled Injector Products; represents industry best practice; and is protective of the environment and human health, as explained further below.

The County should approve MED-Project's petition under Ordinance section 18C-19(C) to autoclave Pre-filled Injector Products. Under Ordinance section 18C-19(C), MED-Project:

may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in sections 18C-19(A) and 18C-19(B), or equivalent protection at lesser cost.

Ordinance § 18C-19(C). Sections 18C-19(A) and 18C-19(B) refer to disposal at a permitted hazardous waste disposal facility and permitted large municipal waste combustor, respectively.

MED-Project's proposed technology would provide equivalent or superior 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) Reduction or elimination of air, water or land emissions contributing to persistent, bio-accumulative, and toxic pollution.

See Ordinance § 18C-19(C). Additionally, autoclaving is less expensive than incinerating these materials at a hazardous waste disposal facility or large municipal waste combustor.

⁵ Cal. Health & Safety Code § 118225(a) requires that sharps waste be treated and rendered noninfectious at a medical waste treatment facility or a hazardous waste incinerator by incineration, steam sterilization (which includes autoclaving), or an alternative disposal method approved by the California Department of Public Health.

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

Autoclaving would provide superior protection related to the overall impact on the environment and human health than provided by disposal at a permitted hazardous waste disposal facility or municipal waste combustor, satisfying this criterion under Ordinance section 18C-19(C).

As compared to incinerators, autoclaves generate few air emissions.^{6,7} In addition, autoclaves use far less energy to treat sharps than incineration,⁸ 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 proposed autoclave for use in MED-Project's Program to treat Pre-filled Injector Products complies with Texas' regulations regarding the treatment and disposal of medical waste, and operates as a Type V Medical Waste Processing Facility under a medical waste registration permit issued by the Texas Commission on Environmental Quality. The facility is also certified to transport medical waste. The permit and certification serve to ensure that the autoclave is operated in a manner that is environmentally sound and protective of human health. The proposed autoclave facility has an exemplary compliance record, and has not had a single environmental or safety violation since it began operating in 2009.

2. Autoclaving provides superior worker health and safety protections.

Autoclaving provides superior worker health and safety protections by minimizing worker exposure to any potential air contaminants and sharps. The proposed autoclave facility for treating Pre-filled Injector Products under the Program operates in a manner which ensures compliance with all applicable federal and state laws intended to protect workers, including the U.S. Occupational Safety and Health Administration ("OSHA") Bloodborne Pathogens Standard, OSHA Hazard Communication Standard, and U.S. Department of Transportation ("DOT") Hazardous Materials Regulations. For instance, the autoclave facility and its employees that are involved in the handling and treatment of sharps waste operate under the facility's Bloodborne Pathogen Exposure Control

6 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 <http://www.noharm.org/nonincineration> (last accessed Nov. 22, 2005)).

7 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>.

8 *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).

Plan.

Employees at the autoclave 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 autoclave facility has a standard operating procedure regarding personal protective equipment, general handling of waste received by the facility, engineering and work practice controls, spill procedures, and incident response. Autoclave employees are required to wear personal protective equipment, including puncture resistant gloves, steel-toe shoes, full coveralls, and appropriate eye protection. The autoclave facility employs operational controls and automated systems to protect workers from exposure to sharps. These include an automated autoclave and mechanical tippers for dumping the waste into the autoclave bins. The facility utilizes a vacuum autoclave that operates in a closed system and contains any air emissions during the autoclave process, which are ultimately vented outside. The facility also has ridge ventilators that provide for ventilation inside the building. Accordingly, workers should not be exposed to any 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.⁹

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. The California Medical Waste Management Act requires that sharps waste be transported in a "sharps container," defined as "a rigid puncture-resistant container used in patient care or research activities meeting the standards of, and receiving approval from, the United States Food and Drug Administration as a medical device used for the collection of discarded medical needles or other sharps." *See* Cal. Health & Safety Code §§ 118286(b), 117750. 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 municipal waste landfill, where they are deposited into a designated space and covered. This ensures the waste is contained from collection to ultimate disposal.

⁹ 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 <http://www.noharm.org/nonincineration> (last accessed Nov. 22, 2005).

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

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

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

Under the California Medical Waste Management Act, sharps waste must be tracked from collection through treatment and final disposal. Cal. Health & Safety Code § 118040. 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 transported, returned, treated, and disposed of. The autoclave will confirm the materials have been treated and sent to the landfill. No other waste monitoring is required. Thus, autoclaves provide equivalent compliance with all established requirements for emissions and waste monitoring.

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

Autoclaving produces minimal air emissions.¹⁰ Furthermore, because autoclaves typically operate at temperatures between 120°C and 300°C, they consume far less energy than incinerators, and therefore produce less greenhouse gas emissions and toxic air pollution from energy production.

All materials that have been rendered noninfectious through autoclave treatment 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.

Also, according to a California Air Resources Board technical assessment, water effluent

¹⁰ 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>.

from the autoclaving process is negligible provided facilities properly segregate their waste.¹¹ With respect to MED-Project's Program, the effluent from autoclaving Pre-filled Injector Products should not contain hazardous materials.

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.

IV. CONCLUSION

Based on the foregoing reasons, MED-Project respectfully requests that the Director exercise its discretion and authorize the use of autoclaves for treating Pre-filled Injector Products collected from County residents under MED-Project's Program in accordance with section 18C-19(C)

11 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>.

Appendix I

Request for Approval of Inhaler Mail-Back Package Disposal Process

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



January 31, 2018

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

Pursuant to Santa Barbara’s Ordinance 4971, codified at Section 18C-12 through 18-30 of the Santa Barbara County Code (the “Ordinance”) § 18C-19(B), MED-Project LLC (“MED-Project”) requests the Director of the Santa Barbara County Public Health Department’s (the “Director’s”) approval to use a permitted municipal waste combustor for the disposal of Inhaler Mail-Back Packages (as defined in 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.

I. THE PROCESS FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES AT THE COVANTA HUNTSVILLE AND COVANTA MARION FACILITIES

MED-Project is proposing that Inhaler Mail-Back Packages 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 permitted municipal waste combustors for disposal: the Covanta Huntsville, Inc. facility (the “Covanta Huntsville Facility”)¹⁹ or the Covanta Marion, Inc. facility (the “Covanta Marion Facility”).²⁰ The Daniels Facility will scan the unique identifier on each Inhaler Mail-Back Package to record receipt before sending it for incineration to the Covanta Huntsville Facility or the Covanta Marion Facility. 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.

A. 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.²¹ 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.²² 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.²³

B. 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.²⁴ Like the Covanta Huntsville Facility, the Covanta Marion Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control

¹⁹ Covanta Huntsville’s mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.

²⁰ Covanta Marion’s mailing address is 4850 Brooklake Road, NE, Brooks, OR 97305.

²¹ See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, <http://swdahsv.org/waste-to-energy/>.

²² See Covanta, Covanta Huntsville, <https://www.covanta.com/Our-Facilities/Covanta-Huntsville>.

²³ *Id.*; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

²⁴ See Covanta, Covanta Marion, <https://www.covanta.com/Our-Facilities/Covanta-Marion>.

system, a mercury control system, and a continuous emissions monitoring system.²⁵ The Covanta Marion Facility is a member of the Safety and Health Achievement Recognition Program (SHARP), Oregon's safety and health recognition program.²⁶ The Covanta Marion Facility has also been designated as a VPP Star facility by OSHA.²⁷

II. STANDARD FOR THE DEPARTMENT TO APPROVE THE COVANTA HUNTSVILLE FACILITY FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES

Under Ordinance § 18C-19(B), “[t]he Director may grant approval for a Stewardship Plan to dispose of some or all collected Unwanted Covered Drugs [including inhalers] at a permitted large municipal waste combustor . . . if the Director deems the use of a hazardous waste disposal facility . . . to be infeasible for the Stewardship Plan based on cost, logistics or other considerations.”

III. THE USE OF PERMITTED MUNICIPAL WASTE COMBUSTORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 18C-19(B) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project proposes to use the Covanta Huntsville Facility and the Covanta Marion Facility 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. Furthermore, the only Vendor willing and able to offer these services for Inhaler Mail-Back Packages, PureWay Compliance Inc., offers disposal at municipal waste combustors (the Covanta Huntsville Facility and the Covanta Marion Facility). Accordingly, the use of a hazardous waste disposal facility for Inhaler 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 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 permitted municipal waste combustors. In MED-Project’s experience, hazardous waste incinerators typically charge significantly more than municipal waste combustors 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 MED-Project’s Vendor is capable of delivering Inhaler Mail-Back Packages to that facility would cause delay 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 the 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. Any inhalers collected by MED-Project under this Plan are not regulated under the state’s hazardous waste regulations, and therefore are not required to be treated as hazardous waste.

IV. CONCLUSION

Accordingly, the Department should approve the disposal of Inhaler Mail-Back Packages at the Covanta Huntsville Facility and the Covanta Marion Facility as proposed by MED-Project under Ordinance § 18C-19(B).

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

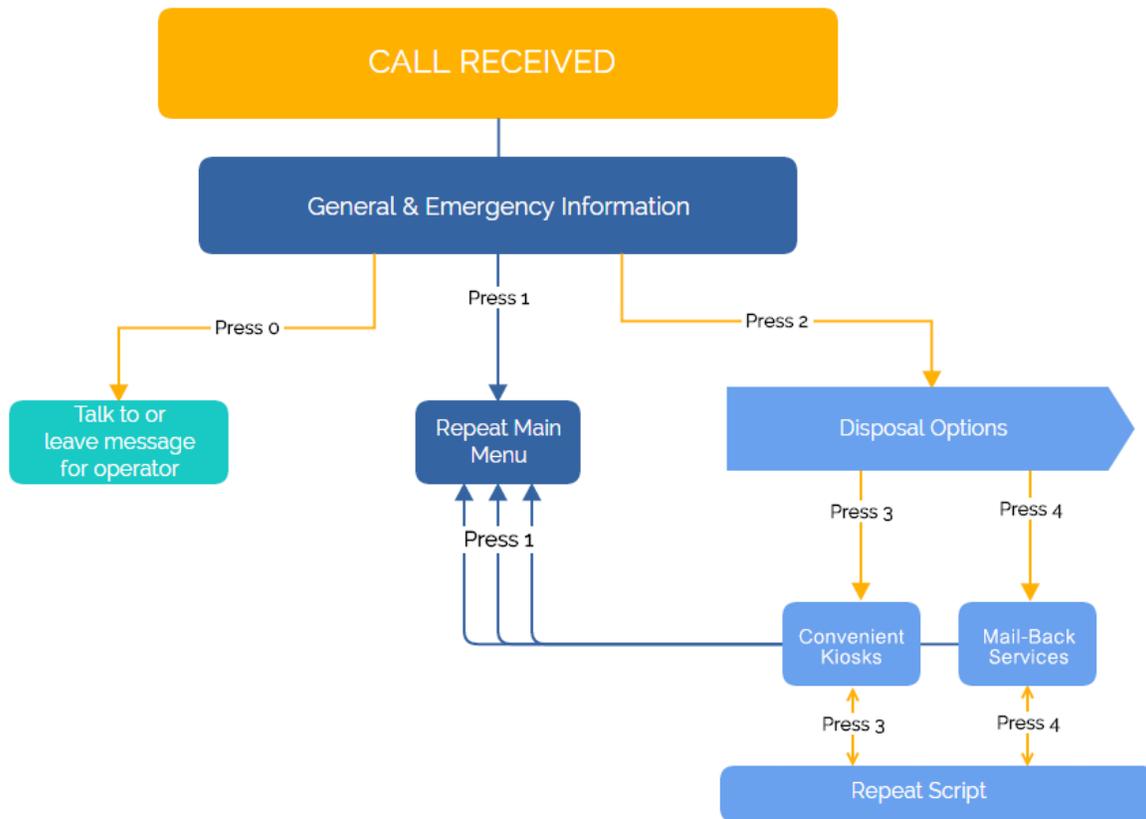
Appendix J

Sample Call Center Script

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 California Poison Control at 800-222-1222.
- Kiosks are located throughout the city 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.
- You may press 0 at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and consumer disposal.

- MED-Project reminds you that taking your medicine as directed by your health care provider is critically important to your health.
- If you have questions about your medication, please hang up and dial your health care provider.
- For additional questions about the proper disposal of expired or Unwanted Medicine 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.*

Kiosk 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, press 0 to speak with an operator or visit MEDProject.org 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. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; inhalers; medical devices; sharps; illicit drugs; or iodine-containing medications will be accepted.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 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 Residents or healthcare professionals providing services to Residents. Mail-Back Services are also available to Residents for Pre-filled Injector Products and inhalers.
- Mail-Back Distribution Locations may also be available near you.
- To request a mail-back package, please press 0 to talk to the operator or visit MEDProject.org.
- Mail-back packages accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; medical devices; sharps; 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 4.
- To return to the main menu, please press 1.
- *Thank you for calling MED-Project.*

Appendix K

MED-Project Website

Translations of the MED-Project Website pages will be available in the Required Languages.

MED-Project
Medication Education & Disposal

Search by Location MEDInfo MEDfaq Contact

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. However, if you have expired or unwanted medication, proper disposal is important and easy.

CLICK ON ANY OF THE RECOMMENDED DISPOSAL OPTIONS BELOW TO LEARN MORE

- CHECK THE PACKAGE
- CONVENIENT KIOSKS
- MAIL BACK
- IN-HOME DISPOSAL

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.

Proposed Web Page

CHECK THE PACKAGE

If there are any specific instructions for disposal on the label, package or package insert, please follow those instructions. Do not flush any medication down the toilet unless specifically instructed to do so.

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
KIOSKS



MAIL
BACK



IN-HOME
DISPOSAL

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.

Proposed Web Page

CONVENIENT KIOSKS

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

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

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

To find the nearest disposal locations, enter your zip code below.

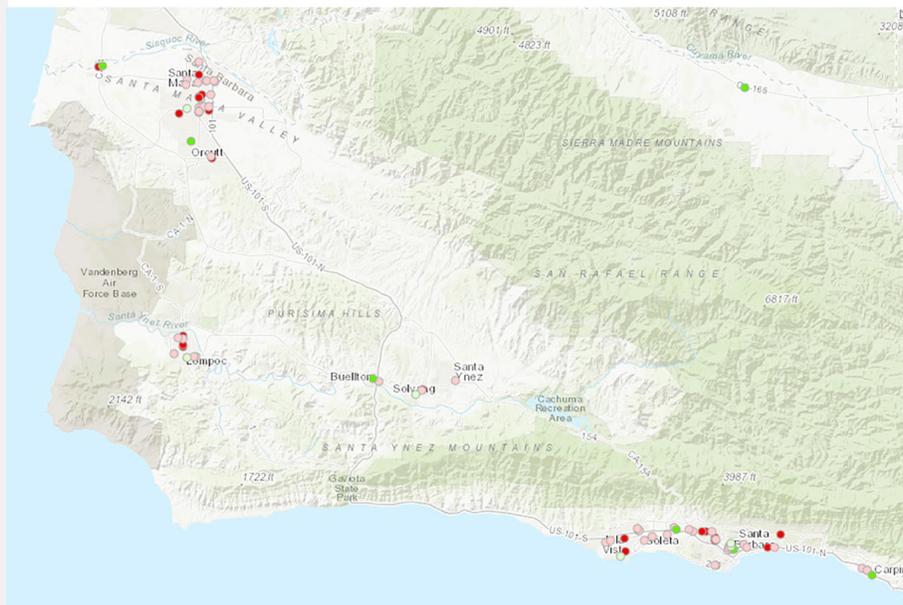
Starting Point

Radius

SEARCH

 Unwanted Medicine Kiosks

CLEAR FILTERS



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.

Proposed Web Page

MAIL-BACK

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



CHECK THE
PACKAGE



CONVENIENT
KIOSKS



MAIL
BACK



IN-HOME
DISPOSAL

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.

Proposed Web Page

IN-HOME DISPOSAL

If no disposal instructions are given on the drug labeling and no take-back program is available in your area, throw the drugs in the household trash following these steps:

1. Remove them from their original container and mix them with undesirable substance, such as coffee grounds, dirt, or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs).
2. Place the mixture in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.*

*Source: U.S. Food and Drug Administration.



CHECK THE
PACKAGE



CONVENIENT
KIOSKS



MAIL
BACK



IN-HOME
DISPOSAL

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

Proposed Web Page

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 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](#)

[Spanish](#)

Frequently Asked Questions:

[English](#)

[Spanish](#)

Mail-Back Services Post Card:

[English](#)

[Spanish](#)

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

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

Proposed Web Page

MEDfaq

- [+ 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?](#)
- [+ Where can I find information about the safe storage of medication?](#)
- [+ Where can I find information about California's Prop 65?](#)
- [+ Can I flush my medication down the toilet?](#)
- [+ Should I remove my personal information before disposing of my medication?](#)
- [+ Where are the MED-Project disposal locations nearest me?](#)
- [+ Will it cost me anything to dispose of my expired or unwanted medications?](#)
- [+ How do I dispose of my unwanted medicine?](#)
- [+ Where else can I find information about the safe disposal of expired or unwanted medicines?](#)
- [+ I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?](#)
- [+ What is recommended for safe disposal of expired or unwanted medicine?](#)
- [+ Ver esta página en español](#)

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.

Proposed Web Page

CONTACT

If you are experiencing a medical emergency, please dial 9-1-1. If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 800-222-1222. If you have questions about your medication, please dial your health care provider.

For answers to some frequently asked questions about MED-Project, [click here](#).

Pharmacies and Law Enforcement Offices

If you are a retail pharmacy or law enforcement agency interested in hosting a drop-box, contact:

Dr. Victoria Travis, PharmD, MBA, MS
Program Director
MED-Project LLC
Phone: (844) 677-6532
Fax: (510) 686-8837
Email: santabarbaracounty@med-project.org

Drug Producers

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

Phone: (202) 495-3131
Email: compliance@med-project.org

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

Appendix L

Sample Brochure

Translations of the brochure will be available in the Required Languages.

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-PROJ

What should you do with your expired or unwanted medicines?

- CHECK THE PACKAGE
- CONVENIENT KIOSKS
- MAIL-BACK
- IN-HOME DISPOSAL

MED-Project
Medication Education & Disposal
www.med-project.org

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 the MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.

DISPOSAL OPTIONS

1 CHECK THE PACKAGE



If there are specific instructions for disposal on the label, package or package insert please follow those instructions. Do not flush medications down the toilet unless specifically instructed to do so.

2 CONVENIENT KIOSKS



To find convenient kiosks in your area, visit www.med-project.org for more information.

What items can I dispose of at a kiosk?



ACCEPTED:
MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER 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, SHARPS, ILLICIT DRUGS AND IODINE-CONTAINING MEDICATIONS.

DISPOSAL OPTIONS

3 MAIL-BACK



Mail-back services are available in your area. Visit the mail-back section of www.med-project.org to order a mail-back package.

4 IN-HOME DISPOSAL



1. Remove medication from its original container and mix with an undesirable substance, such as used coffee grounds, dirt, or kitty litter.

2. Place the mixture in a sealable bag, empty can,

or other container and throw in your household trash.*



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.

*Source: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, last updated December 5, 2017.

Appendix M

Sample Media List

The following is a representative list of key media outlets to help educate Residents about proper disposal of expired or 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	Coverage Area	Website
Santa Barbara News	Santa Barbara County	http://www.newspress.com
Santa Barbara Independent	Greater Santa Barbara area	http://www.independent.com
The Coastal News	Carpinteria	http://www.coastalview.com
Santa Maria Sun	North County Weekly	http://santamariasun.com
Coffee New	Small Business	http://sbcoffeenews.com
NOOZHAWK	Santa Barbara County	http://noozhawk.com
Santa Ynez Valley News	Santa Ynez Valle	https://svnnews.com
Lompoc Record	Lompoc	http://Lompocrecord.com

Television Outlets	Network
KEYT Television (Ch. 3), News Channel	ABC News-affiliate SB County – Central Coast
KKFX Television (Ch.11)	Fox affiliate SB County, Central Coast
KCOY Television (Ch. 12)	CBS affiliate SB County, Central Coast
KSBY Television (Ch.6)	NBC affiliate SB County, Central Coast
KTAS TV Spanish (Ch.34)	Telemundo affiliate San Luis Obispo, North County
Lompoc Community Media Center (Ch.23,24,25)	Community Television - Public, Education and Government

Radio Outlets	Coverage Area
KIST 107.7 FM Radio Bronco Spanish	Carpinteria, Santa Barbara
K-Lite 101.7 FM	Santa Barbara County Regional
KTMS 990 AM News Talk	Santa Barbara, Ventura County- Regional
Z94.5 FM	Santa Barbara Regional
AM 1290	AM Regional
KCSB 91.9 FM	UC Santa Barbara Public radio SB and surrounding communities

Appendix N

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 and education to the community.

Health Systems & Clinics:	Health Associations and Societies:	Veterinary Services:	Organizations, Districts, and Agencies:
Cottage Rehabilitation Hospital Goleta Valley Cottage Hospital Goleta Valley Hospital Lompoc Healthcare District Milpas Medical Clinic Sansum Clinic Hitchcock Urgent Care Zugan Health Urgent Care Center for Women’s Health Network Medical - Women’s Center Perinatal Center Planned Parenthood Sansum Clinic Obstetrics & Gynecology Santa Barbara Birth Center Santa Barbara Fertility Center King Dental Group Santa Barbara Dental Care Star Dental Group Montecito Dental Group Cosmetic Surgery Center Carrillo Surgery Center Santa Barbara Plastic Surgery Center Premier Surgery Center Community Centered Oriental Medicine Community Counseling & Edu Center Hospice of Santa Barbara Community Centered Oriental Medicine Community Counseling & Edu Center Santa Barbara Healthcare Senior Planning Services Valle Verde Retirement Community	American Heart Association American Red Cross of Central California & Santa Barbara American Diabetes Association Home Care Assistance Santa Barbara Mental Health Association Santa Barbara Diabetes Resource Center American Indian Health & Services William Sansum Diabetes Center Muscular Dystrophy Association	ABC Veterinary Hospital Adobe Pet Hospital Advanced Veterinary Specialists Animal Medical Center of Santa Barbara Artemis Animal Clinic Cat Doctors Dermatology and Allergy Clinic for Animals Foothills Pet Hospital St Francis Pet Clinic La Cumbre Animal Hospital Maritimus The Cat and Bird Clinic San Roque Pet Hospital Santa Barbara Pet Hospital Santa Ynez Humane Society VCA Care Specialty and Emergency Animal Hospital Whites Pet’s Hospital	Department of Social & Health Services Santa Barbara County Health Department

Chambers of Commerce:	Educational Institutions:	Water/Utilities Districts:	Library Systems:
The Chamber of Santa Barbara Region	California Department of Education	City of Santa Barbara Public Works	Santa Barbara County Public Library System
Buellton Chamber of Commerce	Carpinteria Unified School District	La Cumbre Mutual Water Company	Lompoc Public Library System
Carpinteria Valley Chamber of Commerce	Pacifica Graduate Institute	Lincoln Wood Mutual Water	Santa Maria Public Library System
Goleta Valley Chamber of Commerce	Santa Barbara City College	Montecito Water District	
Guadalupe Chamber of Commerce	Santa Barbara County Office of Education	San Ynez River Water Conservation District	
Lompoc Valley Chamber of Commerce	University of California Santa Barbara		
Santa Maria Valley Chamber of Commerce			
Solvang Chamber of Commerce			

Law Enforcement Agencies:	Fire Agencies:
City of Santa Maria Police Department	Cal-Fire
City of Goleta Police Department	City of Lompoc Fire
City of Carpinteria Police Department	City Santa Maria Fire
City of Lompoc Police	Guadalupe Fire
City of Santa Barbara Police Department	Montecito Fire Protection District
Santa Barbara County Sheriff's Department	Santa Barbara City Fire Department
	Santa Barbara County Fire Department

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
City of Santa Barbara	https://www.santabaraca.gov/gov/new/social.asp	@SBCity
Santa Barbara County	https://www.facebook.com/pages/santabarbaracounty.ca.gov	@countyofsb
City of Carpinteria	https://www.facebook.com/carpinteria.ca.us	@visitcarp
City Santa Maria	https://www.facebook.com/cityofsantamaria.org	N/A
City of Guadalupe	https://www.facebook.com/ci.guadalupe.ca.us	N/A
City of Solvang	https://www.facebook.com/solvangconferencevistorcenter	@cityofSolvang
City of Goleta	https://www.facebook.com/cityofgoleta.org	@GoletaPIO
SB Sheriff	https://www.facebook.com/santabarbarasheriff.org	@sbsheriff

