



San Mateo County MED-Project
Medication Education & Disposal

A Product Stewardship Plan For Unwanted Medicine From Households

San Mateo County, California
May 27, 2016

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I. Introduction

San Mateo County MED-Project LLC (“MED-Project”), on behalf of the participating companies identified in Appendix A, 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 households.

II. Stewardship Organization

The Pharmaceutical Product Stewardship Work Group (“PPSWG”), a group of pharmaceutical Producers, has established MED-Project as the Stewardship Organization to operate the Plan.

III. Contact Information

The primary contact person for the MED-Project is:

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San Mateo County MED-Project
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Washington, DC 20036
202-580-6291
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¹ All capitalized terms used but not otherwise defined herein shall have their respective meanings set forth in the Ordinance.

IV. Plan Definitions

County means the unincorporated and incorporated areas of the County of San Mateo²

DEA is the U.S. Drug Enforcement Administration.

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

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 Services is the provision of pre-paid, pre-addressed envelopes 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. Maintenance Technicians will be employed, managed, and directed by the MED-Project Vendor.

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

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

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

Stewardship Organization is an organization designated by a group of Producers to act as an agent on behalf of each Producer to operate a Product Stewardship Program.

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

Unwanted Medicine is defined in Section V of this Plan.

Vendor is Stericycle Environmental Solutions, Inc. (“Stericycle”), the collection and transportation vendor for this Plan.

² 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.*

V. Unwanted Medicine

For the purposes of the Plan, “Unwanted Medicine” includes all materials identified as “Covered Drugs” under Ordinance § 4.116.020(D). According to this provision of the Ordinance, Covered Drugs means “a Drug in any form used by County residents, including prescription, nonprescription, brand name and generic drugs.” § 4.116.020(D). County residents means “human beings residing in the county.” § 4.116.020(B). 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. 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);
- vii. Hard surface and toilet disinfectant cleaners;
- viii. Physician Administered Drugs - drugs administered in hospitals or other clinical settings whereby a patient never handles drug product;
- ix. 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);
- x. 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;
- xi. Compressed cylinders, aerosols, and inhalers;
- 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;
- xiv. Pre-loaded products with a sharp attached containing prescription or over the counter medications;
- xv. Auto injectors;
- xvi. Schedule I or other illicit drugs; and
- xvii. Iodine-containing medications.

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

VI. Collection of Unwanted Medicine

The MED-Project Plan provides services to collect Unwanted Medicine, including controlled substances, in pill, capsule, or liquid form. The collection methods and any 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 all 112 pharmacy and 24 LEA locations in the County of the opportunity to participate as a drop-off site. MED-Project continued outreach to these locations through calls and emails with the goal of establishing Kiosk Drop-Off Sites distributed as uniformly as possible throughout the County. As part of this outreach, MED-Project asked if the sites were interested in participating in the Program, whether the sites currently host a kiosk or other services for the disposal of residential Unwanted Medicine, whether pharmacies are DEA registered collectors, and if the sites would like more information regarding the Program.

LEAs that currently have drop-off sites in the County may transition into the Program pending compliance with all Program requirements. Existing drop-off sites are available at the following locations:

LEA drop-off sites:

1. Belmont Police Department
2. Brisbane Police Department
3. Burlingame Police Department
4. Daly City Police Department
5. Half Moon Bay Police Dept.
6. Hillsborough Police Department
7. Millbrae Police Bureau
8. San Mateo County Sheriff's North Coast Sub-Station
9. Pacifica Police Department
10. San Mateo County Sheriff's Office
11. San Bruno Police Department
12. San Carlos Police Bureau
13. San Mateo Police Department
14. South San Francisco Police Department

2. Implementation

Upon Plan approval, MED-Project will work with sites identified during outreach (see Section VI.A.1.) to obtain Kiosk Drop-Off Site Host signed agreements.

Participation in the Program is contingent upon compliance with all applicable laws, regulations, and other legal requirements and following the MED-Project collection processes provided in Section VI.B.4., including the use of the MED-Project Vendor. MED-Project will review any requests from an interested Program participant, such as an exception to the standard processes. More information on the agreements is provided in Section VI.B.1.

Collection of Unwanted Medicine will begin at Kiosk Drop-Off Sites once agreements have been signed with each location, kiosks have been installed in compliance with the DEA Rule, and, in the case of pharmacies, all DEA and California Board of Pharmacy requirements have been met.

3. Convenience

Kiosk Drop-Off Sites will be strategically placed across the County in order to best meet the service convenience goals established by the Ordinance, which include equitable access to a network of Kiosk Drop-Off Sites. This network will provide County residents a number of different outlets to participate in the Plan.

Per Ordinance § 4.116.050(b)(1), MED-Project will strive to establish at least one (1) Kiosk Drop-Off Site in each Supervisorial District for every 20,000 County residents, geographically distributed to provide reasonably convenient and equitable access for all County residents. MED-Project will work to establish a minimum of 5 Kiosk Drop-Off Sites in each Supervisorial District. In Supervisorial Districts where the minimum number of Kiosk Drop-Off Sites cannot be established, Take-Back Events shall be hosted in order to supplement the disposal of Unwanted Medicine by County residents in those areas.

Mail-Back Services shall be available upon request for differentially-abled or home-bound County residents, thereby offering more opportunities to dispose of Unwanted Medicine.

In addition to the Kiosk Drop-Off Sites, Take-Back Events, and Mail-Back Services outlined above, MED-Project shall operate a Kiosk Drop-Off Site within each County-owned pharmacy jointly with all other County approved Stewardship Plans.

4. Flexible Expansion

During initial stages of the Program, MED-Project will assess performance, gauge feedback, and revise its approach as appropriate. As implementation proceeds, MED-Project shall continue to approach organizations that may be available as future Take-Back Event or Kiosk Drop-Off Site Hosts. These organizations are listed in [Appendix B](#).

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

Take-Back Events shall supplement Kiosk Drop-Off Sites in Supervisorial Districts where the service convenience goals are not met through Kiosk Drop-Off Sites. As MED-Project establishes additional Kiosk Drop-Off Sites, the number of Take-Back Events will decrease in areas where the service convenience goals are met.

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

Mail-Back Services will be available to differentially-abled and home-bound County residents upon request and will be reviewed continuously for availability and effectiveness.

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 County residents a number of different outlets to participate in the Plan.

1. Kiosk Drop-Off Site Locations

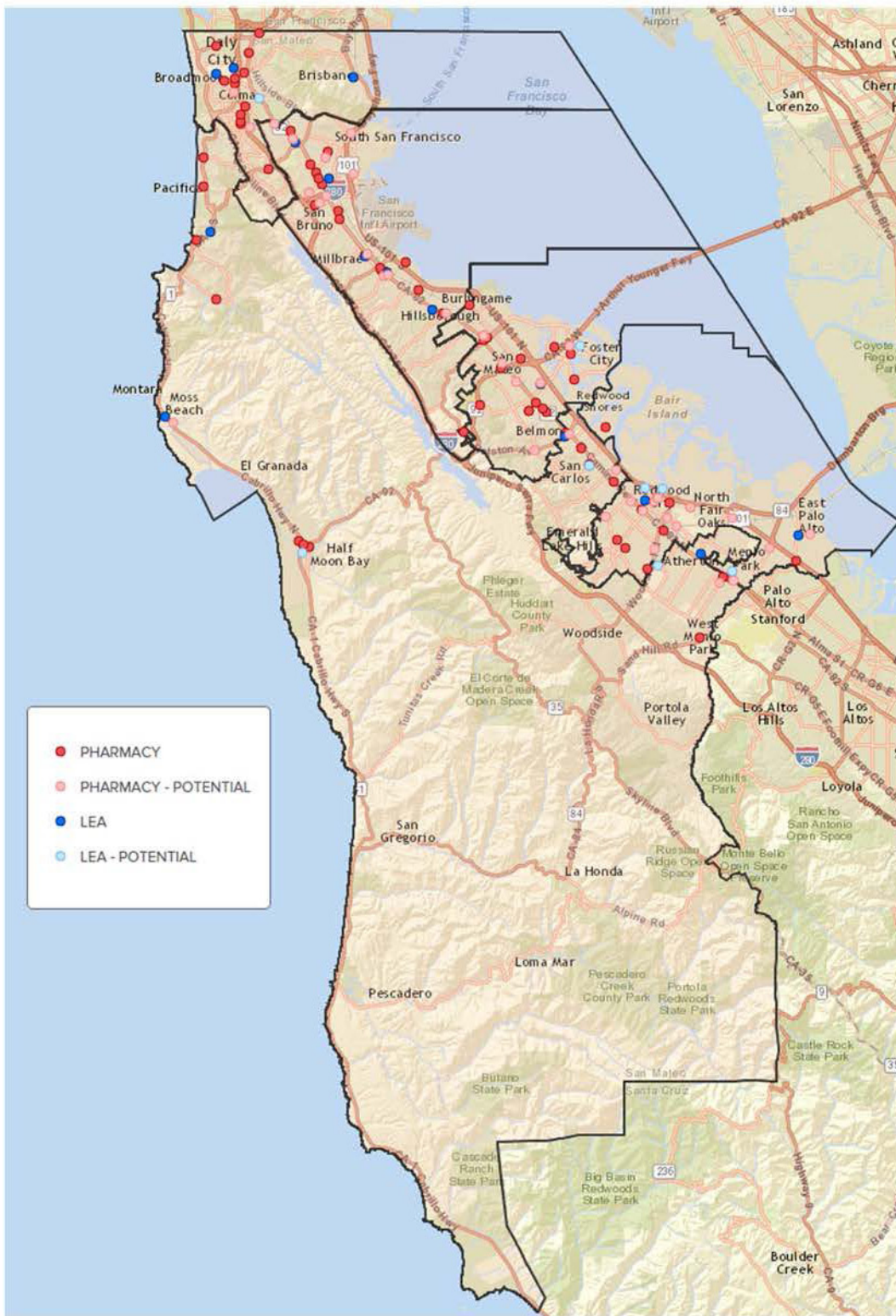
MED-Project contacted 24 LEAs and 112 pharmacies located in the County about the opportunity to serve as a Kiosk Drop-Off Site Host. Of the locations contacted, 15 LEAs and 65 pharmacies expressed interest in participating in the Program. These interested Kiosk Drop-Off Site Hosts are identified in [Appendix C](#). MED-Project will continue communicating with these locations during review of the Plan.

MED-Project has received expressions of interest from more potential Kiosk Drop-Off Site Hosts in every Supervisorial District than required and will contract with each location after Plan approval. A template for the MED-Project Kiosk Drop-Off Site Services Agreement can be found in [Appendix D](#).

District	Population	Available	Interested	Required
1	147,056	39	22	7
2	150,998	27	17	8
3	151,140	20	16	8
4	142,883	32	11	7
5	143,991	18	14	7
Total	736,068	136	80	37

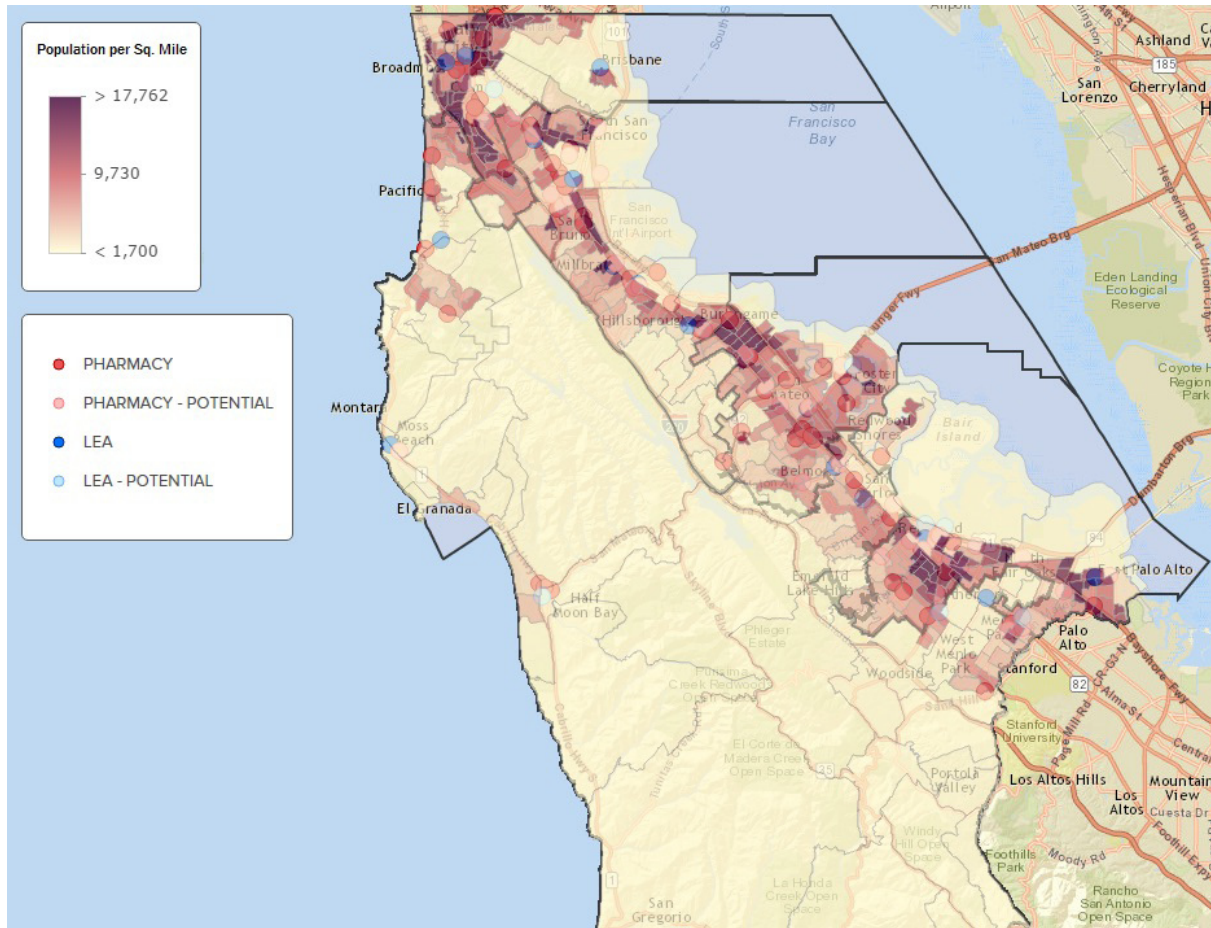
Number of interested Kiosk Drop-Off Site Hosts in each District.

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



MED-Project will continue outreach to potential Kiosk Drop-Off Site Hosts that had not expressed interest in Program participation as of Plan submission. These sites are listed in [Appendix E](#).

The majority of the population of San Mateo County lives in the northeast of the county along the Bay in Districts 1,2,4,and 5,or in the northwest along the coast in District 3. MED-Project has identified Kiosk Drop-Off Sites distributed evenly through each Supervisorial District except District 3. While MED-Project has identified more than the required number of pharmacies interested in participating in the Program in District 3, no Kiosk Drop-Off Sites have been identified in El Granada at the time of Plan submission. The following map shows the distribution of Kiosk Drop-Off Sites relative to population density in the County.



Within 120 days of Plan implementation, MED-Project will schedule a Take-Back Event in El Granada if a Kiosk Drop-Off Site has not been identified, and in any Supervisorial District where fewer than the required number of interested Kiosk Drop-Off Site Hosts sign an agreement to participate in the Program.

For more information on Take-Back Events, see Section VI.C.

As required under Ordinance § 4.116.050(b)(4), the Plan will include as a Kiosk Drop-Off Site any 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. Locations currently serving as a drop-off site may participate in the MED-Project Program by signing an agreement with MED-Project and modifying their DEA registration (if required). The process for modifying DEA registrations is outlined in Section XV.A.1. MED-Project will work with the Kiosk Drop-Off Site Host to transition to the program and Vendor.

2. Drop-Off Site Kiosk Placement and Maintenance Program

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

The maintenance program will address items such as:

- Periodic inspection of kiosks to monitor general wear and tear.
- Service Technician access to the kiosks during the regularly scheduled pick-ups and notification of a Maintenance Technician if necessary.
- Reporting of damage to a kiosk and maintenance service requests.

3. Kiosk Specifications

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 design of the pharmacy kiosk and proposed signage ([Appendix F](#)) 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.³ 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 over-flow once the container has reached its maximum level. 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 Rule⁴.

³ As discussed in Section XII, MED-Project will coordinate with other Product Stewardship Plans to develop clear standardized instructions for County residents to use kiosks and a consistent design. [Appendix F](#) provides the kiosk design and signage MED-Project expects to propose when coordinating with other Product Stewardship Plans.

⁴ 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."

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 identification number for tracking purposes.

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

4. Kiosk Collection

Under § 1317.05(c)(2)(iv), pharmacy Kiosk Drop-Off 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 requirements for illicit controlled substances evidence pursuant to § 1317.35. Law enforcement will record the following information at Kiosk Drop-Off Sites using inner liners: the unique identification number of the sealed inner liner and the 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 drop-off site collection system complies with these DEA requirements for pharmacy and LEA Kiosk Drop-Off Sites. Vendor, pharmacies, and LEAs participating in the Plan will keep all records required under the DEA Rule, including those required under §§ 1304 and 1317.35. Pharmacy Kiosk Drop-Off Sites and the 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 County residents attempt to deposit. See Section VI.B.2. LEA kiosks will be located inside the LEA's physical location. See Section VI.B.2.

Pick-up of Unwanted Medicine collected at Kiosk Drop-Off Sites will be scheduled for all Kiosk Drop-Off Sites, year-round, based on their regular business hours and volume collected. When arriving at a Kiosk Drop-Off Site, the kiosk will be reviewed by the Service Technicians for any damage. If damage is found, the Service Technician will note the need for repair via an electronic reporting log. This electronic report will be transmitted to a Maintenance Technician who will respond to repair requests.

Unwanted Medicine will be securely removed from the kiosk by Service Technicians and Kiosk Drop-Off Site employees following Standard Operating Procedures meeting all DEA requirements, such as those outlined in the template Kiosk Drop-Off Site Services Agreement attached as Appendix E. Specifically, two Kiosk Drop-Off Site employees will hold the two keys to unlock the kiosk. Once the kiosk is unlocked, these two employees will remove the kiosk inner liner and immediately and effectively seal it. The inner liner provided in the kiosk will be opaque to prevent visual recognition of the contents. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Under the supervision of two Kiosk Drop-Off Site employees, the Service Technicians will take the sealed inner liner to a secure vehicle for containment. The inner liner (already marked with a permanent and unique identification number) will be recorded for tracking. The inner liner will then be placed in a container for shipment. This shipping container will be marked with a unique barcode label to track the container to the disposal site. The shipping container will be secured with a tamper evident seal to prevent removal of any material during transport.

5. Disposal of Kiosk Contents

The Vendor shall manage the Unwanted Medicine from Kiosk Drop-Off Sites in compliance with all applicable laws, regulations, and other legal requirements.

Pursuant to § 1317.95, two Vendor employees will transport Unwanted Medicine directly to the destruction facility (constantly moving toward the destruction facility without unnecessary, unrelated, or extended stops). Two Vendor employees will load and unload, or observe the loading and unloading, of the Unwanted Medicine at the destruction facility. Two Vendor employees will also handle or observe the handling of the Unwanted Medicine at the destruction facility until it is rendered non-retrievable, personally witnessing destruction.⁵

All shipments containing the Unwanted Medicine will be transported via permitted ground haulers of waste in compliance with all applicable laws, regulations, and other legal requirements. The Vendor will utilize leased vehicles to manage the service of the Kiosk Drop-Off Sites. All vehicles will be permitted and maintained by the Vendor. Permits will comply with all applicable laws, regulations, and other legal requirements for shipment of the Unwanted Medicine. All Unwanted Medicine will be destroyed no later than 30 calendar days after receipt. See Section XI.B. for additional details.

All Vendor employees who participate in the Program are trained to meet all applicable laws, regulations, and other legal requirements. All haulers will adhere to all applicable security requirements and will be monitored periodically by the Vendor's managers to ensure compliance of each hauler. All shipping containers will be destroyed in their intact, closed state at a disposal facility identified in Section XI.B. Following disposal, a Certificate of Disposal ("COD") will be retained via electronic copy.

⁵ Section 1317.35 applies LEA storage and transfer requirements not to the LEA itself, but instead to "[a]ny controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle . . ." § 1317.35(c), (d). (emphasis added). Thus, the storage and transfer of Unwanted Medicine collected by LEAs will also comply with the LEA requirements outlined above.

6. Frequency of Pick-Up

Initially, all Kiosk Drop-Off Sites will be scheduled for a monthly pick-up from the kiosk. The Vendor will communicate with the Kiosk Drop-Off Site in the event the frequency of pick-up needs to be changed based on the volumes collected over time. It is anticipated that the average site will generate up to 40 pounds of Unwanted Medicine per service, per Kiosk Drop-Off Site. The Vendor will monitor the exact volumes per service to ensure that all sites are receiving the appropriate service frequency. The Vendor will manage services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Kiosk Drop-Off Site. Moreover, the Vendor will monitor the weight of Unwanted Medicine generated at each participating Kiosk Drop-Off Site via an electronic catalog.

The proposed electronic catalog is Vendor's proprietary software system that also allows for tracking of service data not available in the standard required shipping paperwork. This software system will provide the opportunity for Service Technicians to communicate the need for kiosk repairs and other relevant information to ensure the most effective management of the Program. This information will be transmitted electronically within 24 hours of a service event to the Vendor. These Vendors will direct communications to necessary personnel to provide response and support of the needs of the participating Kiosk Drop-Off Sites.

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

The kiosk provided to the Kiosk Drop-Off Site will contain a visual indicator to notify the Kiosk Drop-Off Site Host if the kiosk is full. Upon such notification that the kiosk is full, the Kiosk Drop-Off Site Host shall lock the drop-slot to the kiosk and notify the Vendor of the need for service if prior to the scheduled service date.

The Vendor shall provide a network of trained Service Technicians. The Vendor will communicate this request to field managers responsible for Service Technicians. The 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, the Vendor will be able to respond within hours of the request. If the request does not require an urgent response, the Vendor will plan the response within 2 to 3 business days of the request. The Vendor will not exceed one business week from the initial request. In the interim, pharmacy Kiosk Drop-Off Site Hosts shall be instructed to have two employees remove and immediately seal the inner liner in accordance with the DEA requirements outlined above if DEA storage requirements can be met. These sealed inner liners will be stored in accordance with the requirements of § 1301.75(c), which provides for storage at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access. LEAs will store collected controlled substances in a manner preventing diversion and consistent with that agency's standard procedures for storing illicit controlled substances. See § 1317.35(c).

8. Unplanned Event Preparedness

The Vendor maintains a network of emergency responders that can be contacted in the case of an emergency or spill incident. Vendor ensures service providers operate in compliance with all applicable laws, regulations, and other legal requirements through a qualification process. This process reviews the compliance history, management structure, financial stability, and other key indicators of a reliable emergency response service provider. This system ensures that all participating vendors in the Program will meet the requirements as outlined in the Ordinance. Emergency responders will bring all necessary equipment in order to manage the specific needs of the Kiosk Drop-Off Site requiring emergency response. Responders will be trained to access and remove a damaged kiosk if necessary. The responders will also be trained to adhere to all security requirements of the Program.

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 remove the kiosks within the affected area. Once all repairs are completed at the site, MED-Project will coordinate with the site to install a new kiosk.

Along with major event preparedness, the Vendor provides timely responses to events that may cause an inconvenience to the Kiosk Drop-Off Sites. 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 the Vendor via the dedicated phone number identified below. The Vendor is able to respond within two to three (2-3) 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, the Vendor will respond to a service location within one to two (1-2) business days of the event.

Personal items inadvertently dropped into the kiosk (*i.e.* dentistry, watch, keys, wallet, etc.) will not be retrieved.

C. Take-Back Events

90 days after implementation of the Program, MED-Project will conduct a gap assessment of established Kiosk Drop-Off Sites. 30 days after the gap assessment, MED-Project will schedule a Take-Back Event in any Supervisorial District where the service convenience goals are not met through Kiosk Drop-Off Sites. Take-Back Events will take place throughout the year, and MED-Project will continue to schedule an annual Take-Back Event in any Supervisorial District where the service convenience goals have not been met.

Based upon fully executed contracts with supervising LEAs, MED-Project will confirm to the County the locations and dates to conduct Take-Back Events for the first year of the Program. Targeted events can be viewed in [Appendix G](#). Federal, state, tribal, or local law enforcement shall be in attendance at all Take-Back Events. As stated in the goals (*see* Section VII), it is the intention of MED-Project to conduct Take-Back Events in order to supplement drop-off sites as they are implemented across the County. MED-Project will select the location of the Take-Back Events based upon demographics, current Kiosk Drop-Off Sites, and other population diversity characteristics to maximize County resident access to the events and best meet the service convenience goals. In general, MED-Project will work to conduct the Take-Back Events in coordination with other scheduled events (*i.e.*, Earth Day celebrations, Health and Wellness Fairs) to maximize convenience to County residents.

MED-Project will evaluate existing Kiosk Drop-Off Sites and scheduled Take-Back Events on an on-going basis to ensure that the service convenience goals are met. Due to the continuously changing schedule of Take-Back Events, the list of take-back dates and locations will be maintained on the MED-Project website as events are scheduled.

1. Method

MED-Project will work with participating LEAs to ensure Take-Back Events are compliant and successful. All events will be promoted and communicated to the public through local communication channels as outlined in [Appendix H](#).

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

2. Procedures

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

Under § 1317.65(c), all Take-Back Events should have at least one collection receptacle, and such receptacles should be securely locked, substantially constructed containers with an outer container and removable inner liner as specified in § 1317.65(c). The outer container should include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents. Vendor and the LEA will maintain all records of removal, storage, or destruction of the collected Unwanted Medicine in a manner consistent with the LEA's recordkeeping requirements for illicit controlled substances evidence pursuant to § 1317.35. Law enforcement should record the following information at Take-Back Events using inner liners: the unique identification number of each sealed inner liner transferred to Vendor, size of the sealed inner liner transferred to Vendor, date each sealed inner liner is transferred to Vendor, the Vendor's name and address, and the Vendor's DEA registration number. See § 1317.35. Any collected Unwanted Medicine should be stored to prevent the diversion of controlled substances and in a manner consistent with the LEA's standard procedures for storing illicit controlled substances. Any storage of Unwanted Medicine by Vendor will also comply with the applicable security requirements of §§ 1301 and 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances. Unwanted Medicine collected by the LEA will be transferred to the disposal facility following the procedures outlined in Section VI.B.5. All Unwanted Medicine will be destroyed no later than 30 calendar days after receipt.

Take-Back Events will typically be staffed by at least three Vendor employees. Vendor will work in coordination with MED-Project, the County, and local law enforcement to monitor and ensure collection of all material at Take-Back Events is compliant with all applicable laws, regulations, and other legal requirements and meets the published expectations of the planned event. Vendor will work in conjunction with local law enforcement to ensure all material is placed in a compliant collection receptacle and securely shipped to meet all applicable laws, regulations, and other legal requirements. Any material that is not Unwanted Medicine or does not meet legal requirements will be rejected.

Following the completion of each event, containers will be securely packaged, labeled, and shipped in compliance with all applicable laws, regulations, and other legal requirements. Containers and inner liners will be tracked via unique barcodes to a disposal facility identified in Section XI.B., where they shall be incinerated. Vendor will ship the containers (and inner liners) in accordance with all applicable laws, regulations, and other legal requirements.

3. Fees and Costs

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

D. Mail-Back Services

MED-Project will provide Mail-Back Services at no cost to differentially-abled and home-bound County residents. Mail-back packages will be pre-paid and pre-addressed, and Mail-Back Services shall comply with all applicable laws, regulations, and other legal requirements. Pursuant to DEA Rule § 1317.70(c), the mail-back packages will be:

- nondescript and without any markings or information potentially indicating that they contain Unwanted Medicine, including controlled substances;
- water and spill-proof, tamper-evident, tear-resistant, and sealable;
- pre-addressed with and delivered to the Vendor's registered address;
- pre-paid;
- provided a unique identification number 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 the 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 Mail-Back Services to dispose of Unwanted Medicine. See § 1317.70(d). MED-Project may implement a system under which ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property may notify the Vendor they are mailing a mail-back package simply by providing the mail-back package's unique identification number. See § 1317.70(d). As required under § 1317.70(e), the Vendor will only accept mail-back packages it made available by mail (or packages lawfully forwarded under DEA requirements). Within three business days of receipt, the Vendor will notify the DEA if it receives mail-back packages likely containing controlled substances that the Vendor did not make available or did not agree to receive pursuant to DEA requirements. In accordance with § 1317.70(f), when mail-back packages are received, only employees of the Vendor will handle the mail-back packages. Mail-back packages will not be opened, x-rayed, analyzed, or otherwise penetrated upon receipt by Vendor. See § 1317.70(f). The Vendor will keep all records required under the DEA Rule, including those identified in § 1304.22(f):

- For mail-back packages made available: date, number made available, and unique identification number;
- For mail-back packages received: date received and unique identification number; and
- For mail-back packages destroyed: number of mail-back packages destroyed, date and method of destruction, unique identification number, and names and signatures of two registrant employees that witnessed destruction.

1. Mail-Back Package Availability

Differentially-abled or home-bound County residents may request mail-back packages by calling the call center or through a link on the MED-Project website. Home healthcare professionals providing services to differentially-abled or home-bound County residents may also request mail-back packages on behalf of a County resident through the call center or through a link on the MED-Project website. Upon such request, Vendor shall provide mail-back packages complying with DEA requirements.

Each mail-back package will contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in English, Spanish, Chinese, and Tagalog. See [Appendix I](#) for a sample package.

2. Mail-Back Package Collection and Disposal

Requests to receive mail-back packages will be taken through the call center and a link on the MED-Project website. Vendor will track packages utilizing First Class Mail through the United States Postal Service. All packages shall be logged upon shipment to County residents as well as upon delivery at the approved disposal facility using a unique barcode. County residents will be directed to follow the instructions provided in the mail-back package and to place their Unwanted Medicine in the pre-addressed/pre-paid package. The USPS estimates up to three business days for delivery of First Class Mail. The mail-back package shall be sent to the approved disposal facility listed in Section XI.C.1. Once arriving at the disposal facility, the mail-back packages shall be scanned for receipt verification and then rendered non-retrievable. After this destruction, any remaining mail-back package materials are incinerated at the disposal facility listed in Section XI.C.2. See [Appendix J](#) for more details. Any storage of filled mail-back packages by Vendor will comply with the applicable security requirements of DEA Rule Section 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances. All Unwanted Medicine will be destroyed promptly.

VII. 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 VI.A.2.

MED-Project anticipates that establishment of Kiosk Drop-Off Sites will begin in November of 2016 and continue throughout the year. Due to the shortened year, the Program expects to collect approximately one quarter of the normal volume of Unwanted Medicine during 2016. Once all drop-off locations are fully operational, the program expects to collect approximately 480 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 17,760 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2017. See section VI.B. for more information about Kiosk Drop-Off Site collection.

MED-Project anticipates a continued need in 2017 to supplement Kiosk Drop-Off Sites in a few Supervisorial Districts through Take-Back Events. Based on take-back event collection totals in Alameda County, MED-Project anticipates collection of approximately 200lbs of Unwanted Medicine per take-back event.

MED-Project mail-back packages have a capacity of 8oz. per package. Due to the targeted distribution of mail-back packages to differentially-abled and home-bound County residents and a lack of information available from current MED-Project Programs, Med-Project’s estimated collection totals in 2016 could vary based on actual usage. Collection in 2016 will be used to adjust subsequent years’ collection goals.

Data from 2017 will be utilized to establish baseline collection and estimate collection goals for future years.

Anticipated Collection Amounts (Lbs.):		
Collection Method	2016	2017
Kiosk Drop-Off Sites	3,840	17,160
Take-Back Events	600	600
Mail-Back Services	400	1600
Pounds Collected	4,840	19,360

Goal Area	Short-Term	Long-Term
Collection	Approximately 4,840 pounds of Unwanted Medicine collected through Kiosk Drop-Off Sites, Take-Back Events, and Mail-Back Services.	<p>Approximately 19,360 pounds of Unwanted Medicine collected through Kiosk Drop-Off Sites, Take-Back Events, and Mail-Back Services.</p> <p>Increased reliance on established Kiosk Drop-Off Sites and a limited amount of collection through Take-Back Events.</p>
Education & Public Outreach	<p>Develop baseline number of website page views or unique visitors.</p> <p>Establish a baseline of LEAs; retail pharmacies; other pharmacies (healthcare, etc.); community groups; and other third parties contacted, and report appropriate statistics as outlined in the Survey and Annual Report sections of this Plan.</p> <p>Establish a baseline number of media outlets receiving press advisory, with a minimum of five outlets.</p> <p>Establish a baseline percentage of community centers reached.</p> <p>Establish a baseline number of messages to MED-Project returned within predetermined timeframe.</p>	<p>On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan.</p> <p>MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the Stewardship Plans, assess to what extent Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Results of the review will be published on the website established under Section XII.D.2.</p>
Collector Outreach	Contact LEAs and retail pharmacies and invite them to participate in the Plan. Set targets for LEAs and retail pharmacies.	Ongoing communication with pharmacies and LEAs. Continuous evaluation of Kiosk Drop-Off Sites against the Service Convenience Goals.

VIII. Patient Privacy

Instructions at each kiosk 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 personally identifiable information.

For those people who do not follow the directions on the kiosk, the Vendor has additional protections available for keeping personally identifiable information safe and secure. Service Technicians are well-trained in managing items containing sensitive patient information. Privacy training is part of a Service Technician's prerequisite for field services. As added protection, the liners for the kiosk will be opaque rather than clear, in compliance with the DEA Rule. This will prevent anyone, including the Service Technician, from seeing any information on the containers placed in the kiosks.

Signage at Take-Back Events will inform County residents 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 collection receptacle. Materials to help County residents cross out any personally identifiable information will also be available at the event. This will ensure any patient information on drug packaging will be unreadable.

IX. Call Center

Questions from County residents will be managed by a call center with an interactive voice response (IVR) system and the support of an operator available during business hours of 9:00am to 5:00pm PST Monday through Friday. If the operator is unavailable, a caller will be able to leave a message to which the operator will respond. All operators would be 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;
2. Disposal options;
3. Direction to the Program website for additional information; and
4. Requests for mail-back packages.

At this time MED-Project is unaware of any other Stewardship Organizations that intend to submit a Stewardship Plan in the County. Per Ordinance § 4.116.060, MED-Project will operate a call center jointly with all other Stewardship Programs should other Stewardship Plans be approved by the County.

X. Training

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

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

- Onboarding & on-truck observation of job functions – five days
- DOT Training – two days
- DEA Training – one day
- EPA Waste Characterization – one day
- OSHA Training – one day
- Waste Handling Demo – one day
- Truck Operation – one day
- DEA Handling Demo – one day
- Review & Written Test – one day
- Perform work under supervision to demonstrate proficiency prior to certification to service client accounts – ten days

A. Service Technician Training

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

- United States Department of Transportation (“DOT”) hazardous materials requirements;
- United States Environmental Protection Agency (“EPA”) waste characterization requirements;
- Resource Conservation and Recovery Act (“RCRA”) hazardous waste requirements;
- DEA controlled substances transfer protocols;
- Occupational Safety and Health Administration (“OSHA”) requirements; and
- Health Insurance Portability and Accountability Act (“HIPAA”) requirements.

Upon completion of the initial two-week training period, new hires are assigned to a trained senior technician for two-weeks to perform client services under direct supervision. At the end of this second two-week period, the new hires are formally evaluated to determine whether they can independently perform client services.

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 Take-Back Events, Kiosk Drop-Off Sites, or mail-back collection will have a training base similar to that of Service Technicians, with customized training as needed.

XI. Transporter and Disposal Facility Information

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

1. Primary Transporter

- Name: **Stericycle** will service Kiosk Drop-Off Sites and Take-Back Events and transport the Unwanted Medicine to a permitted hazardous waste incinerator.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: 612-285-9865
- DOT ID Number: MNS 000 110 924
- US DOT Number: 1348411
- Permit Status: All relevant permits are active and in good standing. Available upon request.
- Penalty Record (5 years): See [Appendix K](#)

2. Secondary Transporter

- Name: **21st Century Environmental Management of California** will, alternatively, service Kiosk Drop-Off Sites and Take-Back Events and transport the Unwanted Medicine to a permitted hazardous waste incinerator.
- Address: 11855 White Rock Rd. Rancho Cordova CA 95742
- Phone: (916) 351-0980
- DOT ID Number: CA 0406131
- US DOT Number: 2059497
- Permit Status: All relevant permits are active and in good standing. Available upon request.
- Penalty Record (5 years): None

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

1. Primary Disposal Facility

- Name: **Clean Harbors - Aragonite**
- Addresses: 3 Miles E 7 Miles N of Knolls, Wendover, UT 84083
- Phone: 435-884-8900
- Website: www.cleanharbors.com
- Type: Permitted Hazardous Waste Incinerator
- EPA ID: UTD981552177
- Permit Status: Active
- Penalty Record (5 years): See [Appendix K](#)
- How will this facility be used: This facility will be utilized to incinerate Unwanted Medicine recovered from Kiosk Drop-Off Sites.

2. Secondary Disposal Facility

- Name: **Veolia – Port Arthur**
- Addresses: 7665 Texas Highway 73, Beaumont, TX 77705
- Phone: 409-736-2821
- Website: www.veolianorthamerica.com
- Type: Permitted Hazardous Waste Incinerator
- EPA ID: TXD000838896
- Permit Status: Active
- Penalty Record (5 years): See [Appendix K](#)
- How will this facility be used: This facility will be utilized to incinerate Unwanted Medicine recovered from Kiosk Drop-Off Sites and Take-Back Events.

C. Disposal Facility for Unwanted Medicine from Mail-Back Services

1. Primary Disposal Facility

- Name: **Stericycle, Inc., Indianapolis, Indiana Facility** (“Stericycle Facility”)
- Addresses: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: 317-275-7530
- Website: www.stericycleenvironmental.com
- Type: DEA-compliant and registered collector facility
- DEA Registration No.: RS0331607
- RCRA Permit No: INR000110197
 - o Permit Status:
 - i. A Hazardous Waste: RCRA Part B. Permit Number: INR00010197. Expiration: 1/7/2016 (submitted for renewal in July 2015, pending approval).
 - ii. Solid Waste: Processing Facility. Permit Number: FP 49-57. Expiration: 8/3/2020.
 - iii. Air Quality: Exempt. Permit Number: E097-28740-00671. Expiration: N/A.
 - o Penalty Record (5 years): See [Appendix K](#)
- This facility will be utilized to render mail-back packages and the controlled substances therein non-retrievable.

2. Secondary Disposal Facility

- Name: **Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility** (“Covanta Facility”)
- Address: 2320 S. Harding St., Indianapolis, IN 46221
- Phone Number: 317-634-7367
- Website: <http://www.covanta.com/facilities/facility-by-location/indianapolis.aspx>
- Type: Municipal Waste Combustor
- Title V Air Permit No.: T097-5985-00123
- Industrial Wastewater Discharge Permit No.: 495301
- Solid Waste Permit No.: 49-13
- Permit Status: All permits are current
- Penalty Record (5 years): See [Appendix K](#)
- This facility will be utilized to incinerate non-retrievable materials from the Stericycle Facility

Ordinance § 4.116.070(b) provides that the Director may approve the use of a permitted large municipal waste combustor if the Director “deems the use of a hazardous waste disposal facility . . . to be infeasible for the Stewardship Plan based on cost, logistics or other considerations.” As described in [Appendix J](#), permitted hazardous waste disposal facilities are not available to accept mail-back packages at this time. Thus, MED-Project is proposing a two-phase process using the Stericycle Facility and Covanta Facility to dispose of mail-back packages. Under this two-phase process, mail-back packages are accepted at the Stericycle Facility and rendered non-retrievable on-site. The non-retrievable mail-back package materials are then shipped for incineration to the Covanta Facility, a municipal waste combustor providing energy-from-waste incineration.

MED-Project’s request for approval to use this two-phase process for mail-back package disposal resulting in destruction at a municipal waste combustor was submitted in conjunction with this Plan (see as [Appendix J](#)).

XII. Unwanted Medicine Educational and Outreach Programming

A. Overview

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

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

At this time MED-Project is unaware of any other Stewardship Organizations that intend to submit a Stewardship Plan in the County. As required by Ordinance § 4.116.060, MED-Project will seek to coordinate with other Stewardship Programs to develop a single system of promotion if other Stewardship Plans are approved by the County and the Director provides the required “guidance on the development of a single system of promotion.”

B. Audiences

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

- General public
- Pharmacies, including education for dispensers of Unwanted Medicine
- Retailers of Unwanted Medicine
- Health care providers and their patients
- Veterinary providers and animal owners
- Law enforcement agencies

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

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 all identified demographics. Efforts to ensure that materials are appropriately targeted, translated, and available to these populations will be pursued with associations, agencies, and organizations that can be viewed in [Appendix B](#).

C. Messages

MED-Project messaging will focus on two main goals:

- Educating County residents about the appropriate use, storage, and disposal of Unwanted Medicine, and;
- Providing County residents with clear steps to properly manage the disposal of their Unwanted Medicine, including following instructions found on the medicine label, use of Kiosk Drop-Off Sites, participation in Take-Back Events, and, where no disposal instructions are given on the drug labeling and a take-back program is not available, in-home disposal.

Key points of emphasis will include:

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

D. Tools/Communications Channels

The MED-Project Program will include a number of components designed to reach consumers and provide consistent access to timely and relevant information. Distribution of materials will include audiences such as LEAs, pharmacies, health care providers and systems, health associations, local government agencies, and other community organizations and will be evaluated continuously for effectiveness. Tools and communication channels will include:

1. Phone

MED-Project will provide a toll-free telephone number (1-844-MED-Proj) for County residents to obtain information about Kiosk Drop-Off Sites, educational materials, and other aspects of the Plan for Unwanted Medicine from households. The toll-free number will provide:

- IVR support for English and Spanish. The telephone line will also provide an option for callers to be transferred to a staffed call center.
- Basic information about how the Plan works, where to obtain more information (e.g., the website), and an option to talk with an operator in English or Spanish to find a Kiosk Drop-Off Site or Take-Back Event in the caller's ZIP code or local area.
- A recorded call script directing callers with medical emergencies to call 911 and directing patients with medication-related questions to contact their health care provider(s).

Please see [Appendix L](#) for a sample template of the recorded call script. MED-Project will work to expand IVR support to include Chinese and Tagalog.

2. Website

Upon Plan approval, MED-Project will develop a mobile-friendly website with translations in Spanish, Chinese, and Tagalog. Information available to users will include locations of Kiosk Drop-Off Sites, educational materials, frequently asked questions and responses, Take-Back Event dates and locations, and results of the most recent survey of Plan awareness.

- The website will be available within 60 days of Plan approval. The Plan currently includes a sample mockup of the website and its supporting pages. [Appendix M](#) provides a proof of concept for each page.
- The website will also include access to a public relations toolkit in a downloadable format (see Section XIV.D.3) and contact information for County Residents. A toolkit available on the website includes a flyer/brochure (See [Appendix N](#)), a public service announcement available in broadcast and audio versions ([Appendix N](#)), and a frequently asked questions (FAQ) document ([Appendix N](#)) which will be reviewed and updated periodically. Translations of the brochure and FAQ will be available in Spanish, Chinese, and Tagalog.
- Community and government organizations and other public interest groups seeking materials to promote the Program will be encouraged to access these resources.

3. Materials

Educational materials about the Program and describing how to properly dispose of Unwanted Medicine will be available through the website, at Take-Back Events, through potential third party partners, community organizations, and at Kiosk Drop-Off Sites. These partners will include pharmacies, health care facilities, and veterinary facilities. MED-Project will also provide local governments with materials covering the proper disposal of Unwanted Medicine.

The Plan includes a sample of the educational brochure ([Appendix N](#)) and media advisory promoting Take-Back Events ([Appendix O](#)). Educational materials use plain language and explanatory images to promote consumer education and collection options to County residents with limited English proficiency.

4. Media Outreach

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

- Please see [Appendix L](#) for a sample education and outreach call script with the toolkit including flyers in [Appendix N](#) and website information included in [Appendix M](#).
- Please see [Appendix H](#) for a sample list of key media outlets.
- Please see [Appendix P](#) for a sample list of social media outlets.
- Please see [Appendix O](#) for a sample template media advisory announcing Take-Back Events.

E. Collaboration with County Officials and Community Organizations

MED-Project will work in collaboration with the County as appropriate to build on existing community outreach resources, such as local organizations, media lists, available public media outlets, etc. The following will be initiated upon Plan approval:

- *Briefing Materials Provided to Support Coordination with County Officials:*
 - o MED-Project will provide access to Educational and Outreach Programming materials, including the sample brochure (see [Appendix N](#)), to relevant departments and officials.
- *Outreach through Community Organizations:*
 - o MED-Project will further promote the Plan by engaging relevant stakeholders and community organizations, for example, by providing community organizations identified in [Appendix B](#) with the toolkit included in [Appendix N](#).

F. Disclaimer

The written and verbal educational materials and public outreach tools that are required by the Ordinance and disseminated under this Product Stewardship Plan will include a disclaimer similar to the following: “The material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the MED-Project or individual producers.”

XIII. Survey

Per Ordinance § 4.116.060(a)(4), MED-Project will conduct a biennial survey of County residents, pharmacists, veterinarians, and health professionals who interact with members of the community after the first full year the Stewardship Plans are operating.

Survey questions will be designed to measure, at a minimum, (1) percent awareness of the Plans, (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 thirty days prior to distribution. Results of the survey will be reported to the Director and made public on the website described under Section XII.D.2. The privacy of all survey respondents will be maintained.

The biennial survey will be conducted in English, Spanish, Chinese, and Tagalog.

At this time MED-Project is unaware of any other Stewardship Organizations that intend to submit a Stewardship Plan in the County. Per Ordinance § 4.116.060(c), MED-Project will seek to coordinate with other Stewardship Programs to conduct the survey if other Stewardship Plans are approved by the County and the Director provides the required “guidance on the development of a single system of promotion.”

XIV. 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 and Take-Back Events: a waste stream for drug packaging and a waste stream for the drugs themselves.

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

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

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

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

The Ordinance requires that a Product Stewardship Plan describe how all entities participating in the Plan 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 Plan shall comply with all applicable laws, regulations, and other legal requirements.

A. DEA Controlled Substances Act and Implementing Regulations

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

Under the DEA Rule, collection of controlled substances is limited to Schedule II, III, IV, or V controlled substances that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property. See DEA Rule §§ 1317.75(b) (Kiosk Drop-Off Sites)⁶; 1317.65(d) (Take-Back Events); 1317.70(b) (Mail-Back Services). Schedule I controlled substances, controlled substances that are not lawfully possessed as described above, and other illicit or dangerous substances will not be collected. Additionally, as these provisions of the DEA Rule limit collection of controlled substances to those lawfully possessed by an ultimate user or certain other persons, pharmacies are prohibited from disposing their own inventory or stock through the MED-Project Program. See also § 1317.05.

The DEA Rule provides that LEAs can continue to accept controlled substances for disposal. However, the DEA Rule also provides that pharmacies, reverse distributors, hospitals/clinics with on-site pharmacies, 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 MED-Project Product Stewardship Plan is designed such that all entities that are part of the Plan, including Vendor, are individually responsible to comply with their respective compliance obligations under the DEA Rule. Vendor will ensure that the transportation of Unwanted Medicines collected from Kiosk Drop-Off Sites and Take-Back Events, including controlled substances, complies with all DEA requirements, including those in § 1317.

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

⁶ For Kiosk Drop-Off Site collection, only certain substances "that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected." §1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent's property. See §§ 1317.65(d); 1317.70(b).

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 work with participating pharmacies to educate them as to how to modify their registrations.

B. California Board of Pharmacy

MED-Project will comply with any rules promulgated by the California Board of Pharmacy.

XVI. 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 Plan;
- The amount, by weight, of Unwanted Medicine collected, including the amount by weight from each collection method used (Kiosk Drop-Off Sites, Take-Back Events, and Mail-Back Services);
- A list of Kiosk Drop-Off Sites;
- The number of mailers provided for differentially-abled and home-bound County residents, and the zip codes where mailers were provided;
- The dates and locations of Take-Back Events held;
- Transporters and disposal facilities used;
- Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Medicine and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and improve safety and security;
- A description of public education, outreach, and evaluation activities implemented;
- A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- A summary of the Product Stewardship Plan's goals, the degree of success meeting these goals in the past year, and how these goals will be achieved in the next year if they were not met; and
- The Plan's total expenditures.

Appendix A

MED-Project Participants

The Pharmaceutical Product Stewardship Work Group (“PPSWG”), a group of pharmaceutical Producers, has established a limited liability company, San Mateo County MED-Project LLC (“MED-Project”), as the Stewardship Organization for the Plan. The Participants in MED-Project are provided to the County on an on-going basis. The list was last submitted on May 27, 2016.

Appendix B

Sample Contact List for Outreach and Education to the Community

The following are Associations, Agencies, and Organizations that will be contacted for assistance with outreach and education to the community. They will also be contacted to participate as potential future Kiosk Drop-Off Sites or Take-Back Event sponsors. MED-Project will also contact existing drop-off sites.

Health Systems:

County of San Mateo Health System
San Mateo Medical Center
Kaiser Permanente Medical Center
Lucile S. Packard Children's Hospital
Mills-Peninsula Health Services
Sequoia Hospital
Seton Medical Center
Stanford Hospitals and Clinics
Stanford Medicine Outpatient Center
Veterans Affairs Palo Alto Health Care System
San Bruno VA Outpatient Clinic

Health Associations and Societies:

California State Board of Pharmacy
California Pharmacists Association
The Medical Board of 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
California Health and Human Services Agency
San Mateo County Pharmacists Association
San Mateo County Medical Association

Organizations, Districts, and Agencies:

San Mateo Department of Public Health
San Mateo Public Works
Human Services Agency of San Mateo
University Systems and Campuses
San Mateo Fire Department
American Medical Response San Mateo
CalRecycle
Recology
RecycleWhere.org

Appendix C

Kiosk Drop-Off Sites with Expressions of Interest

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

Below is a list of locations that have expressed interest in participating as a Kiosk Drop-Off Site. The pharmacy and LEA responses below reflect information provided by the pharmacists surveyed as of May 20, 2016. Chain pharmacy interest expressed was at the local pharmacy level. Chain pharmacy participation could be contingent upon agreement with regional and national offices. MED-Project will continue to outreach and work within the corporate structure where applicable.

SITE NAME	ADDRESS	CITY	DISTRICT	TYPE
A & O PENINSULA PHARMACY	1828 EL CAMINO REAL STE 104	BURLINGAME	1	PHARMACY
BURLINGAME POLICE DEPARTMENT	1111 Trousdale Drive	BURLINGAME	1	LEA
CARE4U PHARMACY	474 SAN MATEO AVENUE	SAN BRUNO	1	PHARMACY
CHOICECARE PHARMACY INC	90 S SPRUCE STE W	S SAN FRANCISCO	1	PHARMACY
CVS/PHARMACY #09807	10 BAYHILL SHOPPING CTR	SAN BRUNO	1	PHARMACY
CVS/PHARMACY #09811	1871 EL CAMINO REAL	BURLINGAME	1	PHARMACY
CVS/PHARMACY #09899	186 EL CAMINO REAL	S SAN FRANCISCO	1	PHARMACY
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16439	1150 EL CAMINO REAL	SAN BRUNO	1	PHARMACY
HILLSBOROUGH POLICE DEPARTMENT	1600 Floribunda Ave	HILLSBOROUGH	1	LEA
LUCKY PHARMACY #748	1322 EL CAMINO REAL	SAN BRUNO	1	PHARMACY
MILLBRAE POLICE BUREAU	581 Magnolia Avenue	MILLBRAE	1	LEA
PMC PHARMACY	843 MALCOLM RD	BURLINGAME	1	PHARMACY
SAN BRUNO POLICE DEPARTMENT	1177 Huntington Avenue	SAN BRUNO	1	LEA
SOUTH SAN FRANCISCO POLICE DEPARTMENT	33 Arroyo Drive	SOUTH SAN FRANCISCO	1	LEA
SUNSHINE CENTER PHARMACY	1166 MISSION RD	S SAN FRANCISCO	1	PHARMACY
WALGREENS #00625	615 BROADWAY	MILLBRAE	1	PHARMACY
WALGREENS #02939	333 EL CAMINO REAL	SAN BRUNO	1	PHARMACY
WALGREENS #03346	399 EL CAMINO REAL	SOUTH SAN FRANCISCO	1	PHARMACY
WALGREENS #06655	1160 BROADWAY	BURLINGAME	1	PHARMACY
WALGREENS #07970	45 SOUTH EL CAMINO REAL	MILLBRAE	1	PHARMACY
WALGREENS #12257	260 EL CAMINO REAL	BURLINGAME	1	PHARMACY
WALGREENS #15397	2238 WESTBOROUGH BLVD	SOUTH SAN FRANCISCO	1	PHARMACY
BELMONT POLICE DEPARTMENT	One Twin Pines Lane	BELMONT	2	LEA

CVS/PHARMACY #09554	77 BOVET RD	SAN MATEO	2	PHARMACY
CVS/PHARMACY #09833	4242 S EL CAMINO REAL	SAN MATEO	2	PHARMACY
CVS/PHARMACY #09879	987 E HILLSDALE BLVD	FOSTER CITY	2	PHARMACY
CVS/PHARMACY #09940	872 N DELAWARE ST	SAN MATEO	2	PHARMACY
CVS/PHARMACY #09977	124 DE ANZA BLVD	SAN MATEO	2	PHARMACY
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16490	2220 BRIDGEPOINTE PKWY	SAN MATEO	2	PHARMACY
LUCKY PHARMACY #710	919 EDGEWATER DR	FOSTER CITY	2	PHARMACY
MARINER ADVANCED PHARMACY CORP	43 E 3RD AVE	SAN MATEO	2	PHARMACY
RITE AID 5902	666 CONCAR DRIVE	SAN MATEO	2	PHARMACY
RITE AID 5903	1320 W HILLSDALE BLVD	SAN MATEO	2	PHARMACY
SAN MATEO MEDICAL CENTER	222 W. 39TH AVE	SAN MATEO	2	PHARMACY
SAN MATEO NEIGHBORHOOD PHARMACY	9 37TH AVENUE	SAN MATEO	2	PHARMACY
SAN MATEO POLICE DEPARTMENT	200 Franklin Parkway	SAN MATEO	2	LEA
WALGREENS #00063	900 RALSTON AVE	BELMONT	2	PHARMACY
WALGREENS #03296	191 EAST 3RD AVE	SAN MATEO	2	PHARMACY
WALGREENS #05006	4070 S EL CAMINO REAL	SAN MATEO	2	PHARMACY
ATHERTON POLICE DEPARTMENT	83 Ashfield Road	ATHERTON	3	LEA
CVS/PHARMACY #0550	1324 SAN CARLOS AVE	SAN CARLOS	3	PHARMACY
CVS/PHARMACY #9172	11 EL CAMINO REAL	SAN CARLOS	3	PHARMACY
CVS/PHARMACY #9216	60 CABRILLO HWY N	HALF MOON BAY	3	PHARMACY
CVS/PHARMACY #9330	325 SHARON PARK DR	MENLO PARK	3	PHARMACY
FEEL GOOD COMPOUNDERS	411 DONDEE WAY, UNIT C	PACIFICA	3	PHARMACY
HALF MOON BAY PHARMACY	40 STONE PINE RD STE I	HALF MOON BAY	3	PHARMACY
LUCKY PHARMACY #749	1133 OLD COUNTRY RD	SAN CARLOS	3	PHARMACY
PACIFICA POLICE DEPARTMENT	2075 Coast Hwy	PACIFICA	3	LEA
RITE AID 5885	170 SAN MATEO ROAD	HALF MOON BAY	3	PHARMACY
RITE AID 5890	1400 LINDA MAR BLVD	PACIFICA	3	PHARMACY
RITE AID 5891	200 FAIRMONT SHOP CENT	PACIFICA	3	PHARMACY
SAN MATEO COUNTY SHERIFF'S NORTH COAST SUB-STATION	500 California Avenue	MOSS BEACH	3	LEA
WALGREENS #02126	1414 EL CAMINO REAL	SAN CARLOS	3	PHARMACY
WALGREENS #07087	643 SANTA CRUZ AVE	MENLO PARK	3	PHARMACY
WALGREENS #11261	520 PALMETTO AVE	PACIFICA	3	PHARMACY
CVS/PHARMACY # 10240	700 EL CAMINO REAL	MENLO PARK	4	PHARMACY
CVS/PHARMACY #09690	1301 BROADWAY ST	REDWOOD CITY	4	PHARMACY
CVS/PHARMACY #9329	1039 EL CAMINO REAL	REDWOOD CITY	4	PHARMACY
DREW CENTER PHARMACY	2111B UNIVERSITY AVENUE	EAST PALO ALTO	4	PHARMACY

EAST PALO ALTO POLICE DEPARTMENT	2415 UNIVERSITY AVE	EAST PALO ALTO	4	LEA
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16112	2485 EL CAMINO REAL	REDWOOD CITY	4	PHARMACY
JEFFERSON PLAZA PHARMACY (NOW RITEAID)	3137 JEFFERSON AVE	REDWOOD CITY	4	PHARMACY
NOB HILL PHARMACY #628	270 REDWOOD SHORES PARKWAY	REDWOOD CITY	4	PHARMACY
RITE AID 5892	340 WOODSIDE PLAZA	REDWOOD CITY	4	PHARMACY
RITE AID NO 5893	2150 ROOSEVELT AVE	REDWOOD CITY	4	PHARMACY
WOODSIDE OFFICE OF THE SHERIFF	400 County Center, 3rd Floor	REDWOOD CITY	4	LEA
1800 SULLIVAN PHARMACY (Now CVS)	1800 SULLIVAN AVE STE 102	DALY CITY	5	PHARMACY
BRISBANE POLICE DEPARTMENT	50 Park Place	BRISBANE	5	LEA
BROADMOOR POLICE DEPARMENT	388 Eighty - Eighth Street	BROADMOOR	5	LEA
CHINESE HOSPITAL PHARMACY	386 GELLERT BLVD, SUITE A	DALY CITY	5	PHARMACY
CVS/PHARMACY # 10165	135 PIERCE STREET	DALY CITY	5	PHARMACY
CVS/PHARMACY #9752	375 GELLERT BLVD	DALY CITY	5	PHARMACY
DALY CITY POLICE DEPARTMENT	333 90th St.	DALY CITY	5	LEA
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16111	5001 JUNIPERO SERRA BLVD	COLMA	5	PHARMACY
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16746	133 SERRAMONTE CTR	DALY CITY	5	PHARMACY
LUCKY CALIFORNIA PHARMACY # 707	6843 MISSION BLVD	DALY CITY	5	PHARMACY
NEMS - EASTMOOR PHARMACY	211 EASTMOOR AVE	DALY CITY	5	PHARMACY
WALGREENS #00324	216 WESTLAKE CENTER	DALY CITY	5	PHARMACY
WALGREENS #01807	22 SAN PEDRO RD	DALY CITY	5	PHARMACY
WALGREENS #05365	6100 MISSION STREET	DALY CITY	5	PHARMACY

Appendix D

Template Agreement

**TEMPLATE AGREEMENT:
UNWANTED MEDICINE KIOSK DROP-OFF
SITE SERVICES FOR PHARMACIES AND LAW
ENFORCEMENT AGENCIES**

This Kiosk Services Agreement, including as amended, supplemented or otherwise modified from time to time (the “Agreement”) is entered into between San Mateo MED-Project LLC (“MED-Project”) and [NAME OF DROP-OFF SITE HOST] (each individually, a “Party,” collectively the “Parties”).

Introductory Statement

The County of San Mateo, California, approved the County of San Mateo Safe Medicine Disposal Ordinance for the disposal of household pharmaceutical products in 2015 (the “Ordinance”). Subsequent to approval of the Ordinance, the MED-Project Product Stewardship Plan, which, among other things, provides for the use of kiosks at drop-off sites to collect Unwanted Medicine (defined below) from San Mateo households, was reviewed and approved by San Mateo.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Definitions. The following terms shall have the respective meanings set forth below:

- 1.1. “Applicable Laws” shall mean all applicable federal, state, county, and local laws, statutes, ordinances, codes, rules, regulations, orders, decrees, guidance or pronouncements of any governmental, administrative or judicial authorities including, but not limited to, the County of San Mateo Safe Medicine Disposal Ordinance §§ 4.116.010 through 4.116.190 *et seq.* (2015), federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, U. S. Drug Enforcement Administration controlled substances disposal regulations, 21 C.F.R. §§ 1300 *et seq.*, and any amendments or modifications to these legal requirements.

- 1.2. “DEA” shall mean the U.S. Drug Enforcement Administration.
- 1.3. “Effective Date” shall mean the date defined in Section 21 of this Agreement.
- 1.4. “Emergency Requests” shall mean requests for Services in Section 3.2 of this Agreement in response to any events, situations, activities or circumstances that pose a risk or potential risk of harm or injury to property or persons.
- 1.5. “Host” shall mean [NAME OF HOST]
- 1.6. “Host Collection Site” shall mean the site(s) listed in Exhibit A.
- 1.7. “Kiosk(s)” shall mean DEA-compliant receptacles: (i) used for the collection of Unwanted Medicine (as defined below); (ii) identified in Exhibit B of this Agreement; and (iii) provided by MED-Project.
- 1.8. “Losses” shall mean any costs, expenses, damages or diminution of value.
- 1.9. “Manager” shall mean the individual(s) identified in Exhibit C.
- 1.10. “Plan” shall mean the approved MED-Project Product Stewardship Plan.
- 1.11. “Services” shall mean the obligations identified in Section 3.2 of this Agreement.
- 1.12. “Service Technicians” shall mean the employees designated by Vendor to perform the obligations of Service Technicians in the Standard Operating Procedures, provided as Exhibit D.
- 1.13. “Termination Date” shall mean the date this Agreement terminates pursuant to Sections 8.1.1 through 8.1.5 of this Agreement.
- 1.14. “Vendor” shall mean the qualified vendor contracted by MED-Project and identified further in Exhibit E, including any vendor substituted by MED-Project for the initial Vendor.
- 1.15. “Unwanted Medicine” shall have the same meaning as “Unwanted Medicine” under Section V of the Plan.

2. Representations and Warranties.

- 2.1. Host hereby represents and warrants as follows:
 - 2.1.1. Host possesses all required permits, licenses and qualifications required under Applicable Laws (i) to collect, handle, process and dispose of Unwanted Medicine pursuant to the terms

of this Agreement, and (ii) to collect Unwanted Medicine in such manner as may be required by Applicable Laws and the terms of this Agreement. Host is currently, and shall remain, in compliance with all such permits, licenses and qualifications.

- 2.1.2. Host possesses all required authorizations to enter into this Agreement and this Agreement has been duly authorized and executed by Host in compliance with all required authorizations.
- 2.1.3. Host's execution, delivery, and performance of this Agreement does not, and will not, conflict with any agreement, instrument or understanding to which Host is a party or by which it may be bound.
- 2.2. MED-Project hereby represents and warrants for itself, and to the extent applicable, with respect to Vendor, as follows:
 - 2.2.1. Vendor possesses all required permits, licenses and qualifications required under Applicable Laws to collect, handle, process and dispose of Unwanted Medicine. Vendor is currently, and shall remain, in compliance with all such permits, licenses and qualifications.
 - 2.2.2. MED-Project possesses all required authorizations and corporate authority to enter into this Agreement and this Agreement has been duly authorized and executed by MED-Project in compliance with all required corporate authorizations.
 - 2.2.3. MED-Project's execution, delivery, and performance of this Agreement does not, and will not, conflict with any agreement, instrument or understanding to which MED-Project is a party or by which it may be bound.

3. Services.

- 3.1. Host, Vendor, and MED-Project shall perform all obligations required of them under this Agreement in compliance with Applicable Laws.
- 3.2. MED-Project, through the Vendor, shall:
 - 3.2.1. If the Manager requests a Kiosk from MED-Project, and MED-Project approves the Kiosk request, within 120 days of the approval deliver a Kiosk to Host at a time mutually agreed to by both Parties and when the Manager is present;
 - 3.2.2. Assist Host with installation of the Kiosk if: (1) requested to do so by the Manager; (2) Host Collection Site provides adequate space for

installation of the Kiosk; and (3) the Manager is present at Host Collection Site at the time of Kiosk installation;

- 3.2.3. Review and inspect the Kiosk when Vendor collects Unwanted Medicine from the Kiosk;
 - 3.2.4. Perform maintenance of the Kiosk if requested by the Manager or deemed necessary by Vendor or MED-Project;
 - 3.2.5. Remove Kiosk(s) from Host Collection Site if a replacement Kiosk is scheduled for delivery pursuant to Section 3.2.1 of this Agreement;
 - 3.2.6. Remove Kiosk(s) from Host Collection Site if this Agreement terminates pursuant to Section 8 of this Agreement;
 - 3.2.7. Supply Kiosk(s) with liners in accordance with the Standard Operating Procedures provided in Exhibit D; liners must meet the requirements of Applicable Laws, including, but not limited to, 21 C.F.R. §§ 1300 *et seq.*;
 - 3.2.8. Provide Host with a regular schedule for the collection of Unwanted Medicine from Kiosk(s) and notify the Manager in advance of any changes to this schedule;
 - 3.2.9. Collect Unwanted Medicine in accordance with the schedule identified in Section 3.2.8 of this Agreement or upon request by the Manager and approval by MED-Project;
 - 3.2.10. Conduct collection under Section 3.2.9 of this Agreement in accordance with the Standard Operating Procedures provided in Exhibit D;
 - 3.2.11. Respond to Emergency Requests from Host;
 - 3.2.12. Transport and dispose of Unwanted Medicine collected from Kiosk(s) in accordance with all Applicable Laws and the Plan.
- 3.3. Vendor shall be solely responsible for providing all such Services in Section 3.2. Host agrees to look solely to Vendor for such Services. MED-Project shall have the right on 30 days' prior notice to the Manager to change the Vendor. In such a case, the new entity that becomes the Vendor will be responsible under this Agreement for Services required of Vendor from and after the date of such change.
 - 3.4. Host shall allow MED-Project, through its Vendor, to provide the Services in Section 3.2 of this Agreement at Host Collection Site and shall cooperate with MED-Project and its Vendor in the provision of these Services. Such cooperation includes, but is not limited to:
 - 3.4.1. Identifying a Manager at Host Collection Site;
 - 3.4.2. Requesting Kiosk(s) from MED-Project

within 30 days of the Effective Date of this Agreement and if a Kiosk delivered pursuant to Section 3.2.1 of this Agreement becomes damaged or malfunctions and cannot be repaired by Vendor;

- 3.4.3. Providing adequate space for the installation of Kiosk(s) in compliance with Applicable Laws and making the Manager present at Host Collection Site at the time of Kiosk installation;
- 3.4.4. Notifying Vendor of any Kiosk maintenance concerns or needs, including, but not limited to, any damage to or malfunction of a Kiosk;
- 3.4.5. Notifying Vendor if a Kiosk is full;
- 3.4.6. Ensuring Host employees, including the Manager, perform all of their obligations in the Standard Operating Procedures provided as Exhibit D (including when collection is performed pursuant to Emergency Requests), and;
- 3.4.7. Labeling Kiosk(s) with the signage provided by MED-Project and identified in Plan Appendix F. Host shall not alter the design or appearance of Kiosk(s).

4. Payment.

- 4.1. Host shall not be responsible for paying the charges of Vendor for the Services Vendor renders under Section 3.2 of this Agreement.

5. Nature of the Relationship.

- 5.1. Each Party is entering into and will perform the activities contemplated by this Agreement solely as an independent entity. This Agreement does not create any other relationship between the Parties, or with Vendor, including but not limited to the relationship of partners, joint venturers, or agent or legal representative of the other for any purpose whatsoever. Neither Parties will (i) make any representation that would create an apparent agency, partnership or joint venture relationship with the other Party or with Vendor, (ii) have the power, expressed or implied, to obligate or bind the other or the Vendor in any manner whatsoever, or (iii) be responsible for any act or omission of the other or the Vendor or any employee of the other or of the Vendor. No employee of Host, MED-Project or the Vendor is or will be considered an employee of the other Party or the Vendor for any purpose in connection with the performance of this Agreement.

6. Report of Theft or Diversion.

- 6.1. In the event of any theft or diversion of Unwanted

Medicine collected at a Kiosk, or environmental incident, including spills and releases reported to any governmental authority, occurring during performance of this Agreement, the Party that becomes aware of such condition or event shall notify the other Party immediately.

7. Indemnification.

- 7.1. To the fullest extent permitted by law, MED-Project shall defend, indemnify, and hold harmless Host from and against all Losses to the extent arising out of or related to any and all third party claims, liabilities, liens, demands, obligations, actions, proceedings, suits or causes of action to the extent arising out of or related to MED-Project's (a) breach of this Agreement, or (b) sole negligence, recklessness or willful misconduct.
- 7.2. Notwithstanding the foregoing language in Section 7.1, MED-Project shall not be liable for Losses under Section 7.1 to the extent such Losses arise out of or related to Host's (a) breach of this Agreement, or (b) sole negligence, recklessness, or willful misconduct.

8. Term, Termination.

- 8.1. The term of this Agreement shall commence as of the Effective Date and shall continue in force until:
 - 8.1.1. Notice from Host to MED-Project of MED-Project's breach of this Agreement. This Agreement shall terminate immediately upon such notice.
 - 8.1.2. Notice from MED-Project to Host of Host's breach of this Agreement. This Agreement shall terminate immediately upon such notice.
 - 8.1.3. Notice from either Party to the other Party that this Agreement is terminated without cause. This Agreement shall terminate seven days after such notice.
 - 8.1.4. If the representations and warranties set forth in Section 2.1 or 2.2 cease to continue to be correct, or DEA issues a notice, guidance, regulation or other communication applicable to Host, Vendor or MED-Project making it reasonable to conclude that activities contemplated by this Agreement are viewed by DEA as impermissible or a violation of Applicable Laws, this Agreement shall terminate immediately.
 - 8.1.5. Two years from the Effective Date, unless the Termination Date is extended pursuant to Section 14 of this Agreement.
- 8.2. Compliance with Section 3.2.6 of this Agreement

shall be MED-Project's sole financial obligation with respect to any termination of the Agreement.

9. Severability.

9.1. In the event any provision of this Agreement shall be judicially interpreted or held to be void or otherwise unenforceable as written, such provision shall be deemed to be revised and modified to the extent necessary to make it legally enforceable. In the event that a provision cannot be made legally enforceable, the remaining terms of this Agreement shall be enforceable as though the void or unenforceable provision did not exist.

10. Assignment/Subcontracting.

10.1. Except as expressly contemplated under this Agreement, neither Party shall assign or subcontract any of its duties or obligations hereunder or assign this Agreement or its rights hereunder without the express written permission of the other Party, such consent not to be unreasonably withheld. Any assignment, delegation or subcontracting in violation of the above shall be void and ineffective. Notwithstanding this or any other provision of this Agreement, MED-Project shall have the right at any time to substitute Vendors by notifying Host in writing of such change.

11. Survival.

11.1. The obligations set forth in Sections 5, 7, 8.2, and 17 shall survive termination of this Agreement.

12. Third Party Beneficiaries.

12.1. Except as specifically set forth herein, nothing in this Agreement, express or implied, is intended or shall be construed to confer upon or give to any person, entity, company or organization, other than Host or MED-Project, any right, remedy, cause of action or claim under or by reason of this Agreement or any term or provision hereof, all of which shall be for the sole and exclusive benefit of Host and MED-Project.

13. Notice.

13.1. All notices to be provided in connection with this Agreement, including "requests" in sections 3.2.1, 3.2.2, 3.2.4, 3.2.9, and 3.4.2 of this Agreement, shall be in writing. Notices shall be deemed effective (i) when delivered by hand to the Party entitled to receive notice, (ii) on the next business day after delivery to a nationally-recognized express delivery service with instructions and payment for overnight

delivery, or (iii) upon confirmation of receipt when sent by e-mail.

13.2. All notices in connection with this Agreement shall be sent to the individual or individuals that each Party designates to receive such correspondence on behalf of the Party. Initially, notices shall be provided, if to MED-Project, to:

[MED-PROJECT CONTACT]

and if to Host, to:

[HOST CONTACT]

14. Complete Agreement, Headings, Modification.

14.1. This Agreement, along with its Exhibits, sets forth the complete agreement of the Parties with respect to the subject matter hereof. No prior or contemporaneous oral or written agreement or representation shall be effective to modify the express terms of this Agreement. Headings have been inserted for the convenient reference of the Parties and shall not be used to modify or interpret the express terms of the Agreement. No modification to this Agreement shall be valid unless it is made in writing, specifically states that it amends this Agreement, and is signed by authorized representatives of both Parties.

15. Signatures.

15.1. This Agreement is legally binding when, and not until, each Party has received from the other a counterpart of this Agreement signed by an authorized representative. The Parties may sign separate, identical counterparts of this document; taken together, they constitute one Agreement. The signed counterpart may be delivered by any reasonable means, including electronic transmission.

16. Jurisdiction and Venue.

16.1. This Agreement is made and entered into in California and shall be interpreted and construed in accordance with the laws of California. The Parties submit to the exclusive jurisdiction of California state and federal courts.

17. Publicity/Disclosure.

17.1. Unless required by law, neither Party may disclose the terms or subject matter of this Agreement to any third party, without the prior written consent of

the other Party, except that MED-Project or Host may provide this Agreement to the San Mateo Environmental Health Division and/or San Mateo County Counsel and Vendor.

- 17.2. Neither Party shall use the name, trade name, service marks, trademarks, trade dress or logos of the other Party in releases, advertising or any other publications, without such Party's prior written consent in each instance; except that either Party is authorized to use the other Party's name, trade name and logo with regard to public outreach and educational efforts taken with regard to the Plan. This provision applies to written and online releases and communications, including those appearing on a website and those circulated via social media platforms including, but not limited to, Facebook, Twitter, and LinkedIn.

18. Authority.

- 18.1. Each individual executing this Agreement in a representative capacity represents and warrants that he or she is duly authorized to execute and deliver this Agreement on behalf of the Party and its employees and that upon execution, this Agreement shall be binding upon the Party and its employees in accordance with its terms.

19. Anti-Bribery.

- 19.1. MED-Project shall, at all times, comply with any and all applicable anti-bribery, anti-corruption and/or similar laws, executive orders and/or regulations in the United States and California. Notwithstanding this the MED-Project warrants that it has not, at any time, directly or indirectly, promised, offered or undertaken to promise or offer donations, gifts or other benefits whatsoever in order to influence or benefit any person or company in connection with this Agreement, the Parties to the Agreement (or any of MED-Project's parent, affiliated, associated and/or subsidiary companies) or any other matter contained in this Agreement.

20. Waiver.

- 20.1. No consent or waiver, express or implied by a Party, to or of any breach or default by the other in the performance by that other Party of obligations under this Agreement shall be deemed or construed to be a consent or waiver to or of any other breach or default in the performance by that other Party of the same or any other obligation of that Party under this Agreement. Failure of a Party to complain of any act or failure to act of the other, or to declare the other in default, irrespective of how long that failure continues, shall not constitute a waiver by that Party of rights under this Agreement. The giving of consent by a Party in any one instance shall not limit or waive the necessity to obtain that Party's consent in any future instance.

21. Effective Date

- 21.1. The Agreement shall be effective on the last date signed by a Party in accordance with Section 15 of this Agreement.

IN WITNESS WHEREOF, the Parties hereto by their duly authorized representatives have executed and delivered this Agreement as of the Effective Date.

[Host]

By: _____
Name: _____
Title: _____
Date: _____

San Mateo MED-Project LLC

By: _____
Name: _____
Title: _____
Date: _____

Appendix D

Exhibit A Host Collection Sites

Name	Address

Appendix D

Exhibit B

Kiosks Approved for Inclusion in the Med-Project Plan

[KIOSK DESCRIPTION]

Appendix D

Exhibit C Manager

Name	Work Address	Telephone Number	Email Address

Appendix D

Exhibit D

Standard Operating Procedures

1. Services in Section 3.2 of this Agreement, other than responses to Emergency Requests, will be conducted Monday - Friday from 8:00am - 6:00pm PST. Except for responses to Emergency Requests, these Services will not be conducted on federal holidays recognized by the United States Office of Personnel Management (available at: <https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/>).
2. The Service Technicians will park the service vehicle in an area designated by the Manager and enter the building from an entrance specified by the Manager. The Service Technicians will provide picture identification to the Manager upon request.
3. The Service Technicians shall ensure that, when unattended, the service vehicle shall be locked and the vehicle and its contents secured.
4. Upon entering Host Collection Site, the Service Technicians will ask for the Manager. If the Manager is not available within 15 minutes (or 30 minutes in the case of an Emergency Request), the Service Technicians will exit Host Collection Site and follow-up with the Manager to reschedule service.
5. Once the Manager arrives, the Service Technicians will go directly to the Kiosk along with the Manager and other Host Collection Site employee.
6. The Manager and other Host Collection Site employee will produce keys to access the double-locked Kiosk.
7. The Manager and other Host Collection Site employee will remove the inner container and liner from the Kiosk and seal the inner liner. The Kiosk will then be locked, including the small-opening that allows contents to be deposited into the Kiosk.
8. Under the supervision of the Manager and other Host Collection Site employee, the Service Technicians will take the entire inner container and liner to the service vehicle for packaging.
9. The Service Technicians will place the inner container and liner in the back of the service vehicle.
10. The Service Technicians will weigh the inner container and liner, remove the liner from the container, and place the liner into an appropriately sized shipping container.
11. The shipping container will be lined to prevent any leakage.
12. The Service Technicians will attach a unique barcode label that will be confirmed by Vendor once received at the designated disposal facility.
13. The Service Technicians will secure the shipping container with tamper evident tape.
14. All shipping containers will be marked and labeled in compliance with Applicable Laws.
15. The Service Technicians will return to Host Collection Site with the Manager and other Host Collection Site employee. The Manager and Service Technicians will provide any paperwork required by Applicable Laws. If not otherwise required by Applicable Laws, the Service Technicians will record their own names as well as the names of the Manager and other Host Collection Site employee participating in the service.
16. The Manager, other Host Collection Site employee, and the Service Technicians will return to the Kiosk for inspection. The Manager and other Host Collection Site employee will produce keys to access the double-locked Kiosk.
17. Under the supervision of the Manager and other Host Collection Site employee, the Service Technicians will replace the liner in the inner container and place both into the Kiosk.
18. The Kiosk will be locked by the Manager and other Host Collection Site employee, and the Service Technicians will exit Host Collection Site, completing the service.

Appendix D

Exhibit E

Notice and Contact Data for Vendor

[VENDOR CONTACT INFORMATION]

Appendix E

Potential Additional Kiosk Drop-Off Sites

SITE NAME	ADDRESS	CITY	DISTRICT	TYPE
ANCHOR DRUGS III	161 S SPRUCE AVE	S SAN FRANCISCO	1	PHARMACY
ANCHOR DRUGS PHARMACY LTC	161 S SPRUCE AVE STE 200	S SAN FRANCISCO	1	PHARMACY
COSTCO PHARMACY #422	451 SOUTH AIRPORT BLVD.	SOUTH SAN FRANCISCO	1	PHARMACY
COSTCO WHOLESALE NO 475	1600 EL CAMINO REAL BLVD	SOUTH SAN FRANCISCO	1	PHARMACY
DAVITA RX LLC	1178 CHERRY AVE	SAN BRUNO	1	PHARMACY
KAISER FDN HSP ANNEX PHY 354	1200 EL CAMINO REAL	SOUTH SAN FRANCISCO	1	PHARMACY
KAISER FDN HSP INP/OUT PHY 35A-355	1200 EL CAMINO REAL	SO SAN FRANCISCO	1	PHARMACY
KAISER HEALTH PLAN BAYHILL PHY 353	801 TRAEGER AVENUE	SAN BRUNO	1	PHARMACY
KAISER PERMANENTE PHARMACY #351	1200 EL CAMINO REAL	SOUTH SAN FRANCISCO	1	PHARMACY
KAISER PERMANENTE PHARMACY #358	1200 EL CAMINO REAL	S SAN FRANCISCO	1	PHARMACY
KAISER PERMANENTE PHARMACY NO 357	901 EL CAMINO REAL	SAN BRUNO	1	PHARMACY
MILLS PENINSULA MEDICAL CENTER PHARMACY	1501 TROUSDALE DR	BURLINGAME	1	PHARMACY
SAFEWAY PHARMACY #1547	1450 HOWARD AVENUE	BURLINGAME	1	PHARMACY
SAFEWAY PHARMACY #2878	525 EL CAMINO REAL	MILLBRAE	1	PHARMACY
SAN FRANCISCO INTERNATIONAL AIRPORT POLICE DEPARTMENT	P.O. Box 8097	SAN FRANCISCO	1	LEA
SEVENTEEN FIFTY MEDICAL CENTER PHARMACY	1750 EL CAMINO REAL	BURLINGAME	1	PHARMACY
TRIAD ISOTOPES, INC.	806 DUBUQUE AVE	S SAN FRANCISCO	1	PHARMACY
COSTCO PHARMACY #147	1001 METRO CENTER BLVD.	FOSTER CITY	2	PHARMACY
FOSTER CITY POLICE DEPARTMENT	610 Foster City Blvd.	FOSTER CITY	2	LEA
KAISER PERMANENTE PHARMACY #339	1000 FRANKLIN PKWY W FL 1	SAN MATEO	2	PHARMACY
MEDICROSS PHARMACY	140 SECOND AVENUE	SAN MATEO	2	PHARMACY
MILLS PENINSULA HEALTH CENTER PHARMACY	100 S. SAN MATEO DRIVE ROOM 110	SAN MATEO	2	PHARMACY
MILLS PENINSULA HEALTH CENTER PHARMACY	100 SOUTH SAN MATEO DRIVE	SAN MATEO	2	PHARMACY
SAFEWAY PHARMACY #0668	2100 RALSTON AVE	BELMONT	2	PHARMACY
SAFEWAY PHARMACY #0970	1655 EL CAMINO REAL	SAN MATEO	2	PHARMACY

SAFEWAY PHARMACY #1138	1100 EL CAMINO REAL	BELMONT	2	PHARMACY
TED'S VILLAGE PHARMACY INC	29 WEST 25TH AVE	SAN MATEO	2	PHARMACY
ALPHASCRIP, INC.	1160 INDUSTRIAL RD #17	SAN CARLOS	3	PHARMACY
HALF MOON BAY POLICE DEPARTMENT	537 Kelly Ave	HALF MOON BAY	3	LEA
SAN CARLOS POLICE DEPARTMENT	600 Elm Street	SAN CARLOS	3	LEA
SETON MEDICAL CENTER - COASTSIDE	600 MARINE BLVD	MOSS BEACH	3	PHARMACY
CALIFORNIA HIGHWAY PATROL	355 Convention Way	REDWOOD CITY	4	LEA
COSTCO PHARMACY #1042	2300 MIDDLEFIELD RD	REDWOOD CITY	4	PHARMACY
KAISER FOUNDATION HOSPITAL PHARMACY #37B/378	1100 VETERANS BLVD. HOSP BLDG, FL 3	REDWOOD CITY	4	PHARMACY
KAISER HEALTH PLAN BIRCH PHY 372	910 MARSHALL STREET	REDWOOD CITY	4	PHARMACY
KAISER HEALTH PLAN CYPRESS MOB PHY 371	1150 VETERANS BOULEVARD	REDWOOD CITY	4	PHARMACY
KAISER PERMANENTE PHARMACY #377	1190 VETERANS BLVD	REDWOOD CITY	4	PHARMACY
LPCH CHILDREN'S HOME PHARMACY	4600 BOHANNON DR STE 105	MENLO PARK	4	PHARMACY
MENLO PARK POLICE DEPARTMENT	701 Laurel St	MENLO PARK	4	LEA
MOBIMEDS	133 ARCH STREET SUITE 7	REDWOOD CITY	4	PHARMACY
NIMBLE PHARMACY	900 WILLOW ROAD	MENLO PARK	4	PHARMACY
PHARMACA INTEGRATIVE PHARMACY	871 SANTA CRUZ AVE	MENLO PARK	4	PHARMACY
PORTOLA VALLEY POLICE DEPARTMENT	400 Country Center	REDWOOD CITY	4	LEA
REDWOOD CITY POLICE DEPARTMENT	1301 Maple Street	REDWOOD CITY	4	LEA
SAFEWAY PHARMACY #0305	1071 EL CAMINO REAL	REDWOOD CITY	4	PHARMACY
SAFEWAY PHARMACY #0747	850 WOODSIDE RD	REDWOOD CITY	4	PHARMACY
SAFEWAY PHARMACY #2719	525 EL CAMINO REAL	MENLO PARK	4	PHARMACY
SAFEWAY PHARMACY #4903	2710 MIDDLEFIELD RD	REDWOOD CITY	4	PHARMACY
SEQUOIA HOSPITAL	170 ALAMEDA DE LAS PULGAS	REDWOOD CITY	4	PHARMACY
SOUTH COUNTY COMMUNITY HEALTH CENTER INC DBA RAVENSWOOD FAMILY HE	1885 BAY ROAD	EAST PALO ALTO	4	PHARMACY
STANFORD HEALTH CARE	450 BROADWAY ST	REDWOOD CITY	4	PHARMACY
STANFORD HEALTH CARE	450 BROADWAY ST PAVILION A 3RD FL	REDWOOD CITY	4	PHARMACY
COLMA POLICE DEPARTMENT	1199 El Camino Real	COLMA	5	LEA
KAISER PERMANENTE PHARMACY #341	395 HICKEY BLVD 1ST FL	DALY CITY	5	PHARMACY
KAISER PERMANENTE PHARMACY #343	395 HICKEY BLVD 2ND FL	DALY CITY	5	PHARMACY
SETON MEDICAL CENTER	1900 SULLIVAN AVE	DALY CITY	5	PHARMACY

Sample – Not for Distribution. All text subject to change pending review and approval by San Mateo County.

Appendix F

Picture of Kiosk Prototype



The kiosk is approximately 47” tall x 19” wide x 20” deep (without handle).

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

Appendix F

Sample Kiosk Signage

Front Panel Kiosk Art

SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

- 

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

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

3 Put medicine in the kiosk.

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

 **NOT ACCEPTED:** HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OR OTHER PERSONAL CARE PRODUCTS; COMPRESSED CYLINDERS, AEROSOLS, AND INHALERS; MEDICAL DEVICES; PET PESTICIDE PRODUCTS; SHARPS; ILLICIT DRUGS; IODINE-CONTAINING MEDICATIONS.

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

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

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

MED-Project
Medication Education & Disposal

Sample – Not for Distribution. All text subject to change pending review and approval by San Mateo County.

Appendix F

Sample Kiosk Signage

Side Panel Kiosk Art



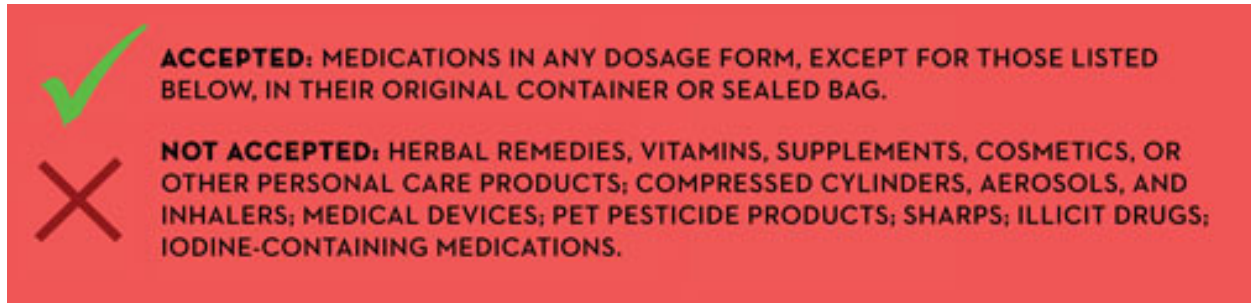
MED-Project


Medication Education & Disposal


Appendix F

Sample Kiosk Signage

Top of Kiosk Art



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

 **NOT ACCEPTED:** HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OR OTHER PERSONAL CARE PRODUCTS; COMPRESSED CYLINDERS, AEROSOLS, AND INHALERS; MEDICAL DEVICES; PET PESTICIDE PRODUCTS; SHARPS; ILLICIT DRUGS; IODINE-CONTAINING MEDICATIONS.

Appendix G

Community Events That May Serve as Future Take-Back Events

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

- DEA National Take Back Day – April 30, 2016 – All San Mateo County police stations
- Millbrae Art & Wine Festival – September 3 & 4, 2016 – District 1
- San Mateo County Fair – June 10 – 18th, 2016 – District 2
- San Mateo Street Festival – June 18, 2016 – District 2
- San Mateo Highlands 4th of July Parade & Celebration – July 4 – District 2
- San Mateo Health & Wellness Fair – September 26, 2014 – District 2
- Pacific Coast Dream Machines Show – April 24, 2016 – District 3
- Half Moon Bay Pumpkin & Art Fest – October 15 & 16, 2016 – District 3
- Menlo SummerFest – July 16 & 17, 2016 – District 4
- Redwood City Salsa Festival – September 24, 2016 – District 4
- Daly City Earth Day – April 16, 2016 – District 5

Appendix H

Sample Media List

The following is a representative list of key media outlets to help educate residents about proper disposal of expired or Unwanted Medicines. The list includes local print, online, television, and radio outlets, as well as outlets specifically targeting the diverse demographic communities within the County.

Print Outlets	City/Coverage Area	Website
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

Appendix H

Sample Media List *continued*

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	City/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 I

Sample Mail-Back Package



Description:

Plastic Package with Merchandise Return Label and instructional flyer

Page Size:

Package: Outer Dimension: 8.25" x 12"; Inner Dimension: 7.375" x 10.375", 2" flap (Hot Melt Tape- Tamper Evident)

Merchandise Return Label: 4" x 4"

Instructional Sheet: 5" x 7"

Paper Stock:

Package: 4mil white/ silver poly mailer w/sequential barcode

Return Label: 60# uncoated label stock

Instructional Sheet: 80# Gloss Text

Color:

Package: 5/3 Print: Silver, white, white, + 2 PMS on clear web; Silver + 2 PMS on white web

Return Label: K/O no bleeds (personalized barcode)

Instructional sheet: K/K

Appendix J

Request for Approval for Mail-Back Package Disposal

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

San Mateo County MED-Project
Medication Education & Disposal

May 25, 2016

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

Pursuant to § 4.116.070(b) of the County of San Mateo Safe Medicine Disposal Ordinance (the “Ordinance”), San Mateo MED-Project LLC (“MED-Project”) requests the San Mateo Environmental Health Division Director’s (“San Mateo’s”) approval to use the Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility (the “Covanta Facility”), via the Stericycle, Inc., Indianapolis, Indiana Facility (the “Stericycle Facility”), for the disposal of mail-back packages. As described below, the Ordinance requires the disposal of “Covered Drugs” at a permitted hazardous waste disposal facility or, upon San Mateo’s finding that such disposal is “infeasible . . . based on cost, logistics or other considerations,” at a permitted large municipal waste combustor. Ordinance § 4.116.070(a), (b). After months of investigation, MED-Project believes there are no permitted hazardous waste disposal facilities with the necessary authorizations to accept mail-back packages under current United States Drug Enforcement Agency (“DEA”) and Resource Conservation and Recovery Act (“RCRA”) or similar state requirements. These legal constraints make disposal of mail-back packages at permitted hazardous waste disposal facilities infeasible.

To dispose of mail-back packages, MED-Project is requesting approval for a two-phase process. First, the Stericycle Facility receives mail-back packages (including any controlled substances therein)¹ and renders them non-retrievable in compliance with DEA requirements. Second, the Covanta Facility, a municipal waste combustor, incinerates any remaining non-retrievable materials. This two-phase process allows MED-Project to dispose of mail-back packages in compliance with all DEA and RCRA requirements at a municipal waste combustor – the Covanta Facility – as permitted under the Ordinance. Because “cost, logistics or other considerations” make mail-back package disposal infeasible at permitted hazardous waste disposal facilities, MED-Project’s proposed Covanta Facility and Stericycle Facility two-phase process should be approved under Ordinance § 4.116.070(b).

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

Under the MED-Project Product Stewardship Plan’s mail-back program, certain San Mateo residents can request a mail-back envelope by calling the MED-Project call center or using the MED-Project website. When MED-Project receives a request, MED-Project provides residents a pre-addressed, prepaid mail-back envelope. Residents will fill the mail-back envelope according to provided instructions and return the mail-back package via United States Postal Service First Class Mail to the Stericycle Facility.² See MED-Project Product

¹ The term “mail-back packages” as used in this submission means both the mail-back envelope itself and the contents therein.

² The Stericycle Facility’s mailing address is Stericycle Inc., 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901.

Stewardship Plan § VI.D. MED-Project proposes a two-phase process for managing and disposing of these mail-back packages.

A. Phase I – The Stericycle Facility Accepts Mail-back Packages from San Mateo Residents and Renders Them Non-Retrievable Pursuant to DEA Requirements

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

The attached Standard Operating Procedures provides a step-by-step description of the Stericycle Facility mail-back package destruction process. *See* Appendix A. Generally, when the Stericycle Facility receives mail-back packages, Stericycle Environmental Solutions, Inc. (“Stericycle”) scans the mail-back packages’ unique barcode to record receipt and then transports the mail-back packages to a DEA vault for controlled substance storage. Approximately once per week (depending on volume received), Stericycle removes mail-back packages from the DEA vault for destruction and re-scans the mail-back packages to record their unique identifiers and destruction date.

Before destroying the mail-back packages, Stericycle passes all mail-back packages through a metallic screening process necessary to protect Stericycle employee safety and equipment.⁴ Stericycle then loads the mail-back packages into a container no larger than thirty gallons. The contents of this container are fed into the mechanical process. The end product of this mechanical process falls into a steel drum filled with fifteen gallons of an activated carbon-based solution that renders the remaining contents “non-retrievable”, as defined in 21 C.F.R. § 1300.05(b). *See* Appendix B (describing the efficacy of activated carbon-based solutions). As needed, Stericycle agitates the fifty-five gallon drum’s contents to ensure all mail-back packages are exposed to the activated carbon-based solution. Through this process, the Stericycle Facility renders all mail-back packages (and any contents therein) non-retrievable.

The end product from the mechanical process is “pea sized.” Stericycle seals these remaining non-retrievable mail-back package materials in the fifty-five gallon drum for secure transportation to the Covanta Facility. Stericycle places a security seal on the trailer transporting

³ The Stericycle Facility’s DEA Registration Number is RS0331607; its RCRA Permit Number is INR000110197.

⁴ If metal is found and does not appear consistent with a pharmaceutical product (i.e., an inhaler), the mail-back package is segregated and returned to storage. These segregated mail-back packages are held pending notification to the DEA Field Division Office for further direction regarding the receipt of an envelope that likely contains materials Stericycle did not agree to receive. *See* 21 C.F.R. § 1317.70.

the non-retrievable materials and verifies this seal upon arrival at the Covanta Facility. A Stericycle witness follows the non-retrievable materials to the Covanta Facility and witnesses their incineration.

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

Phase-two of MED-Project’s proposed process is incineration of the non-retrievable materials from the Stericycle Facility, including mail-back packages and their contents, at the Covanta Facility. As the Covanta Facility is not registered with the DEA, it cannot receive mail-back packages until they are first rendered non-retrievable at the Stericycle Facility. *See* 21 C.F.R. § 1317.70(a).⁵

The Covanta Facility is a permitted large municipal waste combustor, satisfying the requirements of Ordinance § 4.116.070(b).⁶ An “energy-from-waste” facility, the Covanta Facility uses municipal solid waste, like non-retrievable mail-back packages, to generate renewable energy. Steam recovered from incineration at the Covanta Facility helps power the Indianapolis downtown heating loop, which includes Indiana University and Purdue University’s Indianapolis campus. *See* Covanta, Covanta Indianapolis (April 13, 2016), <https://www.covanta.com/Our-Facilities/Covanta-Indianapolis>.

II. Standard for San Mateo to Approve a Municipal Waste Combustor for the Disposal of Mail-back Packages

Under Ordinance § 4.116.070(b):

The Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor . . . if the Director deems the use of a hazardous waste disposal facility . . . to be infeasible for the Stewardship Plan based on cost, logistics or other considerations.

As described below, MED-Project proposes to use the Covanta Facility and Stericycle Facility two-phase process because conflicting legal requirements make the disposal of mail-back packages at permitted hazardous waste disposal facilities infeasible at this time.

III. The Covanta Facility and Stericycle Facility Two-Phase Process Should Be Approved Because Cost, Logistics or Other Considerations Prohibit Disposal of Mail-back Packages at Permitted Hazardous Waste Disposal Facilities

The Ordinance provides that “Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted hazardous waste disposal facility as defined by the United States

⁵ Stericycle is a DEA-registered collector. *See supra* note 4.

⁶ *See* Indiana Department of Environmental Management, Permitted Solid Waste Facilities List (Mar. 1, 2016), <http://www.in.gov/idem/landquality/2412.htm> (Permitted Solid Waste Facilities List, PDF page 25).

Environmental Protection Agency under 40 C.F.R. parts 264 and 265.” Ordinance § 4.116.070(a). MED-Project and its vendor, Stericycle, spent months attempting to identify a permitted hazardous waste disposal facility capable of disposing mail-back packages. While these efforts remain ongoing, disposal of mail-back packages at permitted hazardous waste disposal facilities is infeasible at this time because of conflicting DEA and RCRA (or state-analog) requirements.

Under DEA regulations, only law enforcement or certain DEA-registered “collectors” may conduct mail-back programs. *See* 21 C.F.R. § 1317.70(a). MED-Project is only aware of a few permitted hazardous waste disposal facilities that are DEA registered collectors and therefore able to conduct a mail-back program. Unfortunately, these facilities’ RCRA permits require the sampling and/or inspection of controlled substances before destruction. Such sampling or inspection is prohibited by DEA regulations, which state that “[u]pon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened . . .” 21 C.F.R. § 1317.70(f). Thus, even those permitted hazardous waste disposal facilities possessing the necessary DEA registration to conduct a mail-back program are unable to destroy mail-back packages at this time.

Because MED-Project is unaware of any permitted hazardous waste disposal facilities capable of disposing mail-back packages in compliance with legal requirements, disposal at a permitted hazardous waste disposal facility is, at minimum, “infeasible . . . based on cost, logistics or other considerations.” Ordinance § 4.116.070(b).⁷ Accordingly, San Mateo should approve the disposal of mail-back packages at the Covanta Facility, a municipal waste combustor, via the Stericycle Facility as proposed by MED-Project under Ordinance § 4.116.070(b).

IV. Conclusion

For the foregoing reasons, MED-Project’s proposed Covanta Facility and Stericycle Facility two-phase process for the disposal of mail-back packages should be approved under Ordinance § 4.116.070(b).

⁷ Under a nearly identical legal standard, King County, Washington, recently approved MED-Project’s request to use of this same disposal process. *See* Approved Standard Stewardship Plan, Secure Medicine Return Regulations King County, Washington, <https://kingcountysecuremedicinereturn.org/standard-stewardship-plan-2/> (King County MED-Project Plan § VIII.C.)

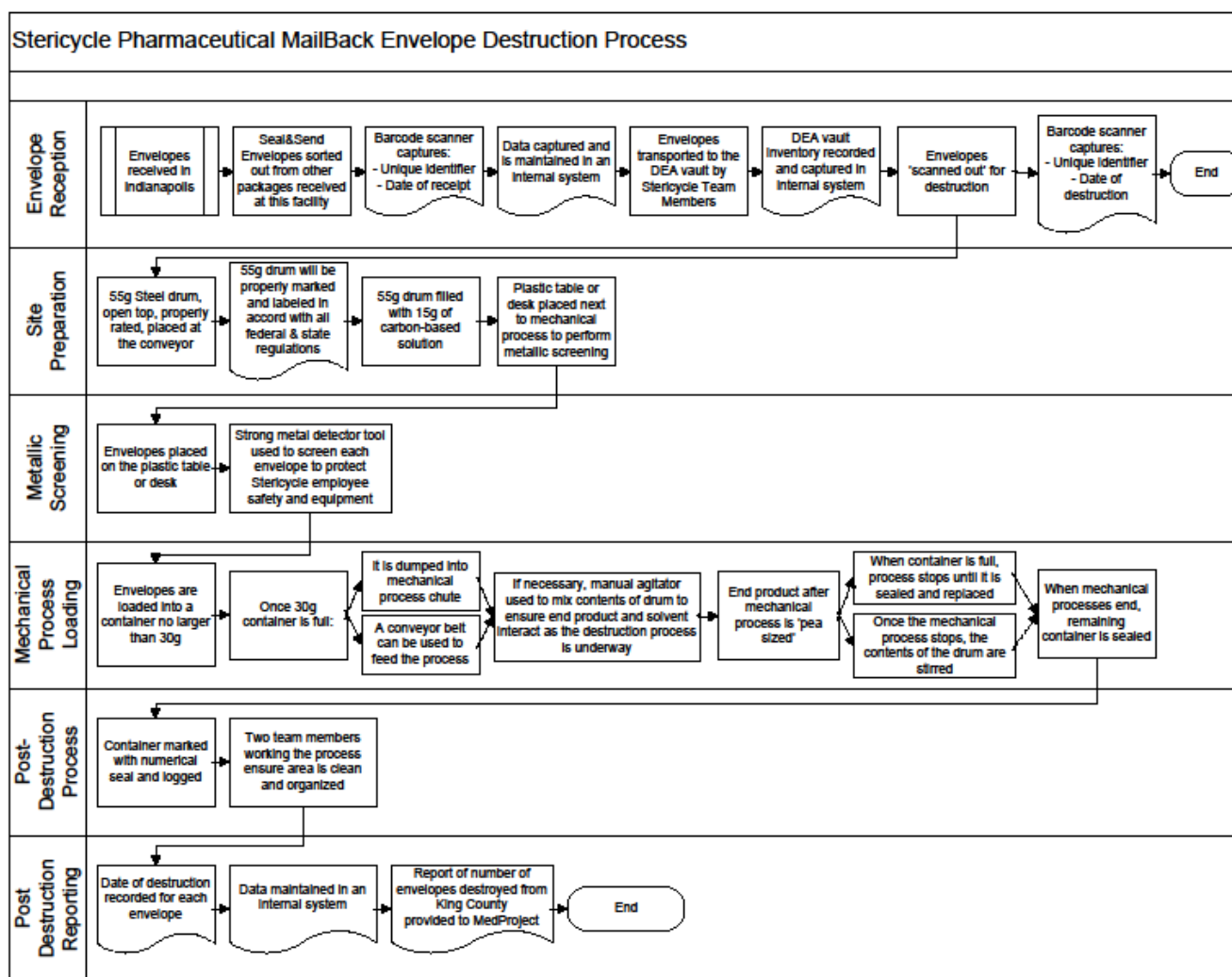
Appendix A: Stericycle Facility Standard Operating Procedures

This SOP explains Stericycle's Seal & Send pharmaceutical Mail Back envelope service.

Scope and Applicability

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

Process Flow



Procedure

Part 1 Envelope Reception

- 1a) The Seal&Send envelopes shall be received at the Stericycle facility in Indianapolis, via mail, and will be scanned into a tracking spreadsheet. The envelopes shall remain sealed and closed at all times.
 - i) Seal&Send envelopes sorted out from all packages received at the Indianapolis facility.
 - ii) Barcode scanner captures data:
 - Unique identifier
 - Date that the envelope is received
 - iii) Data captured and is maintained in an internal system
- 1b) The envelopes will be transported by Stericycle Team Members to the DEA vault where all controlled substances are held prior to destruction.
 - i) DEA vault inventory recorded and captured in internal system.

Part 2 Envelope Destruction

- 2a) Bi-weekly or as necessary, the envelopes will be “scanned out” for destruction.
 - i) Barcode scanner captures data:
 - Unique identifier
 - Date that the envelope is destroyed
- 2b) Site Preparation
 - i) A new or properly reconditioned 55g steel drum, open top, properly rated for the hazard of the product being used to render the pharmaceuticals non-retrievable, shall be placed at the end of the conveyor where the end product will be accumulated. The 55g steel drum shall be properly marked and labeled in accord with all federal and state regulations.
 - ii) The accumulation drum will be filled with 15 gallons of the carbon-based solution being used to render the pharmaceuticals non-retrievable.
 - iii) A plastic table or desk that contains no metal will be placed next to the mechanical process to perform metallic screening prior to feeding any material into the mechanical process.
- 2c) Metallic Screening
 - i) A team member shall place the envelopes on the plastic table or desk.
 - ii) The team member will use a strong metal detector tool to screen each envelope for metal objects to protect employee safety and company equipment.
- 2d) Mechanical Process Loading

- i) No medicine containers are removed from MailBack envelopes before destruction (and thus no medicines are removed from medicine containers before destruction).
- ii) Envelopes will then be loaded into a small container, no larger than 30 gallons capacity, prior to loading into the mechanical process.
- iii) Once the 30g container is full, it can be dumped into the chute of the mechanical process.
- iv) Alternately, a conveyor belt shall be placed next to the mechanical process to allow envelopes to be placed onto it for conveyance up to the chute above the mechanical process, where they will be dropped by conveyor belt into the mechanical process.
- v) Stericycle team members will monitor the end product material drum, the conveyor line, and monitor for fires. As the mechanical process is underway, if necessary, Stericycle team members will also use a manual agitator to mix the contents of the drum to ensure all product is in contact with the solvent. The end product of envelopes and their contents that go through the mechanical process is pea sized. Any medicine containers (whether containing drugs or not) that residents may have returned inside a MailBack envelope are also destroyed to a pea size.
- vi) The mechanical process shall be stopped if the accumulation drum fills past 9/10ths full.
- vii) Once mechanical process operations stop, the end product material drum contents are stirred to ensure that the solvent mixes with the pharmaceuticals and renders them 'non retrievable'.
- viii) Once the container is filled, mechanical process operations shall stop until the end product material drum is sealed and a replacement container is prepared, following the requirements in the site preparation section of this SOP.

2e) Post-Destruction Process

- i) Once all mechanical process activities have been completed for the shift, the remaining end product material drum shall be closed and sealed according to the container's closure specifications as detailed by the container manufacturer.
- ii) This container shall be marked with a numerical seal and noted on a log present in the area to ensure the container is not reopened.
- iii) After all mechanical process operations are complete, the team members working the mechanical process shall ensure the working area is cleaned up and tidy, so that the next shift operating the mechanical process finds everything in clean and working order.

Part 3 Post-Destruction Reporting

3a) Tracking

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

Appendix B: Activated Carbon Renders Controlled Substances Non-Retrievable

As described above, the Stericycle Facility uses an activated carbon-based solution to render controlled substances non-retrievable. This Appendix demonstrates the efficacy of activated carbon processes like the process used at the Stericycle Facility.

In relevant part, DEA regulations require that mail-back programs render controlled substances non-retrievable. *See, e.g.*, 21 C.F.R. §§ 1317.70(a), 1317.90. Non-retrievable means:

for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance *unavailable and unusable for all practical purposes*. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

21 C.F.R. § 1300.05(b) (emphasis added). The Preamble to the DEA final rule, Disposal of Controlled Substances, 79 Fed. Reg. 53520 (Sept. 9, 2014), explains that "DEA is specifying a required result – non-retrievable – rather than a required method for achieving that result." 79 Fed. Reg. 53548. In fact, "DEA will not evaluate, review, or approve the processes or methods utilized to render a controlled substance non-retrievable, as long as the desired result is achieved." *Id.* This results-based standard "allow[s] public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances." *Id.* at 53522.

The Stericycle Facility uses an activated carbon solution as part of such a secure, convenient, and responsible process to render mail-back packages non-retrievable. MED-Project provides the following analyses describing activated carbon and/or its activity to confirm that the Stericycle Facility's process renders mail-back packages non-retrievable.

1. **Attachment 1 – Henry Nowicki, GAED Test Summary of Activated Carbon Used in [Product Name] (Feb. 19, 2015)**

Describes the activated carbon used at the Stericycle Facility to render the materials in the mail-back packages non-retrievable, concluding that it provides "non-retrievable drugs destruction for practical purposes." Attachment 1 at 2-3. This analysis also notes that the activated carbon "has been engineered to inhibit any reverse engineering attempts" and that "[t]here is no known process to reverse the liquid phase or solid carbon phase to bring back a medication to its original medically intended form or other form that can be abused." *Id.* at 3.

2. **Attachment 2 – Appendices to GAED Test Summary of Activated Carbon Used in [Product Name] (Feb. 19, 2015)**
Describes research concluding that “some 4000+ chemicals, drugs, plant and microbial toxins, allergens, venoms and wastes are effectively neutralized by activated carbon.” Attachment 2 at 1. Provides test results indicating the activated carbon used at the Stericycle Facility deactivates certain controlled substances. *Id.* at 4.
3. **Attachment 3 – Full GAED Characterization with Aqueous-Phase Comparisons for Sample EE-541 (Feb. 22, 2015)**
Compares the activity of certain activated carbon substances.
4. **Attachment 4 – Henry Nowicki, Analysis of [Product Name] Drug Capacity Per Bottle Size to Support Claims of DEA Non-Retrieveable Standard 1-2 (Apr. 29, 2015)**
Analyzes the amount of activated carbon necessary to render certain quantities of drugs non-retrieveable. This analysis concludes that activated carbon “is the best available technology and practical solution to provide control, safe and environmental friendly disposal of pharmaceuticals.” Attachment 4 at 2.

These submissions demonstrate that the Stericycle Facility’s process, which involves the use of an activated carbon-based solution, chemically and irreversibly alters the state of mail-back packages, rendering them non-retrieveable.

Appendix K

A. Stericycle Penalty Record

Type	Location	Date	Address	Regulatory Body/ Agency	Description of Alleged Violation	Fine Amount	Final Disposition
Transporter	Stericycle	2/16/2012	2850 100th Court NE Blaine, MN 55449	US Department of Transportation	Failing to retain record of training provided to a hazardous material employee.	None	Closed
Transporter	Stericycle	2/16/2012	2851 100th Court NE Blaine, MN 55449	US Department of Transportation	Failing to brace containers of hazardous materials to prevent relative motion between containers.	None	Closed
Transporter	Stericycle	2/16/2012	2852 100th Court NE Blaine, MN 55449	US Department of Transportation	Operating a commercial motor vehicle not in accordance with the laws ordinances, and regulations of the jurisdiction in which it is being operated - Unsafe Driving	None	Closed

Appendix K

B. Clean Harbors – Aragonite Penalty Record

COMPLIANCE HISTORY for the
Clean Harbors Aragonite, LLC
facility
(formerly Safety-Kleen (Aragonite), Inc.,
Laidlaw Environmental Services (Aragonite), Inc.,
and Aptus, Inc.)

Clean Harbors-Owner

ACTION:	NOTICE OF VIOLATION issued April 17, 2014
ISSUES:	Recording inaccurate times when the carbon adsorber is in use. Failing to submit reports of emergency vent openings and baghouse bypasses within seven days. Accepting and managing water reactive wastes. Failing to document the waste characterization procedure for each waste. Failing to properly characterize “waste that inhibits analysis.” Grouping wastes together that are not of the same waste type for sampling and determination of incineration parameters. Failing to note deficiencies on the inspection logs, failing to generate and reference work orders, failing to conduct some of the daily and weekly inspections, and failing to document some of the inspections. Failing to provide all of the required training. Failing to submit a report of a fire within fifteen days. Failing to note manifest discrepancies on the manifest, failing to attempt to reconcile a manifest discrepancy, and failing to submit a letter describing the discrepancy and attempts to reconcile it. Failing to document when the reject determination was made for materials to be rejected, failing to preserve the date the reject determination was made, failing to identify wastes in reject status on the <i>Drum Reject Report</i> , storing rejected wastes in Building E-3, failing to update the date of the waste tracking activity code when a rejected waste is shipped off-site, failing to capture wastes that are initially rejected, but later accepted, on the <i>Drum Reject Report</i> , and failing make the determination of acceptance within 60 days of receipt for wastes that are initially rejected and later accepted. Storing incoming vans of containers in areas other than east of the container storage buildings. Failing to copy and file the tracking history and other information prior to untracking wastes in the waste tracking system. Failing to maintain a database of all required equipment, failing to maintain drawings that show the approximate location of each piece of equipment, and failing to mark all of the equipment. Failing to maintain a history of the movement of each container, failing to track wastes in real time so that their location is known at any time, and failing to notify the Director within 30 days of making changes to the waste tracking system for containers that have been lost. Storing cyanide-bearing wastes in Building E-2, and storing oxidizers in Building E-6. Storing compressed gas cylinders in Building E-5 for more than 24 hours. Placing incompatible waste or materials in the same container, and failing to perform compatibility testing prior to comingling any liquids or sludges.

Failing to unload transport vehicles within ten days of being received.
 Failing to stack containers neatly, wrapped, or both, to provide stability.
 Failing to automatically shut down the vacuum pump on the robberoller when the LEL of the combined dilution air and vacuum pump vent reaches 60%.
 Placing wastes with a pH of greater than 12.5 into tank T-324.
 Filling the small sludge storage tank above the compliance limit.
 Failing to maintain the tank farm secondary containment systems free of cracks and gaps.
 Failing to annually monitor the positive pressure sections of the vent system.
 Failing to replace the carbon in the carbon adsorber after 1,066 hours of use.
 Failing to seal the crane bay man door during backup operations.
 Failing to calibrate monitoring instruments.
 Failing to enter the correct DOT information on the manifest for a rejected hazardous waste.
 Failing to obtain the signature and date on the manifest from the transporter of a rejected waste, failing to sign as the designated facility on the manifest for the return shipment of rejected waste, and failing to send a copy of the manifest to the facility that returned the rejected waste to the generator within 30 days of delivery.
 Failing to submit an Exception Report when it has not received a signed copy of the manifest for rejected waste within 45 days.
 Combusting hazardous wastes with waste codes prohibited from combustion.

RESOLUTION:

pending

Clean Harbors-Owner

ACTION:

NOTICE OF VIOLATION issued June 17, 2013

ISSUES:

Collecting samples that were not representative of the waste being sampled and not obtained in accordance with required sampling procedures.
 Failing to clean up spilled material.
 Failing to notify the Director of an emergency vent opening and baghouse bypass; and failing to submit reports of vent openings within seven days.
 Failing to follow the Standard Operating Procedures for the cyanide and sulfide screens.
 Failing to document the waste characterization procedure for each waste.
 Failing to have an inventory list for each labpack; and by failing to determine the incineration parameters from the lab pack inventory sheets.
 Failing to properly characterize “waste that inhibits analysis.”
 Failing to properly characterize “debris.”
 Failing to generate work orders for deficiencies found on inspections; failing to document repairs through the work order system; failing to properly track work completed on work orders; and failing to inspect and/or document inspections.
 Failing to provide all of the required training.
 Having fire doors that were blocked and fusible links that were compromised.
 Failing to submit a report to the Director for a fire near the front wall of the kiln.
 Failing to note manifest discrepancies on the manifest, failing to attempt to reconcile a manifest discrepancy with the generator or transporter, and failing to notify the Director of the unmanifested waste or discrepancy and attempts to reconcile it.
 Failing to maintain the berms in the container storage area in good repair; and failing to maintain the epoxy coating on the container storage containment system floor.
 Holding rejected wastes for longer than 60 days, failing to properly document that waste that was initially rejected and later accepted was done so within 60 days of receipt of the

waste; failing to document rejected wastes in the waste tracking system and when the rejection determination was made; and failing to properly label containers of rejected wastes.

Failing to maintain a history of the movement of each container from the time it is placed into the container management areas until it is either incinerated or manifested offsite, and failing to track all wastes in real time so that their location is known at any time.

Holding infectious wastes on site longer than seven days without refrigeration.

Failing to maintain the level in tank T-312 at or below the compliance limit.

Failing to take corrective actions for oxygen concentrations above five percent in the hydrocarbon vent system; and failing to document the causes of the elevated oxygen concentrations and the corrective actions taken.

Failing to annually calibrate the bulk solids vent flow switch.

Accumulating hazardous wastes in containers for longer than 90 days; failing to mark each container with the date upon which each period of accumulation began, failing to mark each container with the words "Hazardous Waste," failing to maintain containers closed except when it is necessary to add or remove waste, and failing to transfer hazardous waste from a container that begins to leak to a container that is in good condition.

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was approved by the Utah Solid and Hazardous Waste Control Board on November 13, 2014. It includes a penalty of \$71,155.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION** issued April 16, 2012

ISSUES: Failing to maintain and operate instruments to ensure measurements taken are accurate.
Failing to follow the Standard Operating Procedure for Physical Description of Wastes.
Failing to document the waste characterization procedure for each waste.
Failing to sample and analyze "routine wastes."
Failing to properly characterize "waste that inhibits analysis."
Failing to note deficiencies on the inspection logs, failing to properly complete work orders, failing to inspect and/or document inspections, and failing to report problems that will take longer than 72 hours to remedy.
Failing to provide all of the required training.
Failing to report a fire on the kiln front wall.
Failing to note significant manifest discrepancies on the manifest, failing to properly cross reference manifests for loads of rejected wastes, failing to resolve manifest discrepancies with the generator, and failing to notify if the discrepancy is not resolved within 15 days.
Holding rejected wastes for longer than 60 days, and failing to properly document rejected wastes in the waste tracking system.
Failing to record the location of each container and to maintain a history of the movement of each container from the time it is placed into the container management areas until it is either incinerated or manifested offsite, and failing to track all wastes in real time so that their location is known at any time.
Failing to record the signature of the person performing instrument calibrations.
Failing to mark each container with the date upon which each period of accumulation began, failing to mark each container with the words "Hazardous Waste," failing to maintain containers closed except when it is necessary to add or remove waste, and failing to

transfer hazardous waste from a container that begins to leak to a container that is in good condition.

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on May 2, 2013. It includes a penalty of \$85,017.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION** issued June 29, 2010

ISSUES: Accepting and managing pyrophoric wastes at the facility.
Failing to use the same waste analysis procedures for wastes generated on site by Aragonite as wastes accepted from off-site sources.
Failing to check that the warning signs on the perimeter fence are legible, failing to check that the temperature in the refrigerated trailers is less than or equal to 40°F, failing to complete an annual inspection of the closed vent system, failing to complete an annual inspection of the carbon adsorption vessels, failing to include instruments to be checked on a daily basis; failing to have the supervisor sign off that the instrument is in good working order, and failing to monitor the hydrocarbon vent system carbon canisters.
Failing to conduct the Material Handler "Quals" and to document them in the individual training records.
Failing to note significant discrepancies on the manifest, failing to copy the manifest tracking number from the old manifest to the *Special Handling and Additional Information Block* of the new manifest and indicate that the shipment is a rejected waste from the previous shipment when a waste is rejected, and failing to copy the manifest tracking number from the new manifest to the manifest reference line in the *Discrepancy Block* of the old manifest when a waste is rejected.
Failing to measure the temperature before and after combining representative samples of the wastes to be mixed when conducting the compatibility test.
Failing to maintain a database of all required equipment, failing to maintain drawings that show the approximate location of each piece of equipment, and failing to mark all equipment with a tag containing a unique equipment identification number.
Storing wastes with a flash point less than or equal to 140°F in a bulk solids tank.
Failing to notify the Executive Secretary of a Class 1 modification and/or failing to submit a modification request to the Executive Secretary prior to implementing a Class 2 or a Class 3 modification.
Failing to annually measure the VOC concentrations in the closed vent system, failing to annually monitor the duct work section between the vacuum pump dilution air fan and the combustion air plenum, and failing to maintain the Natural Draft Openings allowed during normal operations.
Failing to maintain containers closed except when it is necessary to add or remove waste.
Storing hazardous wastes restricted from land disposal for longer than one year.

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on September 26, 2011. It includes a penalty of \$78,048.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION and COMPLIANCE ORDER** issued March 3, 2008

ISSUES: Failing to operate the waste management areas in a manner that minimizes the possibility of fires and releases of hazardous waste constituents; failing to investigate and determine

the causes of the incidents; and failing to implement corrective measures to prevent future occurrences.

Accepting and managing pyrophoric wastes at the facility.

Failing to clearly document the waste characterization procedure from the Waste Analysis Plan which applies to each waste stream accepted at the facility.

Failing to inspect, sample, and analyze “routine wastes” and failing to determine the incineration chemistry from analyses of the samples.

Failing to ensure that an inventory list accompany each lab pack, and accepting lab packs for storage and/or treatment before any load discrepancies have been adequately resolved.

Failing to ensure the generator supply a picture or a detailed written description of the waste stream for “wastes that inhibits analysis”; failing to inspect the contents of each container or each bulk load for physical appearance; failing to provide a detailed written description to waste acceptance personnel so that they can easily determine if the waste matches the profile; failing to estimate the percentages of each type of material in the waste; failing to use a matrix, that lists the various materials and the corresponding incineration parameters for each of these materials, along with the percentages of each type of material, to develop an overall estimate of the incineration parameters for the waste; and failing to collect and analyze a representative sample of the material in containers that contain more than four ounces of a material that could be analyzed to determine appropriate management and storage of the waste.

Failing to monitor all incoming waste shipments for radioactivity; and failing to conduct daily calibration checks; and failing to take and record three measurements of each sample; and failing to take and record the background reading each sampling day prior to each sample event.

Failing to conduct the ignitability screen and/or failing to heat samples to 140°F when conducting the ignitability screen.

Determining corrosivity for waste management decisions using pH paper, and failing to determine accurate pH measurements of incoming wastes.

Failing to obtain the proper laboratory certification for analyzing wastes at the facility.

Failing to conduct weekly inspections of the LEL and oxygen meters to ensure that the instruments are operable.

Failing to clear the cylinder storage area of vegetation.

Failing to maintain documentation of training; failing to maintain a current organization chart which specifies the names of the people that fill the job titles in the Personnel Training Plan; and failing to provide Training Program Descriptions which specify the training requirements for a person to be able to fill specific duty areas.

Blocking fire doors so that they could not completely close automatically in a fire emergency.

Failing to clean up spill areas.

Failing to submit a written report to the Executive Secretary within 15 days after fires and discharges in areas where waste management occurs.

Recording negative results in the lab notebook for tests that were not being performed.

Storing wastes in areas prohibited from storage; and failing to maintain the required aisle space.

Failing to maintain the LEL/O₂ monitors/alarms in the decant and repack rooms in Building E4 in good repair.

Holding rejected wastes on site for longer than 30 days; failing to specify the location of all rejected wastes in the computerized waste tracking system; and failing to clearly show that the material is to be rejected and when this determination was made.

Failing to properly mark wastes which have been accepted; moving containers from the receiving and holding areas to the storage or processing areas before the waste has been accepted; storing wastes which have not yet been accepted in areas not designated for such storage; and storing wastes which have not yet been accepted for longer than ten days in Row A of Buildings E2, E3, E6, and E7.

Identifying containers which have not been repacked or consolidated as “REPACK” or “CONS.”

Failing to affix a barcode label to each container.

Failing to maintain a database of all required equipment; failing to maintain drawings that show the approximate location of each piece of equipment; and failing to mark all equipment with a tag containing a unique equipment identification number.

Storing liquids with a flash point of less than or equal to 140°F in container management areas other than Buildings E6 and E7.

Storing cyanide or sulfide bearing wastes and oxidizers in container management areas other than the bays in Buildings E-1 and E-5; and storing potentially incompatible wastes together in the container management areas.

Failing to transfer the hazardous waste from a container that is not in good condition or begins to leak, to an acceptable container as soon as possible.

Failing to sample containers under fume exhausters in Building E5.

Failing to mark cylinders that are moved to the cylinder storage area prior to acceptance with the document and item number; and failing to clearly identify the rack as having cylinders that are not yet accepted.

Failing to record the location of each container and to maintain a history of the movement of each container from the time it is placed into the container management areas until it is either incinerated or manifested offsite; failing to update the waste tracking database by no later than the following business day when bulk materials are accepted and unloaded, and within two business days each time a transfer is made; and failing to track all wastes in real time so that their location is known at any time.

Failing to stack containers neatly and in a manner that will not cause them to fall or leak; stacking containers more than one pallet high in the receiving and holding areas of Building E5; and failing to store containers on pallets.

Failing to store infectious waste sharps in leak-proof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.

Failing to label containers of infectious waste that are not red or orange with the international biohazard sign and an appropriate biohazard label.

Failing to store infectious waste at or below 40°F when it was on site for longer than seven days.

Failing to incinerate infectious waste within 30 days after collection from the generator.

Failing to ground containers during decant operations.

Failing to provide an interlock to automatically shut off the vacuum pump that decants a container to a direct burn tanker when the LEL of the combined dilution air and vacuum pump vent reaches 60% LEL.

Failing to place drums inside the drum direct burn glove box and seal and vent the glove box prior to opening the drums or feeding to the kiln.

Failing to ground containers holding flammable liquids at the drum pumping station prior to and while waste is being fed to the kiln.

Storing wastes with a flash point less than or equal to 140°F in the bulk solids tanks; and failing to measure the Lower Explosive Limit of wastes placed in the bulk solids tanks.

Failing to maintain the level of the blend liquids Tanks T-303 and T-312 below the compliance limit.

Failing to document the cause of the elevated oxygen concentrations in the hydrocarbon vent system; and failing to document the corrective actions taken.

Failing to annually test to demonstrate that the bulk solids building meets the criteria for a permanent total enclosure; and failing to annually measure the required minimum flow during backup operation.

Failing to maintain the flow of combustion air above 12,000 acfm when the vacuum pump/dilution air fan are operating.

Exceeding the maximum permitted feed rates of metals to the incinerator.

Failing to record and preserve the history of containers before they were “untracked” in the waste tracking system.

Accumulating hazardous waste in containers for longer than 90 days; failing to mark each container with the date upon which each period of accumulation began; failing to mark each container with the words “Hazardous Waste;” failing to maintain containers closed except when it is necessary to add or remove waste; and failing to transfer hazardous waste from a container that begins to leak to a container that is in good condition or manage the waste in some other way to remedy the leak.

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on December 16, 2009. It includes a penalty of \$519,697.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION and COMPLIANCE ORDER** issued December 15, 2006

ISSUES: Failing to unload transport vehicles carrying containers within ten days of being received at the facility

Failing to record the location and movement history of each container placed in the container storage areas, and track these wastes in real time so that their location is known at any time

Failing to record and preserve the history of a container before that container is “untracked” in the waste tracking system

Placing incompatible wastes or materials in the same container

Failing to flush the drum pumping system before pumping waste that was not compatible with the last waste pumped

Placing reactive cyanides in tank T-404B

Improperly labeling and dating containers, having open containers, and accumulating wastes in containers that were leaking

Holding rejected wastes on site for longer than 30 days, failing to specify the location of all rejected wastes in the waste tracking system, and failing to document when a waste was determined to be rejected

Failing to place barcode labels on each container

Failing to attempt to reconcile a manifest discrepancy with the generator and failing to notify the Executive Secretary when the discrepancy was not resolved within 15 days

Failing to store infectious waste at or below 40°F when it was onsite for longer than seven days

Failing to incinerate infectious waste within 30 days after collection from the generator
Failing to properly code containers of infectious waste
Conducting the radioactivity screen with the sample bottle closed and conducting the ignitability screen without heating the sample to 140°F
Failing to provide an automatic interlock to shut off the vacuum pump that decants a container to a direct burn tanker
Failing to submit a written report to the Executive Secretary within 15 days after the explosion in the drum pump station
Failing to prepare and submit a complete biennial report by March 1, 2006
Failing to close the shredder area clean up door, and failing to close and seal the crane bay man door during backup operations
Failing to sample containers under fume exhausters in Building E5
Failing to mark all equipment with a tag containing a unique equipment identification number
Failing to document inspections of the emergency showers and eyewashes in the drive through direct burn station and the truck unloading building
Failing to maintain emergency equipment as necessary to assure its proper operation in time of emergency

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on October 5, 2007. It includes a penalty of \$147,389.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION and COMPLIANCE ORDER** issued December 8, 2005
ISSUES: Failing to record and preserve the history of a container before that container is “untracked” in the waste tracking system
Holding rejected wastes on site for longer than 30 days, by failing to properly identify and specify the location of rejected wastes in the waste tracking system; and by failing to document when a waste was determined to be rejected
Improperly labeling and dating containers, and having open containers
Failing to ensure that containers are stacked neatly and in a manner that will not cause them to fall or leak
Failing to record the location and movement history of each container placed in the container storage areas, and track these wastes in real time so that their location is known at any time
Failing to place the required warning signs on the infectious waste storage unit
Failing to store infectious waste at or below 40°F when it is on-site for longer than seven days
Failing to incinerate infectious waste within 30 days after collection from the generator
Failing to properly code containers infectious waste
Failing to use the debris matrix for characterization of debris for incineration parameters
Failing to factor in specific information when characterizing certain wastes for incineration parameters; and by failing to document how the incineration parameters were determined
Failing to clearly document the waste characterization procedure from the Waste Analysis Plan which applies to each waste stream accepted at the facility
Failing to prepare laboratory quality assurance reports as required
Failing to document the laboratory TCLP room temperature
Failing to place a unique barcode label on each container
Storing wastes which have not yet been accepted at the facility in an area not designated for

such storage
Failing to vent the bulk solids building, shredder, and small sludge tank to the carbon adsorption system during backup operations
Failing to maintain a database of all required equipment, failing to maintain drawings that show the approximate location of each piece of equipment, and failing to mark all equipment with a tag containing a unique equipment identification number
Failing to maintain emergency equipment as necessary to assure its proper operation in time of emergency
Failing to maintain a firebreak around the facility, and by failing to maintain the emergency evacuation exits on the south side of the facility
Failing to maintain the required signs on the perimeter fence
Filling the small sludge tank above the compliance level

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on October 18, 2006. It includes a penalty of \$37,293.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION and COMPLIANCE ORDER** issued February 4, 2005
ISSUES: Placing incompatible waste or other material in the same container
Failing to unload transport vehicles carrying containers within ten days of being received at the facility
Failing to attempt to reconcile a manifest discrepancy with the generator and failing to notify the Executive Secretary when the discrepancy was not resolved within 15 days
Holding rejected wastes on site for longer than 30 days, and failing to properly identify waste to be rejected in the waste tracking system
Storing hazardous wastes restricted from land disposal for more than one year
Storing compressed gas cylinders in areas not permitted for such storage
Failing to secure compressed gas cylinders to prevent falling, and failing to use appropriate measures to protect compressed gas cylinder valves from physical damage
Accumulating hazardous waste in containers for longer than 90 days, improperly labeling and dating containers, having open containers, and failing to accumulate hazardous waste in containers
Failing to ensure that containers are stacked neatly and in a manner that will not cause them to fall or leak and by exceeding the stacking height limitations
Failing to record the location and movement history of each container placed in the container storage areas, and track these wastes in real time so that their location is known at any time
Storing wastes in areas prohibited from storage in the permit
Failing to store infectious waste at or below 40°F when it is on-site for longer than seven days
Failing to ensure that infectious waste is contained in containers that are securely sealed to prevent leakage of the waste during storage and handling
Failing to use the information from the waste profile and the Infectious Waste Matrix for characterization of infectious waste for incineration parameters
Failing to clearly document the waste characterization procedure from the Waste Analysis Plan which applies to each waste stream accepted at the facility
Failing to have inventory sheets for lab packs accepted at the facility
Failing to place a unique barcode label on each container and appropriately marking

containers which have been accepted
 Storing wastes which have not yet been accepted at the facility in an area not designated for such storage
 Failing to indicate the date waste was first placed into temporary storage and storing wastes for longer than 10 days in the temporary storage areas
 Failing to clearly mark or label wastes manifested to another facility as transfer wastes
 Failing to annually monitor the sections of the closed vent system operated under positive pressure
 Failing to maintain a database of all required equipment, failing to maintain drawings that show the approximate location of each piece of equipment, and failing to mark all equipment with a tag containing a unique equipment identification number
 Blocking a fire door so that it could not completely close automatically in a fire emergency
 Failing to maintain emergency equipment as necessary to assure its proper operation in time of emergency
 Failing to provide an interlock to automatically shut off the robberoller vacuum pump when the vent reaches 60% LEL
 Failing to maintain and operate the robberoller vent in a manner that minimizes the possibility of a fire or explosion
 Failing to minimize the possibility of fires in the drum dumping system
 Filling the small sludge tank above the compliance level

RESOLUTION: A **STIPULATION AND CONSENT ORDER** was signed on September 29, 2005. It includes a penalty of \$114,912.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION and COMPLIANCE ORDER** issued March 3, 2004
 ISSUES: Exceeding the mercury emission standard
 Failing to attempt to reconcile a manifest discrepancy with the generator and failing to notify the Executive Secretary when the discrepancy was not resolved within 15 days
 Holding rejected wastes on site for longer than 30 days
 Failing to have inventory sheets for lab packs accepted at the facility
 Storing flammable liquids in building E-2
 Failing to transfer hazardous waste from a container that is leaking to a container that is in good condition or manage the waste in some other way to remedy the leak
 Failing to include the name of the individual who packaged the containers and provided the certifications of the contents of containers of infectious waste
 Placing incompatible waste in tank T-404B
 Failing to record the location and movement history of each container placed in the container storage areas, and track these wastes in real time so that their location is known at any time
 Incinerating a drum of arsenic trioxide
 Blocking a fire door so that it could not close automatically in a fire emergency
 Having open containers more than three feet from the ventilation hood

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed on April 4, 2005. It includes a penalty of \$21,536.00.

Clean Harbors-Owner

ACTION: **NOTICE OF VIOLATION** issued March 31, 2003
ISSUES: Placing reactive sulfides into tank T-308
Failing to record in the PI system when the plant was on waste
Failing to record the location and movement history of each container accepted in the container storage areas, and track these wastes in real time so that their location is known at any time; and failing to update the waste tracking system within two business days of making a transfer between tanks
Exceeding the direct burn feed rate limit
Accepting water reactive wastes
RESOLUTION: **STIPULATION AND CONSENT ORDER** signed November 4, 2003. It includes a penalty of \$2,536.00.

Safety-Kleen-Owner

ACTION: **NOTICE OF VIOLATION** issued March 26, 2002
ISSUES: Filling the small sludge tank above the compliance level
Failing to ensure that wastes to be rejected do not remain on-site for more than 30 days
Failing to record the location of each container accepted in the container storage areas, and track these wastes in real time so that their location is known at any time
Exceeding the sludge feed rate limit
RESOLUTION: **STIPULATION AND CONSENT ORDER** signed September 12, 2002. It includes a penalty of \$5,900.00.

Safety-Kleen-Owner

ACTION: **NOTICE OF VIOLATION** issued June 1, 2001
ISSUES: Exceeding the permitted feed rate of cadmium to the incinerator
Storing used oil fuel (VFS Distillate) from the Safety-Kleen East Chicago facility in the fuel oil tank and burning it in the incinerator when the incinerator did not meet all of the operating conditions for burning hazardous waste
Failing to record the location of each container accepted in the container storage areas, and track these wastes in real time so that their location is known at any time
Accepting pyrophoric wastes
Placing incompatible wastes or materials in the same container and failing to document any evaluation of the compatibility of the absorbent with the liquid
Failing to immediately submit to the Executive Secretary a letter describing a manifest discrepancy which was not resolved within 15 days after receiving the waste, and describing any attempts to reconcile the discrepancy
Overfilling one of the direct burn vessels
Filling the small sludge tank to overflowing
Failing to limit the heat content of containers fed to the incinerator to 4.76 MMBtu
Failing to retain the data recorded by the PI archiving system for at least three years
Failing to maintain systems to automatically cut off hazardous waste feed to the incinerator at a pH of less than 6.2 in the second stage packed tower effluent
RESOLUTION: **STIPULATION AND CONSENT ORDER** signed May 9, 2002. It includes a penalty of \$53,326.00. Since the violations occurred both prior to and after Safety-Kleen filing for

Chapter 11 bankruptcy protection, the penalty is divided into two parts. A penalty \$5,814 for the post-petition violations will be paid within 60 days of entry into the Consent Order. A penalty of \$47,512 for the pre-petition violations will be resolved through the bankruptcy court when Safety-Kleen emerges from bankruptcy.

Safety-Kleen-Owner

ACTION: **NOTICE OF VIOLATION and ORDER FOR COMPLIANCE** issued August 4, 2000
ISSUES: Using a bond to provide financial assurance for closure which exceeded the underwriting limitations of the surety issuing the bond without the necessary reinsurance agreements in place
Failing to re-establish other financial assurance for closure within the 60-day period after Frontier Insurance Company was no longer considered an acceptable surety
RESOLUTION: On August 25, 2000, Safety-Kleen entered into a Consent Agreement with EPA which allows an extended time frame for replacing the necessary financial assurance for closure. The state of Utah is a participating state in this Consent Agreement. The initial deadline for replacing financial assurance for closure was December 15, 2000, but was extended to February 28, 2001. The deadline for replacing financial assurance for closure was extended further by EPA to April 30, 2001. This deadline was extended again by EPA to September 30, 2001. Due to the events of September 11, 2001, the deadline was again extended by EPA to October 18, 2001. The deadline was again extended by EPA to November 30, 2001. Compliant financial assurance was later obtained and the issue resolved as of January 14, 2002.

Safety-Kleen-Owner

ACTION: **NOTICE OF VIOLATION** issued March 1, 1999
ISSUES: Placing waste into a tank which was not nitrogen blanketed
Exceeding the sludge feed rate limit and failing to accurately monitor and record the sludge feed rate
Failing to record the location of each container accepted in the container storage areas, and each bulk waste managed at the facility, and track these wastes in real time so that their location is known at any time
Failing to maintain systems to automatically cut off hazardous waste feed to the incinerator at the specified setpoints in the first stage packed tower liquid feed and the second stage packed tower effluent and by failing to correct any malfunctions of the automatic waste feed cut-off systems before restarting the incinerator
Making changes to the facility without following the specified procedures for modifying the permit.
Failing to have a test plan that was submitted to the Executive Secretary signed and certified as required
Failing to retain a copy of a manifest at the facility for at least three years
Failing to analyze the slag for methanol daily until analyses showed the treatment standards had been achieved for seven consecutive days after methanol was detected at a level above the treatment standards

Entering the wrong generator name, address, and phone number on manifests accompanying wastes shipped by Safety-Kleen (Aragonite), Inc. for off-site treatment, storage, or disposal

Failing to submit a certificate of hazardous waste liability insurance prior to the date of the policy expiration

Failing to maintain documentation to demonstrate that a batch of lab packs was approved

Failing to inform the generator in writing that they have the appropriate permits for, and will accept, the waste the generator is shipping when receiving hazardous waste from an off-site source

Failing to resolve discrepancies prior to accepting wastes and/or by failing to clearly document the resolution of discrepancies in the operating record

Exceeding the maximum stacking height of containers per pallet; failing to wrap or otherwise secure the containers to provide stability; and failing to place a barcode label on each container so that they could be tracked in the plant wide database

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed January 7, 2000. It includes a penalty of \$21,710.00.

Laidlaw Environmental Services- Owner

ACTION: **NOTICE OF VIOLATION** issued December 4, 1997

ISSUES: Failing to operate the facility to minimize the possibility of a fire or unplanned discharge of hazardous waste constituents into the air which could threaten the environment or human health

Failing to adjust the closure cost estimate for inflation and submit a copy of that adjusted closure cost estimate to the Executive Secretary within the required time frames, and by failing to increase the amount of the letter of credit or obtain other financial assurance whenever the current closure cost estimate increases to an amount greater than the amount of the letter of credit

Exceeding the sludge feed rate limit

Failing to record the location of each container accepted in the container storage areas, and each bulk waste managed at the facility, and track these wastes in real time

Failing to maintain systems to automatically cut off hazardous waste feed to the incinerator at the specified setpoints (and associated delays if applicable) for afterburner chamber pressure, first stage scrubber feed pH, second stage scrubber feed pH, second stage scrubber effluent pH, afterburner oxygen concentration, spray dryer temperature, blend liquid feed rates, and aqueous feed rates

Managing containers of infectious waste that were not colored or labeled as required; storing infectious waste longer than seven days without refrigeration; and failing to treat or dispose of infectious waste within 30 days after collection from the generator

Failing to notify all persons on the facility mailing list for various modifications and a temporary authorization request within the required time frames; and by failing to notify the Executive Secretary concerning a modification within seven calendar days after the change was put into effect

Failing to document through a work order the repairs made to a malfunctioning level transmitter on a hazardous waste storage tank

Failing to monitor the fumes in the carbon canister system at the required frequency

Storing hazardous waste from a hazardous waste storage tank tanker trucks in areas not authorized in the permit

Failing to place all containers in the repack workstations into storage each day by the end of each shift
Failing to annually update a waste stream profile and failing to complete all of the required waste acceptance procedures prior to accepting wastes
Failing to verify the contents of lab packs by unpacking them and comparing the contents to the load inventory sheets
Failing to transfer the hazardous waste from a container which is not in good condition or begins to leak to a container that is in good condition, and by handling and/or storing containers of hazardous waste in a manner which may cause them to leak
Failing to label or mark each container accumulating hazardous waste with the words "Hazardous Waste," failing to mark each container with the date upon which each period of accumulation began; failing to maintain containers holding hazardous waste closed except when it is necessary to add or remove waste; and accumulating hazardous waste for longer than 90 days in an area without a permit
Disposing of hazardous waste without a permit
Failing to maintain a current organization chart which specifies by name which person fills each job title listed in the Personnel Training Plan

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed December 4, 1998. It includes a penalty of \$58,385.

Rollins Environmental Services, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued December 11, 1996
ISSUES: Failing to operate the facility to minimize the possibility of a fire or unplanned discharge of hazardous waste constituents into the air which could threaten the environment or human health
Failing to record the location of each container in the container storage areas and track these wastes in real time
Failing to conduct and to document all of the required inspections; failing to inspect for all of the types of problems required; failing to provide acceptable criteria in the detailed written instructions for conducting the inspections; and failing to identify corrective actions performed when items were noted to be unacceptable
Failing to monitor the fumes in the carbon canister system at the required frequency
Failing to inform the generator in writing that they have the appropriate permits for, and will accept, the waste the generator is shipping when receiving hazardous waste from an off-site source
Storing hazardous waste in an unpermitted area east of the bulk solids tanks
Failing to unload a transport vehicle within ten days following arrival at the site
Failing to maintain a firebreak around the entire facility and to maintain an emergency evacuation route for the facility through the east gate on the south fence
Failing to maintain the level of tank T-312 at or below the compliance limit and for filling the tank to overflowing
Accepting a prohibited waste (dry picric acid, a D.O.T. Division 1.1 explosive) and treating it without a permit; also, accepting trinitrobenzene sulfonic acid (a D.O.T. Division 1.1 explosive)
Storing containers that have not been bar coded/accepted in a temporary storage area for longer than ten days
Failing to sample containers under fume exhausters in buildings E-1 and E-5

Managing containers of infectious waste that were not colored or labeled as required
Failing to compare the actual load samples to the profile samples prior to accepting a load of waste
Failing to identify the associated TC waste codes for a waste stream
Failing to collect and analyze representative samples from waste streams prior to approving the waste streams for storage and/or treatment at the facility
Failing to label or mark each container accumulating hazardous waste with the words "Hazardous Waste," and by accumulating hazardous waste for longer than 90 days in an area without a permit

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed October 7, 1997. It includes a penalty of \$33,811.

Rollins Environmental Services, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued September 18, 1995
ISSUES: Failing to maintain systems to automatically cut off hazardous waste feed to the incinerator at a pH of less than 6.2 in the first stage packed tower liquid feed and at a carbon monoxide rolling average concentration of greater than 100 ppm
Accepting wastes that do not conform with the manifest and failing to draw a sample from as deep a cross section as possible at each location on bulk solids loads
Failing to notify the Executive Secretary and submit, within the required time frames, a proposed time schedule for correcting a leak from the sludge tank system
Failing to maintain a minimum of 2.5 feet of aisle space in the drum storage area
Canceling or terminating the liability insurance without providing prior written notice to the Board within the required time frames
Installing and using the one-inch stainless steel tubing from the aqueous waste feed line (header D) to the repack room in building E-4 without first obtaining authorization from the Executive Secretary of the Board through the permit modification process
Failing to notify the Executive Secretary, within the required time frames, for the March 28, 1995 spill of hazardous waste from the C header to the ground near the carbon canister system, west of the tank farm
Failing to maintain records to document that the applicable training has been given to each individual
Failing to manage liquid removed from sump SP627 as a hazardous waste
Stacking containers with a capacity of fifty gallons or greater more than one high in the receiving and holding area of building E-5; failing to stack containers in storage neatly and/or wrap them to provide stability; and exceeding the capacity of 11,000 gallons in the receiving and holding area of building E-5
Exceeding the maximum allowable feed rates for antimony and lead
Failing to equip and maintain in good operating condition at the facility all the equipment set forth in Attachment II-5

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed June 10, 1996. It includes a penalty of \$40,320.

Rollins Environmental Services, Inc.-Owner

ACTION: **WARNING LETTER** issued April 7, 1995

ISSUES: Confined space permit not located at the entry to the work area; confined space work area not roped off; Several changes were made in the confined space permit without indication that the changes had been approved or communicated to all appropriate personnel; the job safety analysis specified continuous O₂/LEL monitoring, but was done only initially; the job safety analysis specified sliding clips to be used on the ropes to protect them from being cut, none were noted being used; both observers were noted to be performing other functions and there were times when neither of the observers was in visual contact with the entrant; the attendants' respirators were laying on the ground and hanging on the end of a pole

The combustion air pressure indicator for the kiln front wall is located upstream of the damper having apparently been moved from an earlier downstream location. This would allow the kiln secondary combustion air to be cut off by closing the damper without activating the automatic waste feed cut-off (since the pressure indicator is upstream of the damper)

The high level alarm was deactivated for Tank T-310 for an unknown period of time

A general lack of importance was noted being placed on the inspections performed on-site; lack of consistency on how inspection forms are being filled out; different opinions between inspectors on what constitutes an unsatisfactory status for the same or similar items; a tendency to not mark down deficiencies if the status has not changed over time; there is a perceived lack of knowledge on the part of the inspectors on what is the acceptable criteria for many items; there does not appear to be a consistent and timely procedure for following up on work orders and corrective action

Open containers without labels and dates were noted under hoods in the lab

Site-generated waste was transferred from a tank with a 30-day extension to the 90-day accumulation period, to a tank without the extension to the accumulation period

The maximum feed rate of solids to the kiln was exceeded

RESOLUTION: Issues satisfactorily resolved through a response from Aptus dated April 28, 1995 and subsequent permit modifications.

Westinghouse, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued December 20, 1994

ISSUES: Perimeter fence signs missing or obscured

Labeling, dating, and segregation requirements not being met for containers in the "A" aisles of the container storage buildings

Open containers in the container storage building

Failing to recognize necessary corrective action required during inspections, and not promptly performing corrective actions

Incinerating wastes carrying a waste code not allowed by the permit

Storing containerized waste bearing free liquid outside of bermed areas as specified in a temporary authorization

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed April 21, 1995. \$12,120 penalty paid May 15, 1995.

Westinghouse, Inc.-Owner

ACTION: **WARNING LETTER** issued September 8, 1994

ISSUES: Failure to label or mark each container accumulating hazardous waste with the words "Hazardous Waste"; failure to clearly mark each container with the date upon which each period of accumulation began; accumulation of hazardous waste for longer than 90 days without first submitting, and receiving approval of the Executive Secretary for, a hazardous waste operation plan for that facility

Site-generated wastes were not being subjected to the same waste analysis procedures as wastes accepted from off-site sources

Operating record requirements for wastes pumped from sumps to storage tanks were not being met

No response time tests were conducted in 1992 and 1993 for the CO and O₂ monitors

No RATA was conducted following installation of a new oxygen monitor on August 1, 1993

The Aptus Lakeville Laboratory lost their certification for RCRA metals and during this time metals data from the Lakeville lab was used by Aptus to make waste management decisions at the Aragonite facility

On two occasions Aptus operated the low range CO monitor in the high range mode while burning waste

RESOLUTION: Issues satisfactorily resolved through responses from Aptus dated October 7, 1994 and January 31, 1995.

Westinghouse, Inc.-Owner

ACTION: **WARNING LETTER** issued May 27, 1994

ISSUES: Temperature conditions in the laboratory were not acceptable

Laboratory personnel combining parts from several different methods to develop SOPs

Fume hoods in the laboratory not adequately venting with all the instruments and reagent bottles inside; several analyses being performed on the bench-top appear to be candidates for being done under a hood/ventilation system

The Quality Assurance function in the laboratory needs to be more independent from method development; more frequent internal data validation is necessary; more management oversight and review of daily workbooks is needed

Laboratory standards not being maintained with a consistent expiration period

Not all of the required laboratory QC requirements were being followed; not routinely analyzing method blanks and duplicates; method spikes/method spike duplicates need to be performed at the required frequency; tuning log and continuing calibration documentation must be maintained

The laboratory working standards and solutions do not have the necessary information on the label to properly identify the material

The laboratory refrigerator and freezer temperatures were not being properly maintained

The laboratory water system does not conform to Type I water specifications

The two shifts in the laboratory are not consistent in following protocol

There needs to be more interaction between the chemist and the field personnel so that the bench chemist knows the needs of field operations

Temperatures of samples at the time of analysis not being taken

Data from outside labs must be validated; these labs must use the same methods as are specified in the Waste Analysis Plan; outside labs must be Utah certified for the

appropriate parameters and must submit sufficient QC information with each data package to allow for data validation

Many of the test methods in the Waste Analysis Plan are either not adequate or are not being performed as required

Excessive fugitive emissions being released to the atmosphere through an access on top of the deslagger chute

The door to bulk solids tank T404A was apparently not closed as soon as possible after unloading a truck; the door was still open while shredding operations were ongoing; questions raised about the adequacy of the ventilation system in the bulk solids building

Waste in the bulk solids tanks being piled much higher than the height of the walls of the tanks exceeding the permitted capacity

Daily sump inspection forms have been revised from those specified in the permit

RESOLUTION: Issues satisfactorily resolved through a response from Aptus dated June 27, 1994 and subsequent permit modifications.

Westinghouse, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued March 8, 1994

ISSUES: Failure to label or mark each container accumulating hazardous waste with the words "Hazardous Waste"; failure to clearly mark each container with the date upon which each period of accumulation began; accumulation of hazardous waste for longer than 90 days without first submitting, and receiving approval of the Executive Secretary for, a hazardous waste operation plan for that facility

Exceeding the maximum allowable arsenic, cadmium, chromium, and mercury feed rates to the incinerator

Failure to maintain the automatic waste feed cut-off system to automatically cut-off the waste feed at established setpoints for combustion air pressure, waste liquid pressure, and atomizing air pressure; failure to test, on a quarterly basis, the four signals (loss of flame, low combustion air pressure, low atomizing air pressure, and low waste liquid air pressure) which cause the Burner Management System on each burner to shut down, causing a waste feed cut-off

Failure to record in the operating record the date(s) of treatment of wastes and the location of each hazardous waste within the facility

Storing and/or incinerating wastes carrying waste codes not allowed by the permit

Failure to maintain a nitrogen blanket on the sludge storage tank

Failure to monitor and record the one hour rolling average concentration of carbon monoxide (CO) in the stack on a continuous basis

Failure to limit the feed rate of containerized waste to a maximum of 20 containers per hour; failure to limit the thermal input to the incineration system to 120×10^6 Btu per hour

Failure to continuously monitor and record the feed rate of pumpable sludge; failure to monitor and record, on a periodic basis equal to the charging cycle, the feed rate of bulk solid wastes

Failure to include in the notification to the treatment or storage facility, the corresponding treatment standards or the applicable five-letter treatment code when the treatment standards are expressed as specified technologies

Failure to take manual LEL measurements at the bulk solids tanks, the sludge tank, and the "A" damper every three hours when fumes are not going to the kiln; failure to take and record manual PID (or equivalent) readings at the bulk solids tanks, the sludge tank, and

the "A" damper every three hours and/or when unloading trucks, whichever is less, when the combustion air fans are off

Failure to inspect the leak detection system of the bulk solids tank; failure to follow the inspection schedule found in the permit; failure to record that sumps were not empty; failure to empty sumps containing material within 24 hours

Failure to maintain and operate monitoring equipment to measure the stack carbon monoxide level, corrected to 7% oxygen, while incinerating hazardous waste

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed June 16, 1994. \$70,000 penalty paid June 16, 1994.

Westinghouse, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued November 9, 1992

ISSUES: Failure to maintain the level of the sludge storage tank at or below the compliance limit and for filling the sludge storage tank to overflowing

Failure to perform the Tank Level Instrumentation Procedure for the sludge storage tank; failure to document in the Operating Record that these tests have been completed and the results obtained for tank T-302; failure to transfer enough of the liquid contents to another tank to lower the level to the maximum operating level following the completion of the Tank Level Instrumentation Procedure for tank T-302

Failure to monitor the direct burn flow rate continuously during the trial burn

Failure to label or mark each container accumulating hazardous waste with the words "Hazardous Waste"; failure to clearly mark each container with the date upon which each period of accumulation began; accumulation of hazardous waste for longer than 90 days without first submitting, and receiving approval of the Executive Secretary for, a hazardous waste operation plan for that facility

Failure to change out the carbon canisters in the tank farm when the reading between the canisters exceeded 100 ppm; failure to use the correct form to record these carbon canisters readings

Failure to have all reports submitted to the Executive Secretary signed as required

Failure to conduct all of the required personnel training

RESOLUTION: Through formal correspondence from Aptus received December 23, 1992, each of issues identified in the November 9, 1992 **NOTICE OF VIOLATION** was satisfactorily resolved. No penalty was assessed in connection with this action.

Westinghouse, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued July 22, 1992

ISSUES: No dates and/or labels on containers and open containers

Failure to test all of the required parameters in the automatic waste feed cut-off system

Failure to maintain the automatic waste feed cut-off system to automatically cut-off the hazardous waste feed to the incinerator at the specified setpoints

Exceeding the maximum specified turndown ratio

Incinerating wastes having waste codes not allowed by the Permit

Exceeding the maximum allowable arsenic feed rate to the incinerator

RESOLUTION: **STIPULATION AND CONSENT ORDER** signed February 3, 1993. \$7500.00 penalty paid February 18, 1993.

Westinghouse, Inc.-Owner

ACTION: **NOTICE OF VIOLATION** issued April 22, 1991
ISSUES: No dates and/or labels on containers and open containers
Disposing of hazardous waste without a permit
Failure to use the analytical test method specified in the permit
Failure to have a completed profile for each waste stream managed at the facility and failure to follow the specified sampling strategy
RESOLUTION: **STIPULATION AND CONSENT ORDER** signed February 14, 1992. \$17,500 penalty paid February 28, 1992.

Westinghouse, Inc.-Owner

ACTION: **WARNING LETTER** issued January 22, 1991
ISSUES: Improper certification statement on permit submissions
RESOLUTION: Not Applicable

Appendix K

C. Veolia Port Arthur Penalty Record

Type	Location	Date	Address	Regulatory Body/ Agency	Description of Alleged Violation	Fine Amount	Final Disposition
Disposal Facility	Veolia Port Arthur	3/1/2011	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to maintain required kiln temperature, submit an accurate Title V Semiannual Deviation Report, and an accurate Annual Compliance Certification.	None	Submitted corrective action plan. Letter received from TCEQ that issues resolved and no further action is necessary.
Disposal Facility	Veolia Port Arthur	3/1/2011	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to provide proper calibration gas for quarterly CEM audits, failure to repair a leaking pressure relief valve within 5 days of detecting a leak, failure to remonitor a repaired pump within 15 days of pump being placed back into service, and failure to submit data assessment reports as required.	None	Submitted corrective action plan. Letter received from TCEQ that issues resolved and no further action is necessary.
Disposal Facility	Veolia Port Arthur	2/22/2012	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to operate incinerator in compliance with the minimum and maximum operating parameters specified in the permit including, the minimum combustion temperature, minimum voltage to the IWS and minimum power to the WESP, and excessive CO emissions.	None	Veolia had self-identified these deviations of the operating permit in the October 2011 Subpart EEE semiannual report. Veolia submitted a corrective action plan to the TCEQ on 4/6/12. TCEQ responded on 5/9/12 that the violations have been adequately resolved.

Appendix K

C. Veolia Port Arthur Penalty Record

Disposal Facility	Veolia Port Arthur	2/29/2012	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to maintain CO emissions below permitted limit. Failure to maintain required kiln temperature. Failure to maintain minimum voltage to the ionizing wet scrubber and minimum power to the wet electrostatic precipitator.	None	Submitted response to TCEQ with corrective actions. Received letter from TCEQ on 8/23/12 stating that the violations have been adequately resolved.
Disposal Facility	Veolia Port Arthur	5/30/2012	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	TPDES alleged violations for not collecting CBOD and ammonia samples during a discharge.	None	Response submitted by Veolia to the TCEQ NOV on 1/22/13. Response received from the TCEQ and no further action required.
Disposal Facility	Veolia Port Arthur	12/14/2012	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Alleged RCRA violations for not removing accumulated precipitation in secondary containment, failure to implement spill prevention measures, failure to complete OJT for a driver.	None	Veolia submitted a written response to the TCEQ on 1/11/13. Received letter from TCEQ on 5/22/13 that no further action is required.
Disposal Facility	Veolia Port Arthur	5/2/2013	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to maintain minimum power to the wet electrostatic precipitator. Failure to conduct periodic audits of processes. Failure to maintain CO emission rate below permitted limit.	\$13,050	Veolia submitted a response to the TCEQ on 5/24/13. For the violation relating to the CO emissions, Veolia received an Agreed Order assessing a \$13,050 penalty.
Disposal Facility	Veolia Port Arthur	10/1/2014	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Alleged RCRA violations related to documentation of inspections, maintenance of related records, and failure to maintain a current NOR.	None	Veolia submitted a written response to the TCEQ on 10/22/14. Received TCEQ documentation on 2/9/15 that no further action is required.

Appendix K

C. Veolia Port Arthur Penalty Record

Disposal Facility	Veolia Port Arthur	1/6/2015	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Failure to operate incinerator in compliance with the CO emission limits for the time period April - August 2014.	None	Veolia has submitted a written response including the corrective actions taken.
Disposal Facility	Veolia Port Arthur	1/16/2015	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Drinking water inspection noted deficiencies in plant operations recordkeeping, inspections, and notification of system changes.	None	Response submitted by Veolia to the TCEQ NOV on 5/20/15. Response received from the TCEQ and no further action required.
Disposal Facility	Veolia Port Arthur	4/22/2015	7665 Texas Highway 73, Beaumont, TX 77705	Texas Commission on Environmental Quality	Alleged violations for TPDES compliance including failure to sample outfall in compliance with Water Quality Discharge Permit, failure to properly calculate the daily average for E coli and failure to correctly report effluent data on the DMR.	None	Response submitted by Veolia to the TCEQ NOV on 1/22/13 and response received from the TCEQ that no further action required.

Appendix K

D. Stericycle Inc., Indianapolis, Indiana Facility (“Stericycle Facility”) Penalty Record

Type	Location	Date	Address	Regulatory Body/Agency	Description of Alleged Violation
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	6/23/2015	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	6/26/2014	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	3/26/2014	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	6/28/2013	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	12/11/2012	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	4/23/2012	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.
Disposal Facility	Stericycle, Inc., Indianapolis, Indiana Facility (“Stericycle Facility”)	4/21/2011	2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901	Resource Conservation and Recovery Act	Violations or compliance issues were found.

Sample – Not for Distribution. All text subject to change pending review and approval by San Mateo County.

Appendix K

E. Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility (“Covanta Facility”) Penalty Record

Type	Location	Date	Address	Regulatory Body/Agency	Description of Alleged Violation
Disposal Facility	Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility (“Covanta Facility”)	2013	2320 S. Harding St., Indianapolis, IN 46221	IDEM	Agreement Order issued with regards to baghouse bags and nicotine gum.

Appendix L

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

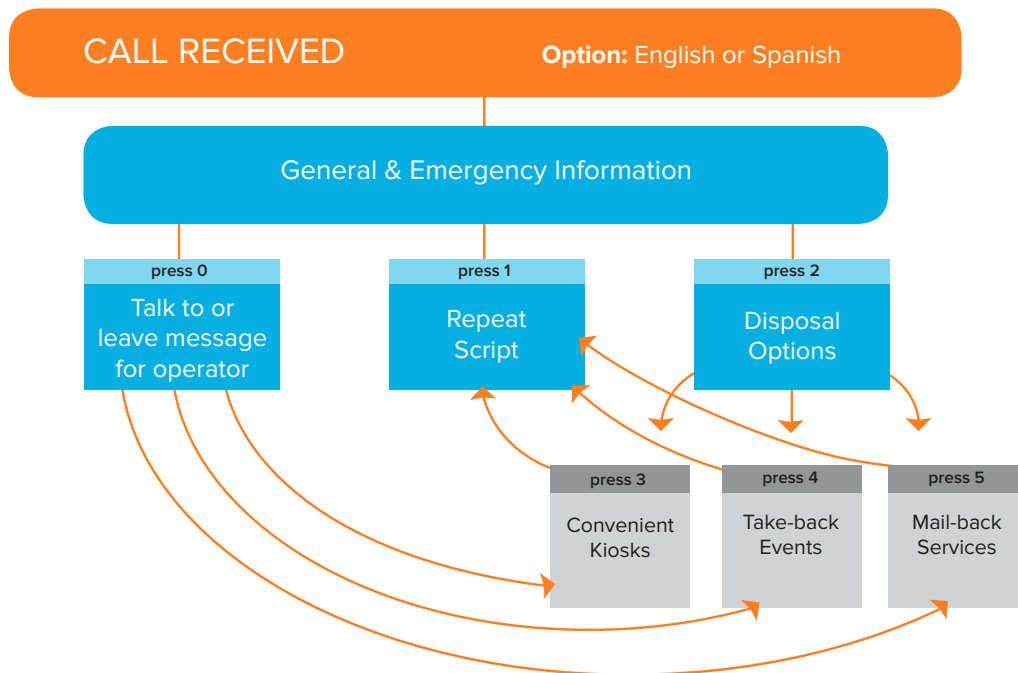
Residents will also be able to select a Spanish version.

Pending guidance from the Director, MED-Project will coordinate with other Stewardship Plans to provide Chinese, and Tagalog versions.

MED-Project

Medication Education & Disposal

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



Press 1 for Spanish or remain on the line for English

- 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 medicines. [Press 3](#) for more information about convenient kiosks.
- Take-back events are scheduled throughout the year and offer residents a free and convenient way to dispose of expired or Unwanted Medicines. [Press 4](#) for more information.
- Mail-back services are available to San Mateo residents. [Press 5](#) for more information.
- You may [press 0](#) at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and consumer disposal.
- MED-Project reminds you that taking your medicine as directed by your health care provider is critically important to your health.
- If you have questions about your medication, please hang up and dial your health care provider.
- For additional questions about the proper disposal of expired or unwanted medications from households, please go to www.med-project.org or [press 0](#) to talk to an operator.
- To hear this menu again, please [press 1](#).
- *Thank you for calling MED-Project.*

Kiosk Script for when 3 is selected:

- Kiosks to collect expired and unwanted medicine are located conveniently through the city. To locate the kiosk site nearest you, or for precise information about kiosk hours of operation, press 0 to speak with an operator or visit: www.med-project.org/locations/san-mateo/convenient-kiosks to search by your zip code.
- Kiosks accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; sharps; illicit drugs; or iodine-containing medications will be accepted.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications.
- To repeat this information, press 3.
- To return to the main menu, please press 1.
- *Thank you for calling MED-Project.*

Take-back Script for when 4 is selected:

- MED-Project is working with local law enforcement and other community organizations to offer regular expired and unwanted medicine take-back events. For a complete list of take-back events, please press 0 to speak to the operator or visit: www.med-project.org/locations/san-mateo/take-back-events.
- Take-back events accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; sharps; illicit drugs; or iodine-containing medications will be accepted.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications.
- To repeat this information, press 4.
- To return to the main menu, please press 1.
- *Thank you for calling MED-Project.*

Mail-back Package Script for when 5 is selected:

- Mail-back services are available to residents who are home-bound or differentially-abled or home healthcare professionals providing services to differentially-abled or home-bound residents.
- To request a mail-back package, please press 0 to talk to the operator or visit: www.med-project.org/locations/san-mateo/mail-back.
- Mail-back packages accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; sharps; illicit drugs; or iodine-containing medications will be accepted.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications.
- To repeat this information, press 5.
- To return to the main menu, please press 1.
- *Thank you for calling MED-Project.*

Appendix M

MED-Project Website

Translations of the website will be available in Spanish, Chinese, and Tagalog.

The screenshot displays the MED-Project website interface. At the top left, the logo reads "MED-Project" in orange and teal, with "Medication Education & Disposal" underneath. To the right of the logo is a navigation bar with four icons: a location pin labeled "Search by Location", an information icon labeled "MEDInfo", a magnifying glass labeled "MEDfaq", and an envelope icon labeled "Contact".

The main content area features a teal text block on the left: "Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It's vitally important that patients take their medicines as prescribed by their health care provider. However, if you have expired or unwanted medication, proper disposal is important and easy." To the right of this text is an image of three pill bottles. The first bottle is labeled "EXPIRED" and contains yellow pills. The second bottle is partially full of yellow pills. The third bottle is labeled "UNWANTED" and contains yellow pills.

Below the text and image is a horizontal line, followed by the text "CLICK ON ANY OF THE RECOMMENDED DISPOSAL OPTIONS BELOW TO LEARN MORE". Underneath this text are five circular icons, each with a corresponding label below it: a blue document icon with a globe labeled "CHECK THE PACKAGE"; a red calendar icon labeled "TAKE-BACK EVENTS"; a teal map icon with red location pins labeled "CONVENIENT KIOSKS"; a red envelope icon labeled "MAIL-BACK"; and an orange house icon labeled "IN-HOME DISPOSAL".

At the bottom of the page, a solid orange bar contains the following text: "This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers."

MED-Project Website

CHECK THE PACKAGE

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



CHECK THE
PACKAGE



TAKE-BACK
EVENTS



CONVENIENT
KIOSKS



MAIL-BACK



IN-HOME
DISPOSAL

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MED-Project Website

TAKE-BACK EVENTS

Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. The local authorities and MED-Project may also sponsor drug take-back events in your area.



CALENDAR OF LOCAL TAKE-BACK EVENTS

Thursday, July 14, 2016
TAKE-BACK DAY
City of San Mateo Police Department
200 Franklin Pkwy
San Mateo, CA 94403
Start Time: 2:00 pm
End Time: 5:00 pm
[Link to Website](#)



CHECK THE PACKAGE



TAKE-BACK EVENTS



CONVENIENT KIOSKS



MAIL-BACK




IN-HOME DISPOSAL

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or Individual producers.

MED-Project Website

MED-Project
Medication Education & Disposal


Search by Location


MEDinfo


MEDfaq

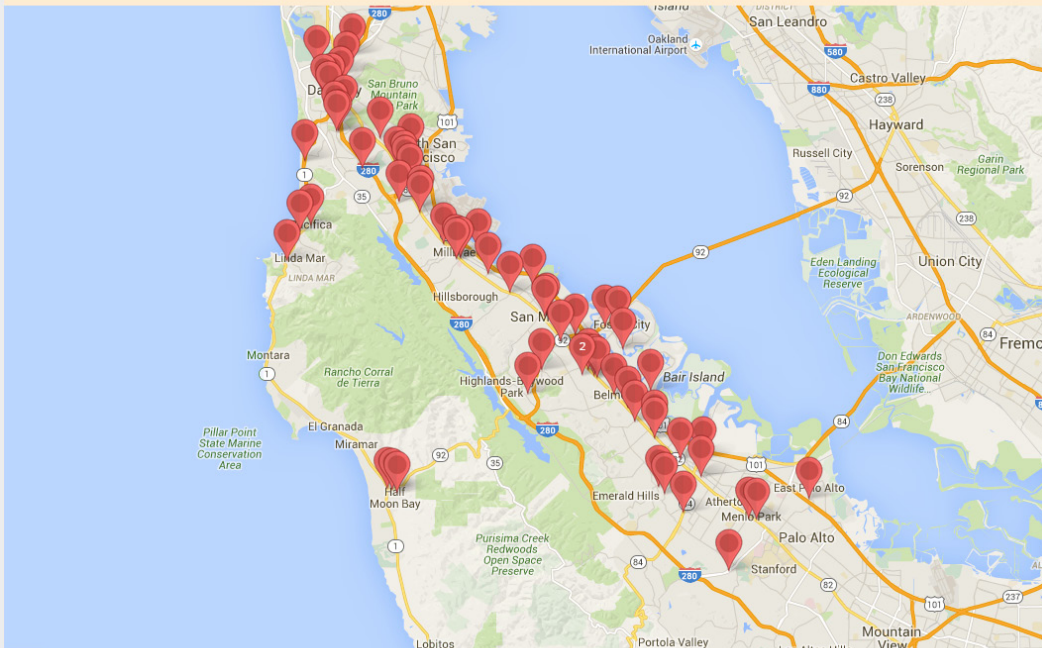

Contact

CONVENIENT KIOSKS

Community drug take-back locations allow residents to bring expired or unwanted medicines to a convenient, centralized location for proper disposal. To find the nearest disposal kiosk, enter your zip code below.

Enter your zip code

SUBMIT



This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MAIL-BACK

Mail-back services are available to differentially-abled and homebound residents. Please complete the below form to request a pre-paid, pre-addressed mail-back package.

First Name*

Last Name*

Email*

Address 1*

Address 2

City*

State/Region*

Zip Code*

[Submit Request!](#)



CHECK THE PACKAGE



TAKE-BACK EVENTS



CONVENIENT KIOSKS



MAIL-BACK



IN-HOME DISPOSAL

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MED-Project Website

IN-HOME DISPOSAL

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

1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds, dirt, or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs).
2. Place the mixture in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.*
3. Alternatively, mail-back services will be available to differentially-abled and homebound residents. [Click here](#) to request a pre-paid, pre-addressed mail-back package.

*Source: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, last updated April 27, 2016.



CHECK THE
PACKAGE



TAKE-BACK
EVENTS



CONVENIENT
KIOSKS



MAIL-BACK



IN-HOME
DISPOSAL

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MED-Project Website

MED-Project
Medication Education & Disposal

 Search by Location

 MEDinfo

 MEDfaq

 Contact

CONTACT

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

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

Pharmacies and Law Enforcement Offices

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

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

Drug Producers

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

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

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MED-Project Website

The screenshot displays the MED-Project website interface. At the top left, the logo reads "MED-Project Medication Education & Disposal". To the right are navigation buttons: "Search by Location" (with a location pin icon), "MEDinfo" (with an information icon), "MEDfaq" (with a magnifying glass icon), and "Contact" (with an envelope icon). Below this is an orange header bar with the text "MEDfaq". The main content area features a list of 15 expandable FAQ items, each with a plus sign icon. The first item is expanded, showing the text: "MED-Project is the entity implementing the San Mateo County MED-Project Product Stewardship Plan for Unwanted Medicine from Households, including the education and outreach programming." At the bottom of the page, a footer contains a disclaimer: "This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers."

MED-Project
Medication Education & Disposal

Search by Location MEDinfo MEDfaq Contact

MEDfaq

- What is the MED-Project?
MED-Project is the entity implementing the San Mateo County MED-Project Product Stewardship Plan for Unwanted Medicine from Households, including the education and outreach programming.
- + What should I do if I am having a medical emergency?
- + What should I do if I think I have ingested something poisonous?
- + What should I do if my pet has ingested medication?
- + Whom should I call with a question about my medication?
- + Where can I find information about the safe storage of medication?
- + Where can I find information about California's Prop 65?
- + Can I flush my medication down the toilet?
- + Should I remove my personal information before disposing of my medication?
- + Where are the MED-Project disposal locations nearest me?
- + Will it cost me anything to dispose of my expired or unwanted medications?
- + What items can I dispose of in the MED-Project kiosks?
- + Will there be any take-back events in my area?
- + Where else can I find information about the safe disposal of expired or unwanted medicines?
- + I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?
- + What is recommended for safe disposal of expired or unwanted medicine in San Mateo?

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.

MED-Project Website

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](#)
[Frequently Asked Questions](#)
[Public Service Announcement](#)

Radio Public Service Announcement (PSA):

[PLAY](#)

[DOWNLOAD](#)

Video Public Service Announcement (PSA):

[PLAY](#)

[DOWNLOAD](#)

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

This material has been provided for compliance with the County of San Mateo Safe Medicine Disposal Ordinance and does not necessarily reflect the views of the Plan owner or individual producers.


Appendix N

Brochure/Flyer Mockup





Translations of the brochure will be available in Spanish, Chinese, and Tagalog.

MEDICATION EDUCATION & DISPOSAL

What should you do with your expired or unwanted medicines?



There are a number of ways to dispose of expired or unwanted medicines:

-  CHECK THE PACKAGE
-  TAKE-BACK EVENTS
-  CONVENIENT KIOSKS
-  IN-HOME DISPOSAL

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.

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 medication labels or packaging before using any of the following disposal options. (Source: U.S. Food and Drug Administration)

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

MED-Project
Medication Education & Disposal

MEDICATION EDUCATION & DISPOSAL

CHECK THE PACKAGE

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



TAKE-BACK EVENTS

Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. The local authorities, and MED-Project may all sponsor local drug take-back events in your area. To find an event, visit the Take-Back Events section of www.med-project.org.



CONVENIENT KIOSKS

Community drug take-back locations allow residents to bring expired or unwanted medicines to a convenient, centralized location for proper disposal. To find the disposal kiosks in your area, visit the Convenient Kiosks section of www.med-project.org.



IN-HOME DISPOSAL

If no disposal instructions are given on the drug labeling and no take-back program is available in your area, throw the drugs in the household trash following these steps: 1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds, dirt, or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs). 2. Place the mixture in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag*. 3. Alternatively, mail-back services are available to differentially-abled and homebound residents. Visit the Mail-Back section of www.med-project.org to order a mail-back package.



*Source: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, last updated April 27, 2016.

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

Instruction Brochure/Flyer Mockup

Translations of the brochure will be available in Spanish, Chinese, and Tagalog.

MEDICATION EDUCATION & DISPOSAL

- 1 CHECK THE PACKAGE**

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


- 2 TAKE-BACK EVENTS**

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


- 3 CONVENIENT KIOSKS**

To find the drop-off sites in your area, visit the Convenient Kiosks section of www.med-project.org.


- 4 IN-HOME DISPOSAL**
 1. Remove medication from its original container and mix with an undesirable substance, such as used coffee grounds, dirt, or kitty litter.
 2. Place the mixture in a sealable bag, empty can, or other container and throw in your household trash.*
 3. Alternatively, mail-back services are available to differentially-abled and homebound residents. Visit the Mail-Back section of www.med-project.org to order a mail-back package.

*Source: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm, last updated April 27, 2016.



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

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

MED-Project
Medication Education & Disposal

PSA Outline

MED-Project

Medication Education & Disposal

The following is a proposed outline for a public service announcement (PSA) promoting MED-Project.

Radio Script (approx. 60 seconds)

The Medication Education & Disposal Project wants the public to know the best way to dispose of expired and unwanted medications.

First, check the label. If there are specific disposal instructions on the label, follow those. Do not flush prescription drugs down the toilet unless the product information instructs you to do so.

Second, local drug take-back events and kiosks offer residents the option to dispose of unwanted or expired medicines.

Third, if no instructions are provided on the label and there's no take-back program in your area, you can dispose of these drugs at home by following these simple steps.

Remove the expired drugs from their original containers and mix them with an undesirable substance, like coffee grounds or kitty litter (this makes the drug less appealing to children and pets). Next place the mixture in a sealable bag, then place in a trash bag.

For more information on the MED-Project and to hear your disposal options again, visit www.med-project.org or call 1-844-MED-PROJ.

Paid for by MED-Project.

###

MED-Project

Medication Education & Disposal

TV Script (approx. 30 seconds)

Sample Visual	Sample Audio
Open on a panning shot of several prescription drug vials or a hand removing a vial from a medicine cabinet.	VO: There are several ways to dispose of expired and unwanted medications.
Cut to a tight shot of the vial in someone's hands and the finger scans the label.	First, check the label and follow the specific disposal instructions.
Then cut to an over the shoulder shot of a person looking at a laptop and going to the website. We can show screenshot of locator on our website. Alt visual, person making a phone call.	Or check local drug take-back events and kiosks available in your area.
Cut to a person at a kitchen counter with several pill vials. Cut to person dumping the container of one vial into a plastic sealable bag with coffee grounds in it. Cut to hand sealing the bag. Cut to hand placing in a trash can.	Or dispose of expired or unwanted medications by removing them from their original container and mixing them with an undesirable substance like coffee grounds or kitty litter. Then place the mixture in a sealable bag and place in a trash bag.
Cut to white screen with black text: TEXT: For more information on the MED-Project, visit www.med-project.org Or call 1-844-MED-PROJ (1-844-633-7765)	This message is brought to you by the MED-Project.

FAQ Outline

Translations of the FAQ will be available in Spanish, Chinese, and Tagalog.

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

What is the MED-Project?

MED-Project is the entity implementing the Product Stewardship Plan for unwanted medicine in San Mateo County, including the education and outreach programming.

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

If you are having a medical emergency, contact emergency medical services immediately by dialing 911.

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

If you think you have ingested something poisonous, contact emergency services immediately. Please dial 911 or contact your local poison control center.

What should I do if my pet has ingested medication?

If you believe your pet may have ingested human or animal medication not intended for consumption by your pet, please contact your veterinarian or local animal poison control hotline.

Whom should I call with a question about my medication?

Please direct all questions about your medication to your health care provider.

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

You should follow any storage instructions provided by your healthcare provider and any written instructions provided with your medication or listed on its packaging.

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

Where can I find information about California’s Prop 65?

California’s Office of Environmental Health Hazard Assessment (OEHHA) provides information regarding Proposition 65. Information can be accessed via OEHHA’s Proposition 65 web site, available here: <http://oehha.ca.gov/prop65/background/p65plain.html>

Can I flush my medication down the toilet?

Do not flush medications down the toilet unless the information on the label, package, or package insert specifically instructs you to do so.

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

Please remove all personal and identifying information from your medication labels and/or its packaging before disposal.

Where are the MED-Project disposal locations nearest me?

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

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

There will be no fee for medication disposal charged at the point of collection.

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

Kiosks accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; compressed cylinders, aerosols, and inhalers; medical devices; sharps; illicit drugs; or iodine-containing medications will be accepted.

Will there be a take-back event in my area?

Please visit the MED-Project website or dial the hotline at 1-844-MED-PROJ to learn about take-back events in your area.

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

Please dial the hotline at 1-844-MED-PROJ to request a pre-paid envelope to return your unwanted or expired medicine.

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

Several government agencies provide information regarding safe disposal of medication. Please refer to the FDA's website for more information ["Consumer Updates: How to Dispose of Unused Medicines."](#)

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

For more information, please dial the hotline at 1-844-MED-PROJ.

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

The United States Food and Drug Administration developed the following guidelines to encourage the proper disposal of medicines and help reduce harm from accidental exposure or intentional misuse after they are no longer needed:

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

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

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

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

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

¹ <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm>, page last updated 04/27/2016

Sample – Not for Distribution. All text subject to change pending review and approval by San Mateo County.

Appendix O

Sample Temple: Take-Back Event Media Advisory

MED-Project

Medication Education & Disposal

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

MED-Project to Support Take-Back Event on [Date, 2016]

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

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

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

When: [Date], [Time]

Where: [Location]

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

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Contact:

MED-Project Public Affairs at (844) 677-6532 (844-6PROJECT)

Appendix P

Sample Digital and Local Social Networks

The following is a representative list of local organizations and their social media networks in San Mateo County. MED-Project will reach out to relevant groups to help promote San Mateo County drug take-back days.

Outlet	Facebook / Nextdoor	Twitter
San Mateo County Sheriff's Office	/SMCSheriff	@SMCSheriff
San Mateo County Health System	/SMCHHealth	@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		@burlingamepd
City of Daly City	/dalycitygov/ https://nextdoor.com/city/daly-city--ca/	@DalyCityGov
Daly City Police	/dalycitypolice	@DalyCityPD
Daly City Library	/DalyCityLibrary/	@dalycitylibrary
DalyCity-Colma Chamber of Commerce	/dalycity.colmachamber	@dccchamber
Daly City Police Officers' Association	/DalyCityPOA	@DalyCityPOA
City of Brisbane	/brisbane94005 https://nextdoor.com/city/brisbane--ca/	@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 https://nextdoor.com/neighborhood/colmaca--colma--ca/	@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 https://nextdoor.com/city/pacifica--ca/	@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 https://nextdoor.com/city/millbrae--ca/	N/A
Millbrae Police Dept.	/pages/Millbrae-Police-Department/112605438793771	N/A
Millbrae Chamber of Commerce	/MillbraeChamber	@MillbraeChamber
Millbrae Patch	/MillbraePatch	@MillbraePatch
City of Burlingame	/BurlingameCityHall https://nextdoor.com/city/burlingame--ca/	@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 https://nextdoor.com/city/san-mateo--ca/	@CityofSanMateo
San Mateo Police Dept.	/CityofSanMateoPolice	@SanMateoPD
San Mateo Chamber of Commerce	/SanMateoChamber	@sanmateochamber
San Mateo County Health System	/SMCHHealth	@SMCHHealth
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 https://nextdoor.com/city/foster-city--ca/	@CityofFC
Foster City Police	/FosterCityPolice	@FosterCityPD
Foster City News	N/A	@fostercitynews
Foster City Patch	/FosterCityPatch	@FosterCityPatch
City of Belmont Public Works Dept.	/CityofBelmontCA https://nextdoor.com/find-neighborhood/ca/belmont/	@BelmontCA_ PWORK
Belmont Police Dept.	/Belmont-Police-Department/165395370186926	@belmontcapolice
Belmont City Patch	/belmontcapatch	@BelmontCAPatch
City of San Carlos	/cityofsancarlos https://nextdoor.com/city/san-carlos--ca/	@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 https://nextdoor.com/find-neighborhood/ca/menlo-park/	@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
City of East Palo Alto	/CityOfEastPaloAlto https://nextdoor.com/city/east-palo-alto--ca/	@eastpaloalto
East Palo Alto Police Dept.	/EastPaloAltoPD	@epapd
Town of Atherton	/TownOfAtherton https://nextdoor.com/city/atherton--ca/	@townofatherton
Atherton Police Officers Association	/AthertonPOA	N/A
Town of Woodside	/pages/Town-of-Woodside https://nextdoor.com/neighborhood/woodside--woodside--ca/	N/A
Portola Valley	N/A https://nextdoor.com/city/portola-valley--ca/	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

