

A Product Stewardship Plan For Unwanted Medicine from Households

San Mateo County, California January 31, 2018

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I. Introduction

MED-Project LLC ("MED-Project"), on behalf of the participating companies identified in <u>Appendix A</u>, submits this Product Stewardship Plan ("Plan") for Unwanted Medicine in compliance with the County of San Mateo Safe Medicine Disposal Ordinance, San Mateo County Ordinance Code 4.116.010 – 4.116.190 ("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 San Mateo County Residents.

II. Contact Information

The primary contact person for MED-Project is:

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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 San Mateo, California.²

DEAis 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 <a href="

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

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

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

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

Residents means 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.

This Plan does not apply to any incorporated areas of San Mateo County where the governing body of that incorporated area has authorized its own local health officer or environmental director to administer and enforce the provisions of California Health and Safety Code § 117800, et seq.

Service Convenience Goals are the goals established in Ordinance § 4.116.050(b)(1).

Service Technicians are personnel trained to service Program kiosks.

Shipper is United States Postal Service ("USPS"), the shipper used by Vendor for the transport of Unwanted Medicine collected from Residents via Mail-Back Services.

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 Medicine³

For the purposes of the Plan, "Unwanted Medicine" includes all materials identified as "Covered Drugs" under Ordinance § 4.116.020(D) that qualify as Covered Drug[s]" under Ordinance Section 4.116.020(V). According to the Ordinance, Covered Drugs means "a Drug in any form used by County residents, including prescription, nonprescription, brand name and generic drugs." Ordinance § 4.116.020(D). Unwanted Medicine does not include the following:

- i. Expired undispensed samples direct from physicians' offices;
- ii. Unused or expired drugs from hospitals and institutions;
- iii. Bulk animal pharmaceuticals from farms (business use);
- iv. Vitamins or supplements;
- v. Herbal-based remedies and homeopathic drugs, products, or remedies;
- vi. Compressed cylinders 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. Drugs that are biological products, meaning any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man, as these terms are defined by 21 C.F.R. § 600.3(h), if the Producer already provides a pharmaceutical product stewardship or take-back program;
- xii. Medical devices or their component parts or accessories;
- xiii. Used, empty containers, vials, and pouches that do not contain a usable quantity of covered drugs; and
- xiv. Schedule I or other illicit drugs.

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

³ Unwanted Medicine collected at Kiosk Drop-Off Sites does not include inhalers, Pre-Filled Injector Products, and iodine-containing medications.

V. Collection of Unwanted Medicine

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

A. Unwanted Medicine Collection Program Implementation

1. Outreach

Per Ordinance § 4.116.030(e)(2), MED-Project initially notified 115 sites with a licensed pharmacy and 24 LEA locations in the County of the opportunity to participate as a Kiosk Drop-Off Site. MED-Project continues to periodically perform outreach via calls, emails, and site visits, with the goal of establishing Kiosk Drop-Off Sites distributed throughout the County. 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.

LEAs and pharmacies 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 attained for the minimum number of Kiosk Drop-Off Sites through Mail-Back Distribution Locations. *See* Section V for details on how MED-Project 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 § 4.116.050(b)(1), MED-Project will strive to establish at least one Kiosk Drop-Off Site in each Supervisorial District for every 20,000 Residents, geographically distributed to provide reasonably convenient and equitable access for all Residents. MED-Project will work to establish a minimum of five (5) Kiosk Drop-Off Sites in each Supervisorial District. In Supervisorial Districts where a sufficient number of Kiosk Drop-Off Sites cannot be established, Mail-Back Distribution Locations will be established in order to supplement the disposal of Unwanted Medicine by Residents.

Standard Mail-Back Services shall be available upon request for disabled and home-bound Residents, thereby offering more opportunities to dispose of Unwanted Medicine.

In addition to the Kiosk Drop-Off Sites and Mail-Back Distribution Locations as outlined above, MED-Project shall jointly operate a Kiosk Drop-Off Site within each County-owned pharmacy with all other approved stewardship plans.

4. Services

MED-Project will routinely assess performance, gauge feedback, and revise its approach as appropriate. As implementation proceeds, MED-Project shall continue outreach to organizations that may be available to assist locating future Kiosk Drop-Off Sites on a periodic basis, such as those listed in Appendix B.

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites and Mail-Back Distribution Locations. 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. MED-Project will establish Mail-Back Distribution Locations for underserved areas. For every engagement with LEAs and pharmacies, including the establishment of Kiosk Drop-Off Sites, 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 Package Distribution Locations shall supplement Kiosk Drop-Off Sites in Supervisorial Districts where the Service Convenience Goals are not met through executed agreements with Kiosk Drop-Off Site Hosts. As MED-Project obtains additional agreements with Kiosk Drop-Off Site Hosts, these supplemental services will decrease.

Standard Mail-Back Services will be available to disabled and home-bound Residents upon request and will be reviewed routinely for availability and effectiveness. *See* Section V.D for more information about the availability of Mail-Back Services.

Although Kiosk Drop-Off Sites will not provide kiosk collection for Pre-filled Injector Products, inhalers, and iodine-containing medications, Mail-Back Services for Pre-filled Injector Products, inhalers, and iodine-containing medications 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 or iodine-containing medications in collection receptacles or mail-back packages containing controlled substances. If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

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 established by the Ordinance. This network will provide Residents a number of different outlets to participate in the Program. All Kiosk Drop-Off Sites shall provide Residents with access to Program kiosks during regular business hours.

1. Kiosk Drop-Off Site Locations

MED-Project initially contacted 24 LEAs and 115 sites with a licensed pharmacy located in the County about the opportunity to serve as a Kiosk Drop-Off Site. Of the locations contacted, 15 LEAs and 65 pharmacies 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 C.

MED-Project will continue outreach to potential Kiosk Drop-Off Sites that are not participating in the Program according to Ordinance Section 4.116.030(e)(2), such as sites listed in Appendix D.

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 § 4.116.050(b)(4), 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.

2. Drop-Off Site Kiosk Placement and Maintenance Program

Kiosk installation shall be the responsibility of MED-Project at LEAs and pharmacy Kiosk Drop-Off Sites 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 urgent or emergency 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 contracts 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 the regularly scheduled pick-ups and notification of a Maintenance Technician if necessary; and
- Reporting by the Kiosk Drop-Off Site Host of damage to a kiosk or requested maintenance service.

3. Kiosk Specifications

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

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

The proposed design of the pharmacy kiosk and proposed signage (<u>Appendix E</u>) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the drop-slot; a tamper-proof slot; and commercial hinges. The design will increase the likelihood of consumer participation by providing easy access to wheelchair-bound 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 Rule⁵ 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.

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 Site Hosts must dispose of sealed inner liners and their contents either on-site, through common or contract carrier delivery to, or pick-up by, a reverse distributor or distributor, or with DEA assistance.

Section 1317.75(c) 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

⁴ As discussed in Section XI, if applicable, MED-Project will coordinate with other approved product stewardship plans to develop clear standardized instructions for Residents to use kiosks and a consistent design. <u>Appendix E</u> provides the kiosk design and signage MED-Project expects to propose when coordinating with other approved product stewardship plans.

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."

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 Kiosk Drop-Off Site Hosts and Vendor will be instructed never to count, sort, inventory, or individually handle kiosk contents.

Pharmacy kiosks will be located where an employee is present affording employees the opportunity to visually inspect Unwanted Medicines Residents attempt to deposit. *See* Section V.B.2. LEA kiosks will be located inside the LEA's physical location. *See* Section V.B.2. 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 checked 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 inner liner provided in the kiosk will be opaque to prevent visual recognition of the contents. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Under the supervision of two Kiosk Drop-Off Site employees, the Service Technician will package the sealed inner liner for transport. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The Service Technician will schedule a pick-up by 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 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 Sites will be scheduled for a monthly pick-up from the kiosk. Vendor will communicate with MED-Project in the event that the frequency of pick-up needs to be changed based on the volumes collected over time. Vendor will monitor the volumes per service to ensure that all sites are receiving the appropriate service frequency. Vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating

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

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

Along with major event preparedness, Vendor provides timely responses to events that may cause an inconvenience to the Kiosk Drop-Off Site. 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 emergency response. If the request is not an emergency that poses an immediate threat to the environment or health, Vendor will typically respond to a service location within two to three business days of the event.

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

C. Disposal of Unwanted Medicine from Kiosk Drop-Off Sites

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 facilities identified in Section X.

D. Mail-Back Services for Unwanted Medicine

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

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

If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

1. Standard Mail-Back Services

MED-Project will provide Standard Mail-Back Services at no cost to disabled and home-bound 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, Pre-filled Injector Products, or iodine-containing medications, will be:

- Nondescript and without any markings or information potentially indicating that they contain Unwanted Medicine, including controlled substances;
- Water and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with and delivered to Vendor's registered address;
- Pre-paid;
- Provided with a unique identifier enabling tracking; and
- Provided with instructions indicating the process for mailing back the packages, accepted substances, 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 will keep all records required under the DEA Rule, including those identified in § 1304.22(f).

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

For iodine-containing medications, MED-Project will offer all Residents Standard Mail-Back Services and Standard Mail-Back Packages, via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Standard Mail-Back Package to the facility identified in Section X. If the General Public Fact Sheet is modified to allow for commingling of iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

See Appendix F for a sample package and package specifications.

3. 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 G for a sample package and package specifications.

4. 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 (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

See Appendix H for a sample package and package specifications.

5. Mail-Back Package Availability

Disabled and home-bound Residents may request Standard Mail-Back Packages by calling the Call Center or through a link on the MED-Project Website. Home healthcare professionals providing services to disabled and home-bound Residents may also request Standard Mail-Back Packages, on behalf of a Resident, through 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 the required number of signed 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 facilities, such as fire stations and/or libraries, to ensure that Mail-Back Distribution Locations are centrally located.

Standard Mail-Back Services for iodine-containing medications, Injector Mail-Back Services for Pre-filled Injector Products, and Inhaler Mail-Back Services for inhalers, will be available to all Residents through the Call Center and MED-Project Website. As noted above, if the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

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.

6. 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. 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 <u>Appendix I</u>.

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 <u>Appendix J</u>.

The Director approved MED-Project's Standard Mail-Back Package disposal process on September 13, 2016.

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 all Kiosk Drop-Off Sites are fully operational, the Program will collect approximately 360 pounds per Kiosk Drop-Off Site during the calendar year. Assuming 37 Kiosk Drop-Off Sites are operational for the full year, MED-Project anticipates collecting approximately 13,320 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2018. *See* Section V.B. for more information about Kiosk Drop-Off Site collection.

MED-Project anticipates a continued need in 2018 to supplement Kiosk Drop-Off Sites in a few Supervisorial Districts through Mail-Back Distribution Locations.

MED-Project 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 goals.

Goal Area	Short-Term	Long-Term
Collection	Within 90 days of Plan approval, implement Mail-Back Services for inhalers, iodine-containing medications, and Pre-filled Injector Products via the MED-Project Website and Call Center.	Increase retail chain pharmacy participation to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites in a minimum of four (4) Supervisorial Districts. Reduce or eliminate the number of Mail-Back Distribution Locations.
	Continue to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations.	If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).
Education & Public Outreach	Develop baseline number of MED-Project Website page views or unique visitors. Establish a baseline of LEAs; retail pharmacies; other pharmacies (healthcare, etc.); community groups; and other third parties contacted, and report appropriate statistics as outlined in the Survey and Annual Report Sections of this Plan. Establish a baseline number of media outlets receiving press advisory, with a minimum of five outlets. Establish a baseline percentage of community centers reached. Establish a baseline number of messages returned by MED-Project within predetermined timeframe.	On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan. MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the 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 Section XI.D.2.

Coll	ector
Out	reach

Outreach to all potential eligible Kiosk Drop-Off Site Hosts according to requirements as outlined in Ordinance Section 4.116.030(e)(2).

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

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 Unwanted Medicine 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

Per Ordinance § 4.116.060, MED-Project will operate a Call Center jointly with all other approved stewardship programs operating in the County. Questions from Residents will be managed through an interactive voice response ("IVR") system and with 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.

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 Program 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 Unwanted Medicine will complete comprehensive 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 servicing Kiosk Drop-Off Sites and/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.stericycleenvironmental.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-UPSWebsite: 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: <u>www.stericycleenvironmental.com</u>
- 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: <u>www.veiolianorthamerica.com</u>

• 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: <u>www.stericycleenvironmental.com</u>

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) 268-2000Website: 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: <u>www.stericycleenvironmental.com</u>

• 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) 268-2000Website: 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) 268-2000Website: 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

 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

XI. Unwanted Medicine Educational and Outreach Programming

A. Overview

Per Ordinance § 4.116.060, MED-Project will perform public education and outreach to educate Residents about the collection and disposal of Unwanted Medicine from households.

B. Audiences

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

- General public;
- Pharmacies, including education for dispensers of Covered Drugs;
- Retailers of Covered Drugs;
- Health care providers and their patients;
- Veterinary facilities and veterinary hospitals;
- Public health facilities; and/or
- Law enforcement agencies

The Program will include efforts to reach the varied cultural, linguistic, geographic, and age demographics, including through outreach to ethnic, community, and alternate-language media; outreach to community organizations serving a broad range of audiences; availability of alternate language 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 in order to appropriately direct outreach and create educational materials to best serve the unique needs of identified demographics.

C. Messages

MED-Project anticipates that messaging will:

- Educate Residents about the appropriate use, storage, and disposal of Unwanted Medicine, and;
- Educate Residents about available Mail-Back Services; 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 dispose of Unwanted Medicine; and
- Privacy issues (removing personally identifiable information from labeled prescription containers).

D. Tools/Communications Channels

The Program will include a number of components designed to reach consumers and provide consistent access to timely and relevant information. Distribution of materials will likely include audiences such as LEAs, pharmacies, health care providers and systems, health associations, local government agencies, veterinarians, veterinary hospitals, and other community organizations. MED-Project expects that the tools and communication channels will include:

1. Phone

The Program 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 for the take-back of for Unwanted Medicine from households. 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 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 callers with medical emergencies to call 911 and directing Residents with medication-related questions to contact their health care provider(s).

Please see Appendix K for a sample call script.

2. MED-Project Website

MED-Project will develop 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 sample web pages for the MED-Project Website. <u>Appendix L</u> 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 M, for an example) and a frequently asked questions (FAQ). 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, inhalers and iodine-containing medications will be available through the MED-Project Website, through potential third-party partners, community organizations, and at Kiosk Drop-Off Sites.

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

4. Media Outreach

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

- See <u>Appendix K</u> for a call script with the toolkit including flyers in <u>Appendix M</u> and the sample MED-Project Website information included in <u>Appendix L</u>.
- Please see Appendix N for a sample list of key media outlets.
- Please 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:
 - ♦ The Program will provide access to educational and outreach materials, including the sample brochure (see Appendix M), 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 <u>Appendix B</u> with the toolkit included in <u>Appendix M</u>.

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

XII. Survey

Per Ordinance § 4.116.060(a)(4), MED-Project will coordinate with other approved stewardship plans, if applicable, to conduct a biennial survey of Residents, pharmacists, veterinarians, and health 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 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 the Ordinance § 4.116.060(a)(4), draft survey questions will be submitted to the Director for review and comment at least thirty (30) days prior to distribution. Results of the survey will be reported to the Director and made public on the MED-Project Website described under Section XI.D.2. The privacy of all survey respondents will be maintained.

The biennial survey will be conducted in the Required Languages and according to requirements outlined in the Ordinance.

XIII. Packaging

The Ordinance requires that a Plan consider "separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and recycling of Drug packaging to the extent feasible." Ordinance § 4.116.040(h).

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 form 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 risk 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 § 4.116.040(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)⁷; 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 their own inventory or stock through the MED-Project Program. See also § 1317.05.

For Kiosk Drop-Off Site collection, only certain substances "that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected." §1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Standard Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent's property. See §§ 1317.65(d); 1317.70(b).

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

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

The Plan is designed such that all entities that are part of the Program, including Vendor, are individually responsible to comply with their respective compliance obligations under the DEA Rule. Vendor will ensure that the collection, transportation, and disposal of Unwanted Medicine 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 their DEA registration 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 Program, 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 § 4.116.090(a). This report will be provided in the format required by the Ordinance.

For the reporting period, the report will include:

- A list of producers participating in the Program;
- The amount, by weight, of Unwanted Medicine collected, including the amount by weight from each collection method used, including Kiosk Drop-Off Sites and Mail-Back Services (using an average weight per package/container/envelope, as provided by Vendor);
- A list of Kiosk Drop-Off Sites and Mail-Back Distribution Locations;
- The number of mailers provided, by zip code;
- The dates and locations of Take-Back Events previously held;
- 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 alleviate the problem and improve safety and security;
- A description of public education, outreach, and evaluation activities implemented;
- A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- A summary of the 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; and
- The Plan's total expenditures.

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

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:	Health Associations and Societies:	Organizations, Districts, and Agencies:	Veterinary Facilities and Hospitals:
County of San Mateo Health System	California State Board of Pharmacy	San Mateo Department of Public Health	VCA San Mateo Animal Hospital
Hospital Consortium of San Mateo Health Plan of San Mateo	California Pharmacists Association The Medical Board of	San Mateo Public Works Human Services Agency of San Mateo	North Peninsula Veterinary Emergency Clinic
San Mateo Medical Center	California California Nurses Association National Association of Social Workers California Chapter California Board of Registered Nursing California Board of Vocational Nursing California Department of Health Care Services	University Systems and Campuses South Hospita	South Hillsdale Animal Hospital VCA Bayshore Animal
Kaiser Permanente Medical Center		San Mateo Fire Department	Hospital SAGE Centers for
Lucile S. Packard Children's Hospital		American Medical Response San Mateo CalRecycle Recology RecycleWhere.org	Veterinary Specialty & Emergency Care
Mills-Peninsula Health Services			Banfield Pet Hospital
Sequoia Hospital Seton Medical Center			Aragon Veterinary Clinic Inc.
Stanford Hospitals and Clinics			Peninsula Avenue Veterinary Clinic
Stanford Medicine Outpatient Center	California Health and Human Services Agency		Crystal Springs Pet Hospital
Veterans Affairs Palo Alto Health Care System	San Mateo County Pharmacists Association		Laurelwood Veterinary Clinic
San Bruno VA Outpatient	San Mateo County Medical Association		Animal Cove Pet Hospital
Clinic			VCA San Carlos Animal Hospital
			Spruce Avenue Pet Hospital
			Camino Real Pet Clinic

Appendix C

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	Site Address
BURLINGAME PD	1111 TROUSDALE DRIVE, BURLINGAME , CA 94010
SHERIFF - MILBRAE POLICE DEPARTMENT	581 MAGNOLIA AVENUE, MILLBRAE, CA 94030
PROBATION - YOUTH SERVICES	222 PAUL SCANNELL DRIVE, SAN MATEO, CA 94402
PROBATION DEPT - SOUTH SAN FRAN	1024 MISSION ROAD, SOUTH SAN FRANCISCO, CA 94080
SOUTH SAN FRANCISCO POLICE DEPARTMENT	33 ARROYO DRIVE, SOUTH SAN FRANCISCO, CA 94080
SUNSHINE PHARMACY	1166 MISSION RD, SOUTH SAN FRANCISCO, CA 94080
SAN BRUNO POLICE DEPARTMENT	1177 HUNTINGTON AVENUE, SAN BRUNO, CA 94066
HILLSBOROUGH PD	1600 FLORIBUNDA AVE, HILLSBOROUGH, CA 94010
KAISER HEALTH PLAN BAYHILL PHY 353	801 TRAEGER AVENUE, SAN BRUNO, CA 94066
KAISER PERMANENTE PHARMACY NO 357	901 EL CAMINO REAL, SAN BRUNO, CA 94066
KAISER PERMANENTE PHARMACY #351	1200 EL CAMINO REAL, SOUTH SAN FRANCISCO, CA 94080
CVS/PHARMACY #09807	10 BAYHILL SHOPPING CTR, SAN BRUNO, CA 94066
CVS/PHARMACY #09811	1871 EL CAMINO REAL, BURLINGAME, CA 94010
SAN MATEO NEIGHBORHOOD PHARMACY	9 37TH AVENUE, SAN MATEO, CA 94403
BELMONT POLICE DEPARTMENT	ONE TWIN PINES LANE, BELMONT, CA 94002
SAN MATEO POLICE DEPARTMENT	200 FRANKLIN PARKWAY, SAN MATEO, CA 94403
KAISER PERMANENTE PHARMACY #339	1000 FRANKLIN PKWY W FL 1, SAN MATEO, CA 94403
SAN MATEO MEDICAL CENTER	222 W. 39TH AVE. ROOM 121, SAN MATEO, CA 94403
CVS/PHARMACY #09554	77 BOVET RD, SAN MATEO, CA 94402
CVS/PHARMACY #09833	4242 S EL CAMINO REAL, SAN MATEO, CA 94403
CVS/PHARMACY #09879	987 E HILLSDALE BLVD, FOSTER CITY, CA 94404
CVS/PHARMACY #09940	872 N DELAWARE ST, SAN MATEO, CA 94401
CVS/PHARMACY #09977	124 DE ANZA BLVD, SAN MATEO, CA 94402
SHERIFF - SAN CARLOS POLICE DEPARTMENT	600 ELM STREET, SAN CARLOS, CA 94070
SHERIFF - SAN CARLOS POLICE DEPARTMENT	600 ELM STREET, SAN CARLOS, CA 94070
SHERIFF - HALF MOON BAY POLICE DEPARTMENT	537 KELLY AVE, HALF MOON BAY, CA 94019
SHERIFF - NORTH COAST MOSS BEACH SUB-STATION	500 CALIFORNIA AVENUE, MOSS BEACH, CA 94038
PACIFICA POLICE DEPARTMENT	2075 COAST HWY, PACIFICA, CA 94044

Site Name	Site Address
HALF MOON BAY PHARMACY	40 STONE PINE RD # I, HALF MOON BAY, CA 94019
CVS/PHARMACY #0550	1324 SAN CARLOS AVE, SAN CARLOS, CA 94070
CVS/PHARMACY #9172	11 EL CAMINO REAL, SAN CARLOS, CA 94070
CVS/PHARMACY #9216	60 CABRILLO HWY N, HALF MOON BAY, CA 94019
PROBATION DEPARTMENT - EAST PALO ALTO LOCATION	2277 UNIVERSITY AVENUE, EAST PALO ALTO, CA 94303
DREW PHARMACY	2111B UNIVERSITY AVENUE, EAST PALO ALTO, CA 94303
MENLO PARK POLICE DEPARTMENT	701 LAUREL ST, MENLO PARK, CA 94025
SHERIFF - WOODSIDE OFFICE OF THE SHERIFF	400 COUNTY CENTER, 3RD FLOOR REDWOOD CITY, CA 94063
PROBATION DEPARTMENT - COUNTY CENTER	455 COUNTY CENTER, REDWOOD CITY, CA 94063
REDWOOD CITY POLICE DEPARTMENT	1301 MAPLE STREET, REDWOOD CITY, CA 94063
EAST PALO ALTO PD	141 DEMETER ST, EAST PALO ALTO, CA 94303
KAISER HEALTH PLAN BIRCH PHY 372	910 MARSHALL STREET, REDWOOD CITY, CA 94063
KAISER HEALTH PLAN CYPRESS MOB PHY 371	1150 VETERANS BOULEVARD, REDWOOD CITY, CA 94063
CVS/PHARMACY # 10240	700 EL CAMINO REAL, MENLO PARK, CA 94025
CVS/PHARMACY #09690	1301 BROADWAY ST, REDWOOD CITY, CA 94063
CVS/PHARMACY #9329	1039 EL CAMINO REAL, REDWOOD CITY, CA 94063
CVS/PHARMACY #9330	325 SHARON PARK DR, MENLO PARK, CA 94025
CHINESE HOSPITAL PHARMACY	386 GELLERT BLVD, SUITE A, DALY CITY, CA 94015
DALY CITY PD	333 90TH ST., DALY CITY, CA 94015
NEMS - EASTMOOR CLINIC	211 EASTMOOR AVE, DALY CITY, CA 94015
BROADMOOR POLICE DPARTMENT	388 88TH ST, BROADMOOR, CA 94015
BRISBANE POLICE DEPARTMENT	BRISBANE CITY HALL, 50 PARK PL, BRISBANE, CA 94005
KAISER PERMANENTE PHARMACY #341	395 HICKEY BLVD 1ST FL, DALY CITY, CA 94015
CVS/PHARMACY # 10165	135 PIERCE STREET, DALY CITY, CA 94015
CVS/PHARMACY #9752	375 GELLERT BLVD, DALY CITY, CA 94015

Appendix D

Potential Additional Kiosk Drop-Off Sites

Name	Address	City	Zip
A & O PENINSULA PHARMACY	1828 EL CAMINO REAL STE 104	BURLINGAME	94010
ALPHASCRIPT, INC.	1160 INDUSTRIAL RD #17	SAN CARLOS	94070
ANCHOR DRUGS III	161 S SPRUCE AVE	S SAN FRANCISCO	94080
BERKSHIRE PHARMACY	11 BERKSHIRE AVENUE	REDWOOD CITY	94063
CARE4U PHARMACY	474 SAN MATEO AVENUE	SAN BRUNO	94066
CAREKINESIS	401 SOUTH CANAL ST	SOUTH SAN FRANCISCO	94080
CHOICECARE PHARMACY INC	90 S SPRUCE STE W	S SAN FRANCISCO	94080
COSTCO PHARMACY #1042	2300 MIDDLEFIELD RD	REDWOOD CITY	94063
COSTCO PHARMACY #147	1001 METRO CENTER BLVD.	FOSTER CITY	94404
COSTCO PHARMACY #422	451 SOUTH AIRPORT BLVD.	SOUTH SAN FRANCISCO	94080
COSTCO WHOLESALE NO 475	1600 EL CAMINO REAL BLVD	SOUTH SAN FRANCISCO	94080
CVS/PHARMACY # 16111	5001 JUNIPERO SERRA BLVD	COLMA	94014
CVS/PHARMACY # 16112	2485 EL CAMINO REAL	REDWOOD CITY	94063
CVS/PHARMACY # 16439	1150 EL CAMINO REAL	SAN BRUNO	94066
CVS/PHARMACY # 16490	2220 BRIDGEPOINTE PKWY	SAN MATEO	94404
CVS/PHARMACY # 16746	133 SERRAMONTE CTR	DALY CITY	94015
DAVITA RX LLC	1178 CHERRY AVE	SAN BRUNO	94066
FEEL GOOD COMPOUNDERS	59 BILL DRAKE WAY	PACIFICA	94044
GARFIELD BEACH CVS LLC D/B/A CVS/PHARMACY # 17710	1775 E BAYSHORE RD	EAST PALO ALTO	94303
KAISER PERMANENTE PHARMACY #343	395 HICKEY BLVD 2ND FL	DALY CITY	94015
KAISER PERMANENTE PHARMACY #358	1200 EL CAMINO REAL	S SAN FRANCISCO	94080
KAISER PERMANENTE PHARMACY #377	1190 VETERANS BLVD	REDWOOD CITY	94063
LPCH CHILDREN'S HOME PHARMACY	4600 BOHANNON DR STE 105	MENLO PARK	94025
LUCKY CA PHARMACY #707	6843 MISSION BLVD	DALY CITY	94014
LUCKY PHARMACY #710	919 EDGEWATER BLVD	FOSTER CITY	94404
LUCKY PHARMACY #748	1322 EL CAMINO REAL	SAN BRUNO	94066
LUCKY PHARMACY #749	1133 OLD COUNTRY RD	SAN CARLOS	94070
MARINER ADVANCED PHARMACY CORP	43 E 3RD AVE	SAN MATEO	94401

Name	Address	City	Zip
MILLS-PENINSULA HEALTH CENTER PHARMACY	100 S. SAN MATEO DR, RM 110	SAN MATEO	94401
NIMBLE PHARMACY	900 WILLOW ROAD	MENLO PARK	94025
NOB HILL PHARMACY #628	270 REDWOOD SHORES PARKWAY	REDWOOD CITY	94065
PHARMACA INTEGRATIVE PHARMACY INC	871 SANTA CRUZ AVE	MENLO PARK	94025
POSTMEDS INC	1700 S AMPHLETT BLVD #221	SAN MATEO	94402
RITE AID 5885	170 SAN MATEO ROAD	HALF MOON BAY	94019
RITE AID 5890	1400 LINDA MAR BLVD	PACIFICA	94044
RITE AID 5891	200 FAIRMONT SHOP CENT	PACIFICA	94044
RITE AID 5892	340 WOODSIDE PLAZA	REDWOOD CITY	94061
RITE AID 5902	666 CONCAR DRIVE	SAN MATEO	94402
RITE AID 5903	1320 W HILLSDALE BLVD	SAN MATEO	94403
RITE AID NO 5893	2150 ROOSEVELT AVE	REDWOOD CITY	94061
SAFEWAY PHARMACY #0305	1071 EL CAMINO REAL	REDWOOD CITY	94063
SAFEWAY PHARMACY #0747	850 WOODSIDE RD	REDWOOD CITY	94061
SAFEWAY PHARMACY #0970	1655 EL CAMINO REAL	SAN MATEO	94402
SAFEWAY PHARMACY #1138	1100 EL CAMINO REAL	BELMONT	94002
SAFEWAY PHARMACY #1547	1450 HOWARD AVENUE	BURLINGAME	94010
SAFEWAY PHARMACY #2719	525 EL CAMINO REAL	MENLO PARK	94025
SAFEWAY PHARMACY #2878	525 EL CAMINO REAL	MILLBRAE	94030
SAN MATEO MEDICAL CENTER LTC PHARMACY	225 W 37TH AVE. RM G-15	SAN MATEO	94403
SAN MATEO NEIGHBORHOOD PHARMACY	9 37TH AVENUE	SAN MATEO	94403
SEVENTEEN FIFTY MEDICAL CENTER PHARMACY	1750 EL CAMINO REAL	BURLINGAME	94010
SOUTH COUNTY COMMUNITY HEALTH CENTER INC DBA RAVENSWOOD FAMILY HE	1885 BAY ROAD SUITE A	EAST PALO ALTO	94303
STANFORD HEALTH CARE	450 BROADWAY ST	REDWOOD CITY	94063
STANFORD HEALTH CARE	450 BROADWAY ST PAVILION A 3RD FL	REDWOOD CITY	94063
TED'S VILLAGE PHARMACY INC	29 WEST 25TH AVE	SAN MATEO	94403
THE PILL CLUB	969 INDUSTRIAL RD STE G	SAN CARLOS	94070
TRIAD ISOTOPES	806 DUBUQUE AVE	SOUTH SAN FRANCISCO	94080
WALGREENS #00063	900 RALSTON AVE	BELMONT	94002
WALGREENS #00324	216 WESTLAKE CENTER	DALY CITY	94015
WALGREENS #00625	615 BROADWAY	MILLBRAE	94030

Name	Address	City	Zip
WALGREENS #01807	22 SAN PEDRO RD	DALY CITY	94014
WALGREENS #02126	1414 EL CAMINO REAL	SAN CARLOS	94070
WALGREENS #02939	333 EL CAMINO REAL	SAN BRUNO	94066
WALGREENS #03296	191 EAST 3RD AVE	SAN MATEO	94401
WALGREENS #03346	399 EL CAMINO REAL	SOUTH SAN FRANCISCO	94080
WALGREENS #05006	4070 S EL CAMINO REAL	SAN MATEO	94403
WALGREENS #05365	6100 MISSION STREET	DALY CITY	94014
WALGREENS #06655	1160 BROADWAY	BURLINGAME	94010
WALGREENS #07087	643 SANTA CRUZ AVE	MENLO PARK	94025
WALGREENS #07970	45 SOUTH EL CAMINO REAL	MILLBRAE	94030
WALGREENS #11261	520 PALMETTO AVE	PACIFICA	94044
WALGREENS #12257	260 EL CAMINO REAL	BURLINGAME	94010
WALGREENS #15397	2238 WESTBOROUGH BLVD	SOUTH SAN FRANCISCO	94080

Appendix E⁸

Kiosk Prototype and Proposed Signage



⁸ If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles and modify signage accordingly.



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.

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

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.







Proposed Kiosk Signage

Drop-Slot Kiosk Art



Name: 123 Pharmacy

Contact: **(555) 555-555**

Appendix F⁹

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.

If the General Public Fact Sheet is modified to allow for commingling iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for iodine-containing medications (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

Appendix G

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

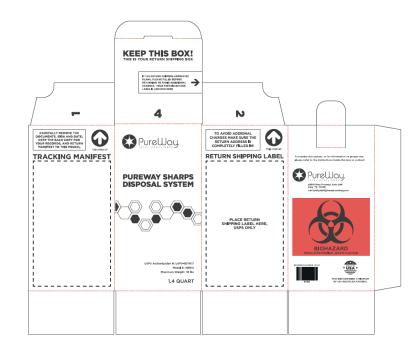
PureWay mail-back solutions are an example of complete, turnkey systems to provide for the safe return of Pre-filled Injector Products through the United States Postal Service. All PureWay solutions are tested and permitted to USPS specifications as outlined in USPS Publication 52.

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

Appendix H¹⁰

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.

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 (except for certain services required pursuant to Ordinance § 4.116.050(b)(5)).

Appendix I

Request for Approval to Autoclave Pre-filled Injector Products

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE COUNTY OF SAN MATEO SAFE MEDICINE DISPOSAL ORDINANCE



January 31, 2018

MED-PROJECT REQUEST FOR APPROVAL TO AUTOCLAVE PRE-FILLED INJECTOR PRODUCTS COLLECTED UNDER THE COUNTY OF SAN MATEO SAFE MEDICINE DISPOSAL ORDINANCE

Pursuant to sections 4.116.070(c) and 4.116.110(f) of the County of San Mateo Safe Medicine Disposal Ordinance (the "Ordinance"), MED-Project, LLC ("MED-Project") respectfully requests approval from the Director of the Environmental Health Division ("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 San Mateo 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 § 4.116.070(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 requesting and petitioning for approval to use autoclaves to treat Pre-filled Injector Products, pursuant to Ordinance sections 4.116.070(c) and 4.116.110(f).

A. Ordinance Section 4.116.070(c)

Under Ordinance section 4.116.070(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 § 4.116.070(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 Prefilled 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 4.116.070(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. For these reasons, the use of autoclaves to treat Pre-filled Injector Products collected under MED-Project's Program should be approved under the petition process for alternative final disposal technologies under Ordinance section 4.116.070(c).

B. Ordinance Section 4.116.110(f)

Under Ordinance section 4.116.110(f), the Director may exercise its discretion to approve a proposed plan and waive strict compliance with the requirements of the Ordinance to achieve the objectives of the Ordinance. The Ordinance is intended to provide a safe and convenient collection system for unwanted medicine, and ensure unwanted medicine is properly handled, transported, and disposed of to protect the environment and human health.

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 the discretion granted in section 4.116.110(f) of the Ordinance and approve autoclaving as a treatment technology for Pre-filled Injector Products.

II. AUTOCLAVING

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

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.

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.

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.

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 California Medical Waste Management Act. Cal. Health & Safety Code § 118225(a). 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. SAN MATEO 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 4.116.070(c) and request under Ordinance section 4.116.110(f). The Director should approve MED-Project's proposed disposal technology under each standard because autoclaving is a widely-used means to dispose of sharps, including Pre-filled Injector Products; represents industry best practice; and is protective of the environment and human health, as explained further below.

A. San Mateo County Should Approve the Use of Autoclaving to Treat Pre-Filled Injector Products Under the Standard for Alternative Final Disposal Technologies at Ordinance Section 4.116.070(c).

The County should approve MED-Project's petition under Ordinance section 4.116.070(c) to autoclave Pre-filled Injector Products. Under Ordinance section 4.116.070(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 subsections (a) and (b) of this Section 4.116.070, or equivalent protection

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.

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.

at lesser cost.

Ordinance § 4.116.070(c). Subsections (a) and (b) of Ordinance section 4.116.070 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 § 4.116.070(c). Additionally, autoclaving is less expensive than incinerating these materials at a hazardous waste disposal facility or large municipal waste combustor.

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

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 4.116.070(c)(4).

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.

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)).

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).

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 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.

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. <u>Autoclaves must comply with all applicable emissions and waste monitoring laws and regulations.</u>

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

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).

established requirements for emissions and waste monitoring.

4. <u>As opposed to incineration, autoclaving would provide equivalent or superior protection</u> 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 from the autoclaving process is negligible provided facilities properly segregate their waste. 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.

B. San Mateo County Should Exercise its Discretion to Waive Strict Compliance with the Ordinance Under Ordinance Section 4.116.110(f) and Approve the Use of Autoclaving to Treat Pre-Filled Injector Products.

The Director should exercise its discretion under Ordinance section 4.116.110(f) to approve MED-Project's Plan and waive strict compliance with the disposal provisions of the Ordinance in order to achieve the Ordinance's goals of ensuring unwanted medicine is properly treated and

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.

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.

disposed of in a manner that is protective of the environment and human health.

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

MED-Project's proposed disposal process also adequately protects human health and safety because all Pre-filled Injector Products collected by MED-Project are containerized throughout the collection, transportation, autoclaving, and disposal process, dramatically reducing the chance that the workers or the public could be exposed to Pre-filled Injector Products. Accordingly, the use of an autoclave to treat Pre-filled Injector Products collected by MED-Project furthers the objectives of the Ordinance.

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 sections 4.116.070(c) and 4.116.110(f) of the Ordinance.

Appendix J

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 San Mateo's Ordinance 04736, codified at chapter 4.116 of Title 4 of the San Mateo County Ordinance Code (the "Ordinance") § 4.116.070(b), MED-Project LLC ("MED-Project") requests the Director of the Environmental Health Division's (the "Director's") approval to use the Covanta Huntsville, Inc. facility (the "Covanta Huntsville Facility") 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 COVANTA HUNTSVILLE FACILITY'S PROCESS FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES

MED-Project is proposing that Inhaler Mail-Back Packages will be pre-addressed and pre-paid for delivery to a transfer facility before transport to the Covanta Huntsville Facility for disposal.¹ The Covanta Huntsville Facility will scan the unique barcode on each Inhaler Mail-Back Package to record its receipt before incinerating it.

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.² 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.³ 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 Star facility by the U.S. Occupational Safety and Health Administration, recognizing the facility's employer's and employees' exemplary achievement in the prevention and control of occupational safety and health hazards.⁴

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

Under Ordinance § 4.116.070(b), "[t]he Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs [including inhalers] at a permitted large municipal waste combustor . . . if the Director deems the use of a hazardous waste disposal facility .

- The Covanta Huntsville Facility's mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.
- 2 See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, http://swdahsv.org/waste-to-energy/.
- 3 See Covanta, Covanta Huntsville, https://www.covanta.com/Our-Facilities/Covanta-Huntsville.
- 4 *Id.*; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

. . to be infeasible for the Stewardship Plan based on cost, logistics or other considerations."

III. THE USE OF THE COVANTA HUNTSVILLE FACILITY TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.070(b) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project proposes to use the Covanta Huntsville 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 a municipal waste combustor (the Covanta Huntsville 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 its 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 Covanta Huntsville Facility. 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

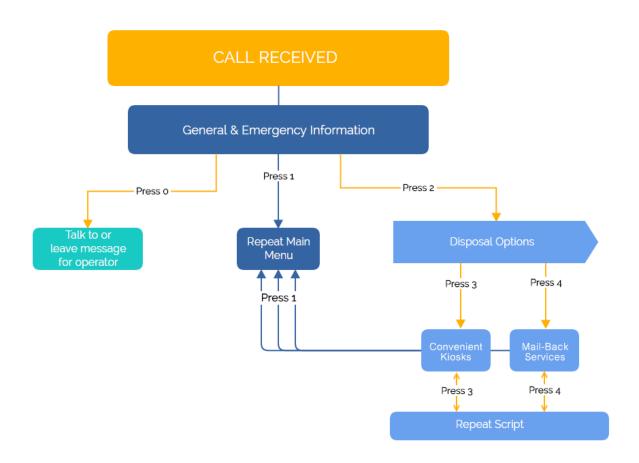
Accordingly, the Department should approve the disposal of Inhaler Mail-Back Packages at the Covanta Huntsville Facility as proposed by MED-Project under Ordinance § 4.116.070(b).

Appendix K

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 <u>press 0</u> at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and

- consumer disposal.
- MED-Project reminds you that taking your medicine as directed by your health care provider is critically important to your health.
- If you have questions about your medication, please hang up and dial your health care provider.
- For additional questions about the proper disposal of expired or Unwanted 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 <u>press 1</u>.
- Thank you for calling MED-Project.

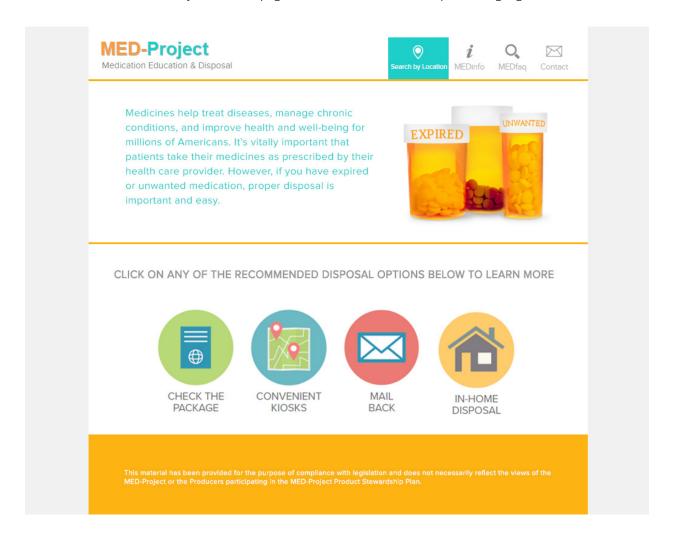
Mail-Back Services Script for when 4 is selected:

- Mail-Back Services are available to Residents who are disabled and home-bound or home
 healthcare professionals providing services to disabled and home-bound Residents. Mail-Back
 Services are also available to all Residents for Pre-filled Injector Products, inhalers, and iodinecontaining medications.
- 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 <u>press 1</u>.
- Thank you for calling MED-Project.

Appendix L

MED-Project Website

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













Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet.

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)







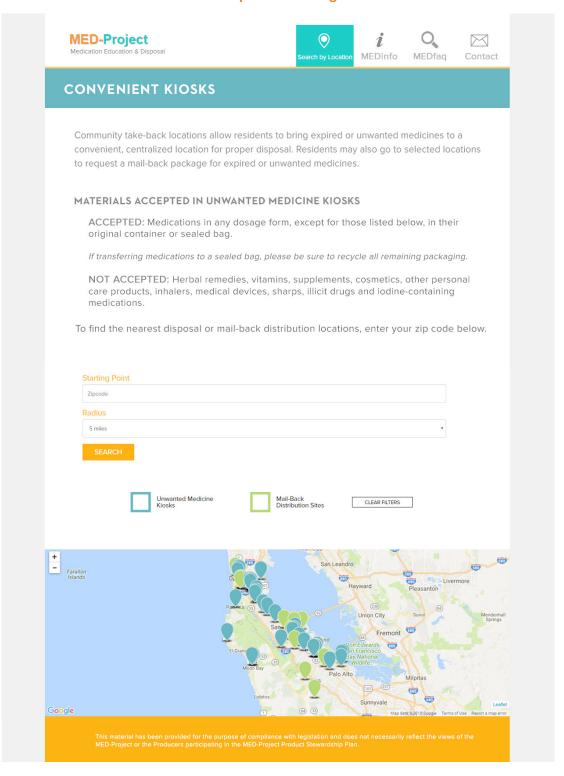
CONVENIENT

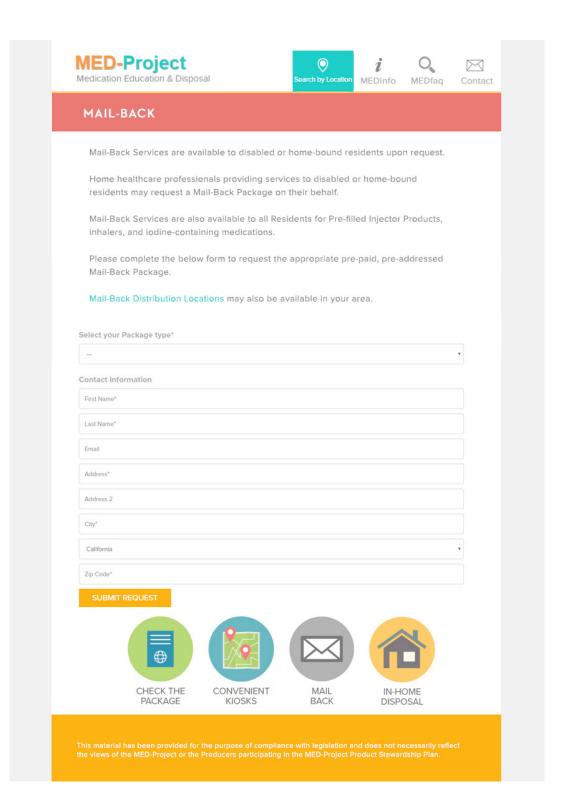


BACK



IN-HOME DISPOSAL















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	Chinese	Spanish	Tagalog
Frequently As	sked Questions:		
English	Chinese	Spanish	Tagalog
Mail-Back Pac	ckage Insert:		
English	Chinese	Spanish	Tagalog
English	Chinese	Spanish	Tagalog

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

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.













CONTACT

If you are experiencing a medical emergency, please call 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 call your health care provider.

查看本页面(中文) Ver esta página en español Tingnan ang page na ito sa Tagalog For answers to some frequently asked questions about MED-Project, click here.

Residents

If you are a resident of San Mateo County and have questions about MED-Project, please contact:

1-(844)-MED-PROJ or 1-(844) 633-7765

Pharmacies and Law Enforcement Offices

If you are a current kiosk drop-box host site, or a retail pharmacy, hospital/clinic pharmacy or law enforcement agency interested in hosting a drop-box, contact:

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

Drug Producers

If you are drug producer interested in participating in the 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 does not recessarily reflect the view of the MED-Project or the Producers participating in the MED-Project Plan.

Appendix M

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

www.med-project.org or call 1-844-MED-PROJ

What should you do with your expired or unwanted medicines?



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

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

(Source: U.S. Food and Drug Administration)



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

CHECK THE PACKAGE



If there are specific instructions for diposal on the label, package or package insert, please follow those instructions. Do not flush medicines down the sink or toilet.

CONVENIENT KIOSKS



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

What items can I dispose of at a kiosk? ACCEPTED: MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER OR SEALED BAG. If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

NOT ACCEPTED:

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

DISPOSAL OPTIONS

3 MAIL-BACK



Mail-back services are available to disabled and home-bound residents upon request. Visit www.med-project.org to order a mail-back package.

4 IN-HOME DISPOSAL



- 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 N

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
Asian Journal (Filipino)	San Bruno	http://asianjournal.com
Bayspo (Japanese)	San Francisco	http://www.bayspo.com
Foster City Islander	Foster City	http://www.fostercityislander.com
Half Moon Bay Review	Half Moon Bay	http://www.hmbreview.com
Korean Times	San Francisco	http://sf.koreatimes.com
Marina Times	San Francisco	http://www.marinatimes.com
Pacifica Tribune	Pacifica	http://www.pacificatribune.com
San Francisco Bay View	San Francisco	http://sfbayview.com
San Francisco Business Times	San Francisco	http://www.bizjournals.com/sanfrancisco/news/
San Francisco Chronicle	San Francisco	http://www.sfgate.com
San Francisco Examiner	San Francisco	http://www.sfexaminer.com
San Mateo County Times	San Mateo	http://www.mercurynews.com/san-mateo-county-times
San Mateo Daily Journal	San Mateo	http://www.smdailyjournal.com
San Jose Mercury News	San Jose	http://www.mercurynews.com
Sing Tao Daily (Chinese)	San Francisco	https://www.singtaousa.com/?variant=zh-hk&fs=16
The Recorder	Silicon Valley	http://www.therecorder.com
World Journal (Chinese)	San Francisco	http://www.worldjournal.com

Television Outlets	Network
KDTV	Univision
KEMO	Azteca America
KGO	ABC
KNTV	NBC
KPIX	CBS
KQED	PBS
KRON	Media General
KSTS	Telemundo

KTVU	FOX
Radio Outlets	Coverage Area
KALW FM 91.7	San Francisco
KCBS AM 740	San Francisco
KCSF (College app radio)	San Francisco
KGO AM 810	San Francisco
KQED FM 88.5	San Francisco
KSFO AM 560	San Francisco
KUSF (College online radio)	San Francisco

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
San Mateo County Sheriff's Office	/SMCSheriff	@SMCSheriff
San Mateo County Health System	/SMCHealth	@smchealth
Get Healthy San Mateo	/GetHealthySMC	@gethealthysmc
San Bruno Beacon	/San-Bruno-Beacon-128284043968223/	@SBBeacon
County of San Mateo	/sanmateoco	@sanmateoco
Half Moon Bay Review	/HMBreview	@hmbreview
Burlingame Police Department	/burlingamepolice/	@burlingamepd
City of Daly City	/dalycitygov/	@DalyCityGov
Daly City Police	/dalycitypolice	@DalyCityPD
Daly City Library	/DalyCityLibrary/	@dalycitylibrary
Daly City - Colma Chamber of Commerce	/dalycity.colmachamber	@dccchamber
Daly City Police Officers' Association	/DalyCityPOA	@DalyCityPOA
City of Brisbane	/brisbane94005	@brisbaneca
Brisbane Chamber of Commerce	/BrisbaneChamberofCommerce	@BrisbaneChamber
Brisbane Police Department	/BrisbanePD	N/A
Colma Police Dept.	/colmapolicedepartment	@ColmaPD
Town of Colma	/Colma-Recreation- Services-1542638555973194	@TownofColma
South San Francisco	/CityofSouthSanFrancisco	@CityofSSF
South San Francisco Police Dept.	/SouthSanFranciscoPoliceDepartment	@SSFPolice
South San Francisco Public Library	/ssfpubliclibrary	@SSFLibrary
South San Francisco Patch	/SouthSanFranciscoPatch	SSFPatch
City of San Bruno	/Sanbrunocommunityservicesdepartment	@CityofSanBruno
San Bruno Police Dept.	/San-Bruno-Police- Department-233146236745593	@SanBrunoPolice
San Bruno Beacon	/San-Bruno-Beacon-128284043968223	@SBBeacon
City of Pacifica	/cityofpacifica	@Pacifica
Pacifica Police Dept.	/Pacifica-Police- Department-718039501543161	@PacificaPolice
Pacifica Chamber of Commerce	/pacifica.chamber	@pacificacoc
Pacifica Tribune	/PacificaTribune	@PacificaTribune
Pacifica Patch	/PacificaPatch	@PacificaCAPatch
City of Millbrae	/City-of-Millbrae-637908862952645	N/A
Millbrae Police Dept.	/pages/Millbrae-Police- Department/112605438793771	N/A
Millbrae Chamber of Commerce	/MillbraeChamber	@MillbraeChamber

Outlet	Facebook	Twitter
Millbrae Patch	/MillbraePatch	@MillbraePatch
City of Burlingame	/BurlingameCityHall	@BurlingameCity
Burlingame News	N/A	@burlingame_news
Burlingame Chamber of Commerce	/BurlingameChamber	@VisitBurlingame
Burlingame Police Dept.	/burlingamepolice	@BurlingamePD
Burlingame Patch	/BurlingameHillsboroughCAPatch	@BurlingamePatch
Hillsborough Police Dept.	/HillsboroughPD	@HillsboroughPD
City of San Mateo	/cityofsanmateo	@CityofSanMateo
San Mateo Police Dept.	/CityofSanMateoPolice	@SanMateoPD
San Mateo Chamber of Commerce	/SanMateoChamber	@sanmateochamber
San Mateo County Health System	/SMCHealth	@SMCHealth
San Mateo Daily Journal	/smdailyjournal	@smdailyjournal
San Mateo News	N/A	@sanmateo_news
County of San Mateo	/CountyofSanMateo	@sanmateoco
San Mateo County Sheriff's Office	/SMCSheriff	@SMCSheriff
San Mateo City News	/SanMateoCountyNews	@sanmateoctynews
San Mateo Patch	/SanMateoPatch	@SanMateoPatch
City of Foster City	/CityofFosterCity	@CityofFC
Foster City Police	/FosterCityPolice	@FosterCityPD
Foster City News	N/A	@fostercitynews
Foster City Patch	/FosterCityPatch	@FosterCityPatch
City of Belmont Public Works Dept.	/CityofBelmontCA	@BelmontCA_PWORK
Belmont Police Dept.	/Belmont-Police- Department/165395370186926	@belmontcapolice
Belmont City Patch	/belmontcapatch	@BelmontCAPatch
City of San Carlos	/cityofsancarlos	@CityofSanCarlos
San Carlos Chamber of Commerce	N/A	@SanCarlosBiz
San Carlos Patch	/SanCarlosPatch	@SanCarlosPatch
San Carlos News	N/A	@sancarlos_news
Half Moon Bay Chamber of Commerce	/hmbchamber	@hmbchamber
Half Moon Bay Review	/HMBreview	@hmbreview
Half Moon Bay Patch	/HalfMoonBayPatch	@HMoonBayPatch
City of Redwood City	/cityofredwoodcity	@RedwoodCity
Redwood City Police Dept.	/RedwoodCityPD	@RedwoodCityPD
Redwood City Patch	/RedwoodCityWoodsideCAPatch	@RedwoodCPatch
City of Menlo Park	/CityofMenloPark	@CityofMenloPark
Menlo Park Police Dept.	/menloparkpd	@menloparkpd
Menlo Park Community Services	/menloparkcommunityservices	N/A
Menlo Park Patch	/MenloParkAthertonCAPatch/	@MenloParkPatch
Menlo Park Buzz	/Menlo-Park-Buzz-131027160272340	@menloparkbuzz

Outlet	Facebook	Twitter
City of East Palo Alto	/CityOfEastPaloAlto	@eastpaloalto
East Palo Alto Police Dept.	/EastPaloAltoPD	@epapd
Town of Atherton	/TownOfAtherton	@townofatherton
Atherton Police Officers Association	/AthertonPOA	N/A
Town of Woodside	/pages/Town-of-Woodside	N/A
Portola Valley	N/A	N/A
NCPP San Mateo		@ncppsanmateo
Redwood City News		@redwoodcitynow
Stanford Healthcare	/stanfordhealthcare	@StanfordHealth
San Bruno Beacon	/San-Bruno-Beacon-128284043968223/	@SBBeacon
San Mateo Patch	/SanMateoPatch	@sanmateopatch
San Mateo Times	/MercuryNews	@sanmateotimes