

AGENDA REPORT

TO: Sabrina B. Landreth

City Administrator

FROM: Sean Whent,

Chief of Police

SUBJECT: Alameda Safe Drug Collection and

Disposal Agreements

DATE:

May 5, 2016

City Administrator Approval

Approval

Date

RECOMMENDATION

Staff Recommends That The City Council Approve A Resolution Authorizing The City Administrator, Or Designee, To Enter Into A Kiosk Services Agreement and Take-Back Services Agreement With The Alameda MED-Project LLC And The Oakland Police Department (OPD) To Implement The Safe Drug Disposal Kiosk Collection Program.

EXECUTIVE SUMMARY

The Alameda County Board of Supervisors approved the Alameda County Safe Drug Disposal (SDD) Ordinance, which requires that drug and medicine manufacturers and retailers in Alameda County operate or participate in a Product Stewardship Program for the disposal of unwanted drugs and medicine. Safe disposal helps to eliminate misuse as well as water contamination. The MED-Project is a nonprofit organization created by a national consortium of pharmaceutical companies to address regional disposal rules. The MED-Project wishes to place safe disposal kiosks in OPD's Police Administration Building (PAB) and Eastmont Substation (EMM) as convenient drop-off locations. The MED-Project will also be holding different drug and medicine drop-off events in the City and will require law-enforcement personnel to be present; the project will reimburse OPD for any personnel costs. OPD and the MED-Project require a Kiosk Services Agreement and a Take-Back Services Agreement to authorize this collaboration.

BACKGROUND AND LEGISLATIVE HISTORY

Countless drugs and medicine help treat diseases, manage chronic conditions, and improve the health and well-being for millions of people. However, once expired or unwanted, drugs and medicine should be disposed of to prevent their misuse. Additionally, unwanted drugs and medicine flushed down toilets find their way into bodies of water such as the San Francisco Bay and negatively impact the water quality. The Alameda County Board of Supervisors approved the Alameda County Safe Drug Disposal (SDD) Ordinance (*Attachment A*) in February 2012, for the disposal of household pharmaceutical products. The ordinance was revised in March, 2016. The ordinance requires that pharmaceutical manufacturers and retailers in Alameda

Item:
Public Safety Committee
June 14, 2016

Sabrina B. Landreth, City Administrator Subject: Alameda Safe Drug Collection and Disposal Agreements

Date: May 05, 2016 Page 2

County operate or participate in a Product Stewardship Program for the disposal of unwanted drugs and medicine by the public who purchase drugs and medicine.

Pharmaceutical manufacturers and retailers created the national Pharmaceutical Product Stewardship Working Group (PPSWG) to respond to regional unwanted prescription and overthe-counter (OTC) drug and medicine collection and disposal regulations. The PPSWG created the MED-Project, a public, non-profit entity, to address unwanted drug and medicine disposal in Alameda County. The MED-Project also supports education and outreach programming. The Alameda County Board of Supervisors approved the MED-Project Product Stewardship Plan on February 25, 2015 following a Public Hearing. Pharmaceutical manufacturers and retailers in Alameda County can partner with the MED-Project to fulfill their legal requirements under the SDD Ordinance. The purpose of the MED-Project is to create and operate take-back events, and to place drug disposal kiosks is public locations, and to collect unwanted prescription and OTC drugs and medicine from Alameda County households.

The MED-Project has partnered with various organizations to place secure drug and medicine disposal kiosks in convenient, safe locations. The MED-Project partners with Stericycle, a national pharmaceutical disposal company, to pick-up and incinerate the drugs and medicine dropped off at the kiosks. The MED-Project also organizes drug and medicine take-back events; the U.S. Drug Enforcement Agency (DEA) requires that law-enforcement personnel be present at these events where controlled substances may be collected for disposal purposes.

ANALYSIS AND POLICY ALTERNATIVES

The MED-Project plans to place drug and medicine disposal kiosks at both the PAB and the EMM because they are safe and central places where the disposed medicine can be safely brought for disposal. Additionally, the MED-Project and County of Alameda Public Health Department plan to hold a number of take-back events within the City of Oakland and the greater Alameda County. Currently, the MED-Project plans to hold a take-back event at the Oakland Zoo as part of the Healthy Living Festival. The MED-Project also plans to hold take-back events in conjunction public hazardous waste material take-back events. The MED-Project will reimburse OPD for personnel costs if OPD chooses to participate in these future take-back events. The MED-Project will advertise these events through diverse communication channels (newsletters, fliers, online media).

OPD is prepared to support MED-Project kiosks at the PAB and EMM to support the safe disposal of household medicines. OPD will need to determine if personnel will be available for future take-back events at other locations in Oakland. The MED-Project will partner with the Alameda County Sheriff's Office if OPD personnel are unavailable.

The Med-Project and OPD both require a Kiosk Services Agreement and a Take-Back Services Agreement before beginning this collaboration. Approval of this resolution will authorize the City Administrator or designee to sign the Kiosk Services Agreement and the Take-Back Event Services Agreement with the MED-Project. These two agreements will stipulate that the MED-Project will comply with all pertinent laws and will possess all required permits, licenses, and authorizations. OPD will not be required to possess any additional permits, licenses or authorizations.

Item:
Public Safety Committee
June 14, 2016

Page 3

FISCAL IMPACT

There is no fiscal impact associated with this resolution. The MED-Project will reimburse OPD for any future personnel costs.

PUBLIC OUTREACH / INTEREST

Many residents will find the Alameda County Product Stewardship Plan and the MED-Project useful. Staff will rely on the MED-Project to conduct public outreach for take-back events and to promote the safe disposal kiosks.

COORDINATION

The Office of the City Attorney and the Controller's Bureau were consulted in the preparation of this report.

SUSTAINABLE OPPORTUNITIES

Economic: No economic opportunities have been identified.

Environmental: Unwanted medicines have historically be flushed down toilets or left in households. Medicine flushed down toilets eventually reaches the San Francisco Bay and negatively affect water quality. The San Francisco Bay will be improved if more people participate in the medicine take-back program and refrain from flushing unwanted medicines. Unwanted prescription and OTC medicine can also be a health hazard to children who find access to medical pills and liquids. Proper disposal of unwanted medicine therefore promotes public safety.

Social Equity: All residents and visitors who benefit from safe, convenient and free access to unwanted medicine drop-off locations. Ultimately, the free, safe and convenient drug and medicine disposal program keep the environment cleaner for everyone and lessens the chance of drug and medicine abuse and misuse.

Item: _____ Public Safety Committee June 14, 2016

ACTION REQUESTED OF THE PUBLIC SAFETY COMMITTEE

Staff Recommends That The City Council Approve A Resolution Authorizing The City Administrator, Or Designee, To Enter Into A Kiosk Services Agreement and Take-Back Services Agreement With The Alameda MED-Project LLC And The Oakland Police Department (OPD) To Implement The Safe Drug Disposal Kiosk Collection Program

For questions regarding this report, please contact Sergeant Robert Muniz, OPD Criminal Investigations Division, at (510) 238-3728.

Respectfully submitted,

Sean Whent Chief of Police

Oakland Police Department

Reviewed by: Tim Birch, Police Services Manager OPD, Office of the Chief, Research and Planning

Robert Muniz, Sergeant OPD, Criminal Investigations Division

Prepared by: Bruce Stoffmacher, Legislation Manager OPD, Office of the Chief, Research and Planning

Attachments (1)

A: Alameda County Safe Drug Disposal (SDD) Ordinance

Item: _____ Public Safety Committee June 14, 2016

SAFE DRUG DISPOSAL ORDINANCE

(Title 6 of the Alameda County Health and Safety Code Sections 6.53.010 through 6.53.120)

6.53.010 - Declaration of findings.

The Board of Supervisors hereby finds and declares the following:

- A. Legal medicinal drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives;
- B. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription and non-prescription drugs and the illegal re-sale of prescription drugs;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription and non-prescription drugs passing through our wastewater treatment centers;
- D. There is no mandatory statewide drug stewardship program for unwanted drugs in California, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

Section 6.53.020 - Title

This Chapter may be cited as the "Alameda County Safe Drug Disposal Ordinance."

Section 6.53.030 - Definitions.

For the purposes of this Chapter, the following terms have the meanings given.

- "Controlled Substance" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.
- "Cosmetics" means (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (ii) articles intended for use as a component of any such articles, and (iii) cosmetics as defined above with expiration dates.

- 3. "Covered Drug" means a Drug sold, offered for sale or dispensed in Alameda County in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand name and generic drugs, and drugs for veterinary use.
 "Covered Drug" does not include:
 - (i) Vitamins or supplements; (ii) Herbal-based remedies and homeopathic drugs, products, or remedies; (iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, 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 ("FFDCA") (21 U.S.C. Sec. 301 et seq. (2002); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1); (v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Section if the Producer already provides a take-back program; (vi)) medical devices or their component parts or accessories if it contains no Covered Drug.
- 4. "Department" means the Alameda County Department of Environmental Health.
- 5. "Drug Wholesaler" means a Person that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.
- 6. "Drug" means: (i) any article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (ii) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) any substance, other than food, intended to affect the substance intended for use as a component of any substance specified in (i), (ii), or (iii) of this definition.
- 7. "Entity" means a person other than an individual.
- 8. "Generic Drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.
- "Mail-Back Program" means a collection method for the return of Unwanted Products from Residential Generators, utilizing prepaid and

- preaddressed mailing envelopes, for shipment to an Entity that will dispose of them safely and legally.
- 10. "Manufacture" means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a Repackager, wholesaler or practitioner who distributes or dispense such substance or device in the course of his or her professional practice.
- 11. "Manufacturer" means a Person engaged in the Manufacture of Drugs.
- 12. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.
- 13. "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal Entity, however organized.
- 14. "Plan" or "Product Stewardship Plan" means a product stewardship plan required under this Chapter that describes the manner in which a Product Stewardship Program will be provided.
- 15. "Prescription Drug" means any drug, including any Controlled Substance, that by federal or state law may be dispensed lawfully only on prescription, or is restricted to use by practitioners only.
- "Producer" means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County. "Producer" does not include (i) a retailer that puts its store label on a Covered Drug and the retailer provides verification and contact information of the Producer; or (ii) a pharmacist who compounds a prescribed individual drug product for direct distribution to a consumer and the pharmacist provides verification and contact information of the Producer; or (iii) a wholesaler and the wholesaler provides verification and contact information of the Producer. For purposes of this section contact information must contain the following: each Producer's name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer's participation in the Stewardship Program.
- 17. "Product Stewardship Program" or "Program" means a program for the collection, transportation, and disposal of Unwanted Products under this Ordinance that is: (1) financed, developed, implemented, and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; (3) approved by the Department; and (4) meets the educational and other requirements set forth in this Ordinance.

- 18. "Repackager" means a Person who owns or operates an establishment that repacks and relabels a product or package containing a Covered Drug for further sale or for distribution without a further transaction.
- 19. "Residential Generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned. "Residential Generators" do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.
- 20. "Stewardship Organization" means an organization designated by a group of Producers to act as an agent on behalf of each Producer to operate a Product Stewardship Program.
- 21. "Unwanted Product" means any Covered Drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

Section 6.53.040. - Product Stewardship Program.

- A. Requirement for sale. This Chapter shall apply only to a Producer whose Covered Drug is sold or distributed in Alameda County. This Chapter shall apply to all of Alameda County including unincorporated and incorporated areas, except for those incorporated areas (cities) where the governing body of that incorporated area (city) has authorized its own local health officer or environmental health director to administer and enforce the provisions of California Health and Safety Code section 117800. This Chapter shall be administered and implemented by the Alameda County Department of Environmental Health. Each Producer must:
 - Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the Department; or
 - Enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Product Stewardship Program approved by the Department.
- B. Product Stewardship Program costs.
 - A Producer, group of Producers, or Stewardship Organization must pay all administrative and operational fees associated with their Product Stewardship Program, including the cost of collecting, transporting, and disposing of Unwanted Products collected from Residential Generators

- and the recycling or disposal, or both, of packaging collected with the Unwanted Product.
- A Producer, group of Producers, or Stewardship Organization must pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.), if required, for a specific Product Stewardship Program and product stewardship Plan.
- 3. No Person or Producer may charge a specific point-of-sale fee to consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Residential Generators or delivered for disposal.
- 4. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the County of Alameda, including but not limited to the Department, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the County of Alameda shall only recover its actual costs of administration and enforcement under this Ordinance and shall not charge any amounts under this Ordinance in excess of its actual administrative and enforcement costs.

6.53.050 - Product stewardship plan.

- A. Plan content. Each Product Stewardship Program shall have a product stewardship Plan that contains each of the following:
 - Certification that the Product Stewardship Program will accept all Unwanted Products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the Plan;
 - 2. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program, including each Drug Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer's participation in the Stewardship Program;
 - 3. A description of the methods by which Unwanted Products from Residential Generators will be collected in Alameda County and an explanation of how the collection system will be convenient and adequate to serve the needs of Alameda County residents;

- 4. A description of how the product stewardship Plan will provide collection services for Unwanted Products in all areas of Alameda County that are convenient to the public and adequate to meet the needs of the population in the area being served.
- 5. The location of each collection site and locations where envelopes for a Mail-Back Program are available (if applicable):
- A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each Person that will be involved in transporting Unwanted Products and each medical waste or hazardous disposal facility proposed to participate in the Product Stewardship Program;
- 7. A description of how the Unwanted Products will be safely and securely tracked and handled from collection through final disposal and a description of the policies and procedures to be followed by Persons handling Unwanted Products collected under the Stewardship Program to ensure security;
- 8. A description of the public education and outreach activities required under this Chapter and how their effectiveness will be evaluated;
- A description of how the scope and extent of the Product Stewardship Program are reasonably related to the amount of Covered Drugs that are sold in the County of Alameda by the Producer or group of Producers;
- 10. A starting date when collection of Unwanted Products will begin;
- 11. A description of how support will be provided to any law enforcement agencies within Alameda County that have, or later agree to have, a collection program for collection of Unwanted Products including: (i) the provision of a collection kiosk with appropriate accessories and signage, (ii) an ability to accept Controlled Substances and other Covered Drugs, (iii) technical support up to and including an appropriate Person to provide on-site assistance at no cost to a participating law enforcement agency;
- 12. A description of how collection sites for Unwanted Products may be placed at appropriate retail stores in Alameda County including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites and nothing in this Ordinance shall be interpreted as requiring such participation; and
- 13. If more than one Producer will be involved in a proposed Product Stewardship Program, then the product stewardship Plan for that Program

must include a fair and reasonable manner for allocating the costs of the Program among the participants in that Program, such that the portion of costs paid by each Producer is reasonably related to the amount of Covered Drugs that Producer sells in the County of Alameda.

- 14. A certification that any patient information on Drug packaging will be promptly destroyed
- B. Department review and approval; updates.
 - 1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with this Ordinance until it has received written approval of its product stewardship Plan from the Department.
 - 2. Product stewardship Plans must be submitted to the Department for approval. The initial Plans must be submitted by July 1, 2013, or at a later date as approved in writing by the Department.
 - 3. Within 180 days after receipt and review of a Product Stewardship Plan, the Department shall conduct a noticed public hearing and determine whether the Plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter.
 - a) As part of its approval, the Department may set reasonable performance goals for the Program.
 - b) If the Department approves a Plan, it shall notify the applicant of its approval in writing.
 - If the Department rejects a Plan, it shall notify the applicant in writing of its reasons for rejecting the Plan. The Department may reject a Plan without conducting a public hearing.
 - d) An applicant whose Plan has been rejected by the Department must submit a revised Plan to the Department within 60 days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, in its sole discretion, the Department may develop, approve and impose its own product stewardship Plan or an approved Plan submitted by other Producer(s) pursuant to this Ordinance. The imposed Plan will be presented at the public hearing. The Department is not required, and nothing in this Ordinance shall be interpreted as requiring, the Department to create or impose a product stewardship Plan.
 - e) If the Department rejects a revised Product Stewardship Plan or any other subsequently revised Plan, the Producer(s) at issue shall be out of compliance with this Chapter and are subject to the enforcement provisions contained in this Chapter. If the

Department imposes its own or another Plan the Producer(s) at issue shall not be considered out of compliance with this Chapter if they comply with that Plan. However, the Producers shall be subject to the enforcement provisions contained in this Chapter as they relate to compliance with an approved Plan.

- 4. At least every three years, a Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall update its product stewardship Plan and submit the updated Plan to the Department for review and approval.
- A Producer who begins to offer a Prescription Covered Drug for sale in the County of Alameda after July 1, 2013, must submit a product stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within 180 days following the Producer's initial offer for sale of a Covered Drug.
 - a) For Producers selling only Non-prescription Covered Drugs, they must meet the requirements of this Ordinance for a Product Stewardship Program no later than February 1, 2017.
 - b) For Producers selling Prescription and Nonprescription Covered Drugs, they must come into compliance for all Nonprescription Covered Drugs no later than March 31, 2016.
 - c) Approved Product Stewardship Programs must immediately begin accepting Nonprescription Drugs.
- 6. Any proposed changes to a Product Stewardship Plan, other than collection of non-prescription Covered Drugs, must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

6.53.060 - Disposal of Unwanted Products.

- A. Compliance with applicable law. Each Product Stewardship Program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of medical waste and Controlled Substances.
- B. Disposal at medical waste or hazardous waste facility. Each Product Stewardship Program must dispose of all Unwanted Products by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must be in possession of all required regulatory permits and licenses.
- C. Producers with Product Stewardship Programs may petition the Department for approval to use final disposal technologies, where lawful, that provide superior

environmental and human health protection than provided by current medical waste disposal technologies for Covered Drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

- 1. Monitoring of any emissions or waste;
- 2. Worker health and safety;
- 3. Reduction or elimination of air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and,
- 4. Overall impact on the environment and human health.
- D. Packaging separation. Each Product Stewardship Program shall encourage Residential Generators to separate Unwanted Products from their original containers, when appropriate, prior to collection or disposal.
- 6.53.070 Product Stewardship Program promotion and outreach.
- A. A Product Stewardship Program must promote the Product Stewardship Program to Residential Generators, pharmacists, retailers of Covered Drugs, health care practitioners, veterinarians, and veterinary hospitals as to the proper and safe method to dispose of Unwanted Products, so that collection options for Covered Drugs are widely understood and to promote the safe storage of Covered Drugs by Residential Generators.
- B. A Product Stewardship Program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of Covered Drugs. These materials may include, but are not limited to, one or more of the following:
 - 1. Signage that is prominently displayed and easily visible to the consumer.
 - Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
 - 3. Advertising and/or other promotional materials related to the Product Stewardship Program.
- C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Alameda County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The Program also must establish a website publicizing collection locations and

Program operations and a toll-free telephone number that Residential Generators can call to find nearby collection locations and understand how the Program works.

- D. Product Stewardship Programs shall not require, conduct or allow any sorting of items brought to collection events or at drop off locations.
- E. A Product Stewardship Program shall provide a kiosk at any location in which a Person requests or volunteers to have a kiosk if the following conditions are met:
 - 1. The approved Product Stewardship Plan includes having physical collection sites, such as kiosks (even if the approved number of sites have been accomplished by the Plan):
 - The Person is a law enforcement agency or a registered manufacturer, distributor, reverse distributor or retail pharmacy that is authorized under 21 CFR 1300 et seq to receive a Controlled Substance for the purpose of destruction.

6.53.080 - Report.

- A. Each year on or before the date set by the department every Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program must prepare and submit to the Department an annual written report describing the Program's activities during the previous reporting period. The report must include the following:
 - 1. A list of Producers participating in the Product Stewardship Program;
 - 2. The amount, by weight, of Unwanted Products collected from Residential Generators collected at each drop-off site and in the entire County of Alameda and, if applicable, the total amount by weight collected by a Mail-Back Program;
 - 3. A description of the collection system, including the location of each collection site and, if applicable, locations where envelopes for a Mail-Back Program are provided;
 - 4. The name and location of disposal facilities at which Unwanted Products were disposed of and the weight of Unwanted Products collected from Residential Generators disposed of at each facility;
 - 5. Whether policies and procedures for collecting, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;

- 6. Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;
- 7. A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and Program activities;
- 8. How the Product Stewardship Program complied with all other elements in the product stewardship Plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the Program; and
- 9. Any other information that the Department may reasonably require.
- B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year, or such other date as established at Plan approval or as may be amended by the Department in a written notice.

6.53.090. - List of Producers.

The Department shall provide on its website a list of all Producers participating in Product Stewardship Programs approved by the Department and a list of all Producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

6.53.100. - Regulations and fees.

- A. The Director of the Department of Environmental Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter. The Director may revise the adopted regulations from time to time after posting the proposed revisions on the Department webpage for not less than ten (10) calendar days with a solicitation for public comments and considering any public comments received.
- B. As soon as practicable, the Department shall submit to the Board of Supervisors a proposed schedule of fees to be charged to the Producers to cover Alameda County's costs of administering and enforcing this Ordinance.

6.53.110. - Enforcement.

- A. The Department of Environmental Health shall administer the penalty provisions of this Chapter.
- B. The Department of Environmental Health may issue an administrative citation to a Producer for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written warning to the Producer as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The Producer shall have 30 days after receipt of the warning to comply and correct any violations.
- C. If the Producer fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.
- D. Any Person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Alameda for a civil penalty in an amount not to exceed one thousand dollars (\$1,000) per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.
- E. In determining the appropriate penalties, the Department of Environmental Health shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.
- F. Any Producer receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County of Alameda holiday, then the deadline shall be extended until the next regular business day.

The request to appeal must:

- 1. Be in writing;
- 2. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
- 3. Specify the basis for the appeal in detail:
- 4. Be postmarked within 21 days from the date the administrative citation was issued; and

- 5. Be sent to the address as set forth on the administrative citation.
- G. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a hearing officer designated by the Director of the Department of Environmental Health. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the Producer appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.
- H. Failure of any Producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that Producer's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that Producer to exhaust administrative remedies.
- I. The Producer requesting the appeal may request the Director of the Department of Environmental Health to recuse a hearing officer for reasons of actual prejudice against the party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence as follows:
 - 1. A valid administrative citation shall be prima facie evidence of the violation;
 - 2. Testimony shall be by declaration under penalty of perjury except to the extent the hearing officer permits or requires live testimony concerning the violation.
 - 3. The hearing officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The hearing officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.
 - 4. The hearing officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer Decision"). The Hearing Officer Decision shall be served by first class mail on the Producer appealing and the Department. The Hearing Officer Decision affirming or dismissing the administrative citation is final, unless a timely notice of appeal is filed for hearing by the Board of Supervisors of the County of Alameda.
- J. A second appeal may be filed with the Board of Supervisors within ten calendar days after the date of service of the Hearing Officer Decision.
 - 1. The appeal may be taken by any Producer or the Department within said ten-day period, by filing with the clerk of the Board of Supervisors a notice

- of appeal specifying the grounds for such appeal. The Board of Supervisors shall not hear any appeal that is untimely filed.
- 2. Upon receiving an appeal, the Clerk of the Board of Supervisors shall indicate upon every notice of appeal received the date upon which it was filed. The Department shall immediately arrange for an administrative record to be made available to the Board of Supervisors of all of the documents constituting the record upon which the action appealed was taken.
- 3. The Board of Supervisors shall give written notice of the time and place for a public hearing on any appeal filed pursuant to this section to the appellant and the Department.
- The Board of Supervisors may hear additional evidence in its sole discretion and may sustain, modify or overrule any order brought before it on appeal.
- 5. The Board of Supervisors may make such findings and decisions as are consistent with state law and the County of Alameda Ordinances. If no motion relative to the Hearing Officer Decision appealed attains a majority vote of the Board of Supervisors within thirty (30) days from the date of the hearing by said board thereon, the Hearing Officer Decision shall stand sustained and be final.
- K. The Department of Environmental Health may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.
- L. Upon the failure of any Producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the Alameda County Counsel's Office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such Person from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not permit the County of Alameda or any court of competent jurisdiction to restrain the sale of any Covered Drug in Alameda County.
- M. Any Person who knowingly and willfully violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and may be prosecuted by the Alameda County District Attorney's Office. A conviction for a misdemeanor violation under this Chapter is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500) for each day per violation, or by imprisonment in the Alameda County Jail for a period not to exceed six (6) months, or by both such fine and imprisonment.

6.53.120 - Additional provisions.

- A. Disclaimer. In adopting and implementing this Chapter, the County of Alameda is assuming an undertaking only to promote the general welfare. Alameda County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any Person or Entity who claims that a breach proximately caused injury.
- B. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable federal or state laws, rules or regulations. Nothing in this Chapter shall authorize any Alameda County agency or department to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such agency or department action is taken. Alameda County shall suspend enforcement of this Ordinance to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted.
- C. Severability. If any of the provisions of this Chapter or the application thereof to any Person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to Persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.
- D. Environmental Findings. The County of Alameda has determined that the actions contemplated in this Ordinance are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.).
- E. Nothing in this Ordinance, or the Program of stewardship in which manufacturers of pharmaceutical products who sell Prescription Drugs in Alameda County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Ordinance be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of California or of the United States.
- F. This Ordinance shall be construed in accordance with California state law, including but not limited to the Medical Waste Management Act set forth at California Health and Safety Code sections 117600, et seq., and shall not be construed in a way that would result in conflict with, or preemption by, any such state law.
- G. This Ordinance is entitled to a categorical exemption of the California Environmental Quality Act ("CEQA") pursuant to 14 California Code of Regulations section 15307, which exempts "actions taken by regulatory agencies, as authorized by state or local ordinance, to assure the maintenance, restoration, enhancement, or protection of the environment where the regulatory process involves procedures for protection."

Approved as to Form and Legality

FILED OFFICE OF THE CIT & CLERK

2016 JUN-2 PM 2: CAKLAND CITY COUNCIL

RESOLUTION NO	C.M.S.	
TRODUCED BY COUNCIL MEMBER		

RESOLUTION AUTHORIZING THE CITY ADMINISTRATOR, OR DESIGNEE, TO ENTER INTO A KIOSK SERVICES AGREEMENT AND TAKE-BACK SERVICES AGREEMENT WITH THE ALAMEDA MED-PROJECT LLC TO IMPLEMENT THE SAFE DRUG DISPOSAL KIOSK **COLLECTION PROGRAM**

WHEREAS, Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of people but once expired should be properly disposed of prevent misuse; and

WHEREAS, unwanted prescription and over-the-counter (OTC) medicines that are flushed down toilets reach natural water bodies and lead to water contamination; and

WHEREAS, The Alameda County Board of Supervisors approved the Alameda County Safe Drug Disposal (SDD) Ordinance in February 2012, and revised in March 2016, which requires that pharmaceutical manufacturers and retailers in Alameda County operate or participate in a Product Stewardship Program for the disposal of unwanted drugs and medicine; and

WHEREAS, Pharmaceutical manufacturers and retailers created the national Pharmaceutical Product Stewardship Working Group (PPSWG) to respond to regional unwanted prescription and over-the-counter (OTC) drug and medicine collection and disposal regulations, and the PPSWG created the MED-Project; and

WHEREAS, the MED-Project LLC (MED-Project) is a public, non-profit entity created to support and implement the Alameda County Product Stewardship Plan, including the education and outreach programming; and

WHEREAS, the Alameda County Board of Supervisors approved the MED-Project Product Stewardship Plan on Feb, 25, 2015 following a Public Hearing; and

WHEREAS, the MED-Project will create and operate take-back events to collect unwanted prescription and over-the-counter (OTC) medicines from Alameda County households; and

- **WHEREAS**, pharmaceutical manufacturers and retailers in Alameda County can partner with the MED-Project to fulfill their legal requirements to develop or participate in a product stewardship plan; and
- **WHEREAS**, the MED-Project plans to place drug and medicine disposal kiosks in the police administration building (PAB) and the OPD Eastmont Substation (ES) where anyone can deposit the unwanted medicine; and
- **WHEREAS**, OPD and the MED-Project require a joint-Kiosk Services Agreement before any kiosks can be placed at the PAB or ES; and
- **WHEREAS**, the MED Project plans to hold various drug and medicine take-back events in Oakland, which require the presence of law-enforcement personnel for the safe drug and medicine collection; and
- WHEREAS, the MED-Project will reimburse OPD for any personnel costs if OPD chooses to participate in take-back events in other locations in the City of Oakland; and
- **WHEREAS**, OPD and the MED-Project require a Take-Back Services Agreement for OPD personnel to participate in take-back events; therefore be it
- **RESOLVED:** That the City Council hereby authorizes the City Administrator, or designee, to enter into A Kiosk Services Agreement and a Take-Back Services Agreement To Implement The Safe Drug Disposal Kiosk Collection and Take Back Program; and be it
- **FURTHER RESOLVED:** That the Kiosk Services Agreement and Take-Back Services Agreement will stipulate that the MED-Project will comply with all pertinent laws and will possess all required permits, licenses, and authorizations, and that OPD will not be required to possess any additional permits, licenses or authorizations; and be it
- **FURTHER RESOLVED:** That the City Administrator, or designee, is hereby authorized to complete all required negotiations, certifications, assurances, and documentation required to accept, modify, extend and/or amend the proposed Kiosk Services Agreement and Take-Back Services Agreement with the MED-Project; and be it

FURTHER RESOLVED: That the City Attorney shall review and approve said proposed Kiosk Services Agreement and Take-Back Services Agreement with the MED-Project and OPD, as to form and legality and a copy shall be placed on file in the Office of the City Clerk.

IN COUNCIL, OAKLAND, CALIFORNIA,	
PASSED BY THE FOLLOWING VOTE:	
AYES - BROOKS, CAMPBELL-WASHINGTON, GALLO, PRESIDENT GIBSON MCELHANEY	GUILLEN, KALB, KAPLAN, REID AND
NOES -	
ABSENT -	
ABSTENTION -	ATTEST:
	LaTonda Simmons City Clerk and Clerk of the Council of the City of Oakland, California