



SUBCOMMITTEE REPORT

PRESENTED FOR COMMISSION MEETING DATE: 02/16/2016

SUBMITTED BY: Mark Polischak

SUBCOMMITTEE NAME: Waste Reduction

SUBMITTED DATE: 02/09/2016

SUBCOMMITTEE MEETING DATE: 01/28/2016

NEXT SUBCOMMITTEE MEETING DATE: 03/07/2016

Subcommittee Meeting Goal:

To focus and educate stakeholders on the reasons for participation and possible ordinance to reduce food waste in the City of Palm Springs and to identify how the city can best implement the transitional reduction goals.

Summary:

Mark met with FIND Food Bank to revisit the use of the Waste No Food App. Hortencia stated she will reach out to The PS Hospitality Association to coordinate a FIND Food/Waste No Food collaboration presentation. WNF has expressed interest in coming to Palm Springs to participate in the presentation and meet with FIND clients to generate interest in the use of their app.

Blaire and Hortencia (FIND) discussed possible ideas for expanding their services to areas in the valley including Palm Springs. One such service would include a Mobile Pantry food trucks to distribute food to those in need. Blaire expressed the need for reusable bags and asked if the city could donate any extra bags that may be available since they prefer not to use plastic bags.

Mark contacted the California Product Stewardship Council again, requesting the City of Palm Springs be included on their site's Take-Back locations map for meds and sharps recycling since no response was received from the first voicemail. There are no email addresses available on the website, so calling is the only contact option.

The subcommittee would like to request consideration for the hiring a consultant who works in the area of Product Stewardship to assist in the process if the Sustainability Committee votes to recommend a Safe Drug Disposal Ordinance for the City of Palm Springs.

The sub-committee is currently reviewing other city/county Safe Drug Disposal ordinances and state legislation for possible development of a Palm Springs Pharmaceutical Product Stewardship ordinance.

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Recommendation/Request

Request budget allowance for a Product Stewardship consultant for development of a Safe Drug Disposal ordinance for the city of Palm Springs
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ACTION ITEMS REQUEST TO COMMISSION	
ACTION ITEMS REQUEST TO OFFICE OF SUSTAINABILITY	
POTENTIAL FISCAL IMPACT/REQUEST IF ANY:	

ORDINANCE AMENDING THE ALAMEDA COUNTY ORDINANCE CODE BY ADDING CHAPTER 6.53, SECTIONS 6.53.010 THROUGH 6.53.120 TO: REQUIRE ANY PERSON WHO PRODUCES A DRUG OFFERED FOR SALE IN ALAMEDA COUNTY TO PARTICIPATE IN AN APPROVED DRUG STEWARDSHIP PROGRAM FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS FROM RESIDENTIAL SOURCES; PROVIDE FOR IMPLEMENTATION, ENFORCEMENT, FEES, AND PENALTIES; AND MAKING ENVIRONMENTAL FINDINGS.

WHEREAS, the County of Alameda has a substantial interest in, and a substantial need for, a drug stewardship program; and

WHEREAS, the health and welfare of the residents of the County of Alameda, particularly children and the elderly, would be improved and advanced by the proper disposal of unwanted, expired or unneeded prescription drugs;

NOW THEREFORE, the Board of Supervisors of the County of Alameda ordains as follows:

Title 6 of the Alameda County Health and Safety Code is hereby amended by adding Chapter 6.53, Sections 6.53.010 through 6.53.120, to read as follows:

6.53.010 - Declaration of findings.

The Board of Supervisors hereby finds and declares the following:

- A. Prescription 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 drugs and the illegal re-sale of prescription drugs;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and 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.

1. "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.
2. "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 all drugs as defined in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. § 353(b)(1) of the FFDCA, including both brand name and Generic Drugs.

“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) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems; and (vii) nonprescription drugs.

4. "Department" means the Alameda County Department of Environmental Health.
5. "Drug Wholesaler" means a business that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.
6. "Drugs" means: (i) articles 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) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) substances, other than food, intended to affect the structure or any function of the body of humans or other animals.

"Drugs" does not mean medical devices, their component parts or accessories, or a Covered Drug contained in or on medical devices or their component parts or accessories.
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.
9. "Mail-Back Program" means a system whereby Residential Generators of Unwanted Products obtain prepaid and preaddressed mailing envelopes in which to place Unwanted Products for shipment to an Entity that will dispose of them safely and legally.
10. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.
11. "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.
12. "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.

13. "Prescription Drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.
14. "Producer" shall be determined, with regard to a Covered Drug that is sold, offered for sale, or distributed in Alameda County as meaning one of the following:
 - (i) The Person who manufactures a Covered Drug and who sells, offers for sale, or distributes that a Covered Drug in Alameda County under that Person's own name or brand.
 - (ii) If there is no Person who sells, offers for sale, or distributes the Covered Drug in Alameda County under the Person's own name or brand, the producer of the Covered Drug is the owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County, whether or not the trademark is registered.
 - (iii) If there is no Person who is a producer of the Covered Drug for purposes of paragraphs (i) and (ii), the producer of that Covered Drug is the Person who brings the Covered Drug into Alameda County for sale or distribution.

"Producer" does not include (i) a retailer that puts its store label on a Covered Drug or (ii) a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for a consumer.

15. "Product Stewardship Program" or "Program" means a program financed and operated by Producers to collect, transport, and dispose of Unwanted Products.
16. "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.
17. "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.
18. "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:

1. Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the Department; or
2. 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.

1. 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.
2. 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:

1. 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;
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);
6. 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 the policies and procedures to be followed to ensure security;
8. A description of the public education and outreach activities required under this Chapter and how their effectiveness will be evaluated;

9. 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 Controlled substances, 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 with the sorting and separation of Controlled Substances at no cost to a participating law enforcement agency. Otherwise, Controlled Substances are expressly excluded from this Chapter notwithstanding any other provision contained herein;
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.

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.
 - c) 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.
 5. A Producer who begins to offer a 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.

6. Any proposed changes to a product stewardship Plan 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. 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, and health care practitioners as to the proper and safe method to dispose of Unwanted Products.

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.
2. 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.

6.53.080 - Report.

A. On or before July 1, 2014 (or at a later date as approved in writing by the Department) and in each subsequent year, 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.

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.

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.
4. 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.”

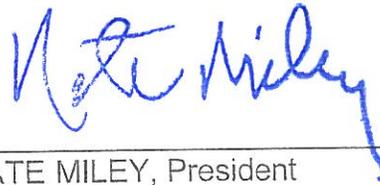
H. This Chapter shall be in effect for a period of ten (10) years following enactment.

Adopted by the Board of Supervisors of the County of Alameda, State of California, on July 24, 2012, by the following called vote:

AYES: Supervisors Carson, Chan, Haggerty, Valle and
President Miley -5

NOES: None

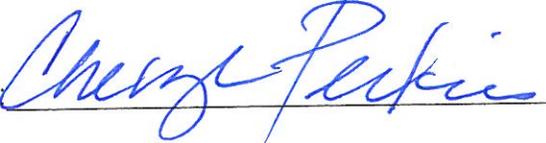
EXCUSED: None



NATE MILEY, President
Board of Supervisors
County of Alameda, State of California

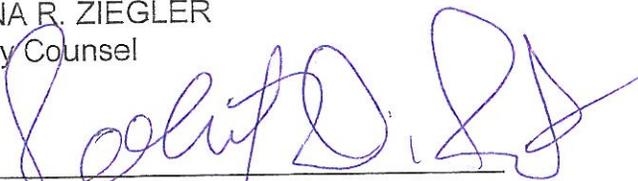
ATTESTED TO:

Clerk Board of Supervisors, County of Alameda

By: 

APPROVED AS TO FORM:

DONNA R. ZIEGLER
County Counsel

By: 
ROBERT D. REITER
Deputy County Counsel

ALAMEDA COUNTY BOARD OF SUPERVISORS

MINUTE ORDER

The following was action taken by the Board of Supervisors on July 24, 2012

Approved as Recommended Other

Read title, waived reading of ordinance in its entirety and adopted Ordinance O-2012-27

Unanimous Carson Chan Haggerty Haggerty Miley - 5
Vote Key: N=No; A=Abstain; X=Excused

Documents accompanying this matter:

- Resolution(s) _____
- Ordinance(s) O-2012-27
- Contract(s) _____

File No. 28292
Item No. 69

Copies sent to:

Kamika Dunlap

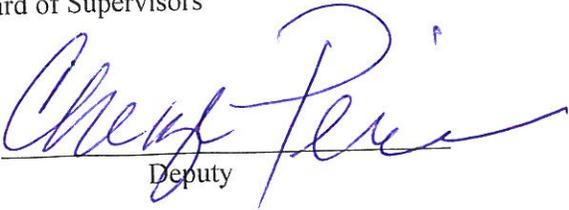
Special Notes:



I certify that the foregoing is a correct copy of a Minute Order adopted by the Board of Supervisors, Alameda County, State of California.

ATTEST:

Crystal Hishida Graff, Clerk of the Board
Board of Supervisors

By: 
Deputy

Alameda County Safe Drug Disposal
REGULATIONS

Alameda County Safe Drug Disposal REGULATIONS

Section 1 – Authority for Regulations

These Regulations were developed under the authority of the Alameda County General Ordinance Code, Chapter 6.53, the Alameda County Safe Drug Disposal Ordinance (the “Ordinance”) to provide clarification and direction for its implementation.

Unless defined herein, the capitalized terms in these Regulations have the same meaning as set forth in the Ordinance.

Section 2 – Definitions

“Administrative Citation” means a citation issued by the Department for a violation of the Ordinance or Regulations.

“Alternative Plan” means a Plan imposed by the Department as a result of failure to timely submit an adequate Revised Plan.

“Annual Report” means the annual report required to be submitted by Plan Owners for each approved Plan describing the activities during the previous reporting period and other information as required by the Ordinance, Regulations and the Department.

“Annual Report Data” means the portion of the Annual Report containing numerical data relating to activities under the Plan.

“Annual Report Narrative” means the portion of the Annual Report containing descriptions, summaries and explanations of the collection efforts, other Plan efforts over the previous year, and future goals of the Plan.

“Collection Point” means a physical location with a secure drop-off kiosk to receive Unwanted Products at no cost to the individual. Collection Points may be located at hospitals, pharmacies, or other convenient physical sites.

“Department” means the Alameda County Department of Environmental Health.

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“Disposal Facility” means a facility that receives, holds or incinerates Unwanted Products collected under a Plan.

“Department Liaison” means the Environmental Health Safe Drug Disposal Liaison, who is the contact for the Department for issues relating to the Ordinance or Regulations.

“Fee Schedule” means the schedule of estimated time and cost to the Department for administration and enforcement of the Ordinance and Regulations, and includes the hourly rate which has been approved by the Alameda County Board of Supervisors.

“Law Enforcement Liaison” means the individual that will act as a liaison to law enforcement agencies for the Plan, and may be the same person as the Plan Liaison.

“Petition For Exception” means a written request to the Department for an exception from or exemption to any requirement of the Ordinance or Regulations.

“Plan Deposit” means the money lodged with the Department to be applied by the Department to cover the fees to be charged to cover the actual cost for administration and enforcement of the Ordinance and Regulations.

“Plan Liaison” means the primary contact for a Plan.

“Plan Owner” means the entity, individual or organization that submits and implements a Plan.

“Producer Contact” means the primary contact for a Producer of a Covered Drug. The Producer Contact is the person authorized to receive notices related to the Ordinance, Regulations and Plan. The Producer Contact cannot be the Plan Liaison.

“Public Hearing” means the noticed public hearing at which the Department will determine whether a Plan complies with the requirements of the Ordinance and these Regulations.

“Revised Plan” means the proposed Plan that must be submitted following rejection of an initial Plan by the Department.

“Transporter” means an individual or entity that is registered with the United States Environmental Protection Agency as a Hazardous Waste Hauler and that is permitted and authorized to haul medical waste under the California Medical Waste Management Act (Health and Safety Code Section 117600 et seq.).

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Section 3 – Fees

- A. Fees shall be charged based on an hourly rate that is approved by the Board of Supervisors. The Fee Schedule can be found at the Alameda County Environmental Health web site at <http://www.acgov.org/aceh>.
- B. The activities and estimated hours contained in the Fee Schedule may from time to time be amended by the Department and the hourly rate may from time to time be amended as approved by the Board of Supervisors.
- C. Upon request by the Department, the Plan Owner shall pay to the Department an initial sum of at least \$10,000 for a Plan Deposit to cover the actual cost for administration and enforcement of the Ordinance and Regulations. At any time a deposit is required, if the balance of the Plan Deposit is less than cost of the action(s) to be taken by the County to administer or enforce the Ordinance or Regulations (based on an estimated of hours to conduct the actions), an additional payment to bring the Plan Deposit balance to the greater of \$2500.00 or the estimated cost of the activity being requested. Failure to pay a Plan Deposit or fees or costs as required pursuant to the Fee Schedule is a violation of the Ordinance and Regulations.
- D. In addition to the fees and costs to the Department identified in the Fee Schedule, the County may also charge Producers for actual costs incurred by other departments and agencies of the County that assist in administration and enforcement of the Ordinance.
- E. The fees collected by the County pursuant to the Ordinance or Regulations shall not exceed the County's actual cost of administering and enforcing the Ordinance and Regulations.

Section 4 – Communications with Department

- A. **Department Contact Information.** The contact for the Department for all issues relating to the Ordinance and Regulations shall be the Department Liaison. All information or notices required by the Ordinance or Regulations to be sent to the Department shall be sent to the Department Liaison by e-mail, unless the Ordinance or Regulations specify otherwise.
 - i. **Written Submissions:**
 - a. All Plans and other materials should be submitted electronically to the Department Liaison at:

SafeDrugDisposalLiaison@acgov.org

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- b. The Department Liaison's mailing address is:

Safe Drug Disposal
Alameda County Environmental Health
1131 Harbor Bay Parkway
Alameda, CA 94502-6577

- ii. **Questions.** Questions regarding the Ordinance or Regulations should be directed to the Department Liaison at (510) 567-6700 or by sending an e-mail to the Department Liaison.

B. Producer Contact Information

- i. **Initial Contact.** Producers subject to the Ordinance shall identify themselves by a letter delivered to the Department prior to the date on which Plans must be submitted to the Department. The initial letter should include the e-mail address, telephone number and mailing address for the Producer Contact. The Department may request that a Producer provide the information required by this section prior to the date on which Plans are required to be submitted to the Department.
- ii. **Notification of Participation in Product Stewardship Organization.** A Producer that participates in a Stewardship Organization must notify the Department. The notification must identify the Producer and include the name, address, e-mail, telephone number and contact person for the Stewardship Organization.

- C. **Department Consultation.** The Department Liaison is available to discuss the requirements of the Ordinance and Regulations, to discuss draft Plans, to answer questions about the Ordinance and Regulations, and to assist Producers or Stewardship Organizations, including setting goals and estimates for Plans. The Department encourages Producers and Stewardship Organizations to consult with the Department Liaison prior to filing a Plan.

Section 5 – Producers

- A. **Determination of Producer.** The Department shall determine who qualifies as a Producer of a Covered Drug. The Safe Drug Disposal Ordinance is based on the principle of Extended Producer Responsibility and requires that the cost of disposal of

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Covered Drugs be borne by the person(s) who sells, offers for sale, or distributes the Covered Drugs into Alameda County.

- i. Any prescription drug sold, offered for sale, or distributed in Alameda County in any form including, but not limited to, drugs in medical devices and combination products, both brand name and generic drugs and drugs for veterinary use are considered Covered Drugs.
- ii. Medical devices and their component parts or accessories are not drugs even if there are residuals of a Covered Drug contained in or on used medical devices or their component parts or accessories.
- iii. A manufacturer or distributor of medical devices that when sold do not have covered drugs in them will not be considered a Producer, unless they also separately meet the definition of Producer.
- iv. A Producer is a person or entity that causes a Covered Drug to be manufactured. A manufacturer that does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if the Covered Drug it manufactures is sold, offered for sale, or distributed in Alameda County by another Person. Accordingly, as used in Section 6.53.030 of the Ordinance, paragraph 14(i), the terms “sells, offers for sale, or distributes” includes all sales, offers for sale, or distribution regardless of whether or not the Covered Drug is sold, offered for sale, or distributed by someone other than the manufacturer, such as by an independent wholesaler or distributor.
- v. A person or entity that has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County who does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if that Covered Drug is sold, offered for sale, or distributed in Alameda County by any other Person. Accordingly, as used in Section 6.53.030, paragraph 14(ii) of the Ordinance, the terms “sells, offers for sale, or distributes” includes all sales, offers for sale, or distribution regardless of whether by a Person who has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County or by someone else.

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- vi. The following are considered biological products which are not Covered Drugs if the Producer already has a take back program in place: vaccines derived from biological products and therapeutic serum. (Biological products are defined in 21 Code of Federal Regulation 600.3(h)).

B. Petition for Exemption

- i. A Producer whose Covered Drugs are made available exclusively to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act, may petition the Department for an exemption from the Ordinance.
- ii. A Petition for an exemption under this section must include the following:
 - a. The petitioning Producer's name and United States business address;
 - b. The trade and chemical name of the Producer's Covered Drugs;
 - c. A description of the uses of each of the Producer's Covered Drugs;
 - d. A description of how each Covered Drug is distributed in Alameda County;
 - e. A declaration under penalty of perjury that the Producer's Covered Drugs are exclusively available to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act and that the Covered Drugs are not dispensed directly to the public;
 - f. A showing that Producer's Unwanted Products are being safely disposed; and
 - g. A deposit for the estimated cost to the County of review, consideration and response to the petition, as set forth in the Fee Schedule.
- iii. The Department shall have the discretion to grant or deny any Petition for exemption made under this section.
- iv. Any exemption, if granted, will specify the time period for the exemption, up to three (3) years. A request for renewal of an exemption must be submitted to the

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Department at least six (6) months before the expiration date. Late requests for exemption renewals will be subject to penalties, including but not limited to late fees and costs to be determined by the Department.

Section 6 – Submission of Plans

- A. **Submission.** For Producers subject to the Ordinance on or before July 1, 2013, Plans must be submitted no later than May 1, 2014.
- B. **Petition For Later Submission Date.** A written petition may be filed for an extension of the deadline to submit a Plan to the Department. Petitions for a later submission date must be received by the Department Liaison no later than five (5) weeks prior to the deadline for submission of a Plan.
- i. **Petition Contents.** A written petition for an extension must include the following:
- a. The proposed extension date;
 - b. An explanation of why an extension is needed;
 - c. Justification for the proposed extension;
 - d. A brief summary of the current status of the draft Plan; and
 - e. A deposit for the estimated cost to the County of review, consideration and response to the petition.
- C. **Late Plan Submissions.** If any Producer does not submit a Plan by the date set forth in paragraph A, or has not submitted a Plan by a later date granted by the Department, such Producer(s) shall be subject to the enforcement provisions of Section 6.53.110 of the Ordinance, including penalties.
- D. **Plan Owners.** A Plan shall be submitted by its Plan Owner, which may be a Producer or any other organization, entity or individual. A Plan may be submitted for approval even if no Producers are participating in the Plan. A Product Stewardship Program may be a Plan Owner. A Product Stewardship Program may be (1) financed and operated by a Producer or Producers or (2) operated by a company, individual or other entity that is retained and compensated by a Producer or Producers to meet the obligations of the Producer or Producers under the Ordinance.
- E. **Preliminary Review of Plan.** Plan Owners may submit a draft Plan prior to the date set forth in paragraph A deadline for preliminary review and comment by the Department. Plan Owners are encouraged to contact the Department to discuss their Plan at least three months prior to the deadline for Plan submission.

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Section 7 – Plan Content

A. **General Information.** A Plan must contain the following general information:

i. **Contact Information.**

a. **Plan Participants.** Identification of the Plan Owner(s) and the Producer Contacts for all Producers participating in the Plan. Identification of the Producer Contact shall include an e-mail address, telephone number and mailing address. Any change in Plan Owner or the Producers participating in a Plan must be provided to the Department within 30 days of the change.

b. **Plan Liaison.** Identification of the Plan Liaison shall include an e-mail address, telephone number and mailing address. The Plan Liaison must be familiar with the Plan, the Covered Drugs of each Producer participating in a Plan, and potential issues related to implementation of the Plan. The Plan Liaison must have authority on behalf of all of the Plan Owners and all participating Producers to make binding representations and determinations related to the Plan. Notice to the Plan Liaison shall be considered notice to the Plan Owner and each Producer participating in the Plan.

ii. **Website.** A Plan must include the address of a website on which the Collection Points, educational materials, public outreach events, and other components of the Plan will be made publicly available. The website does not need to be devoted exclusively to the Plan.

iii. **Telephone Number.** All Plans must include a toll-free telephone number that will be available to Residential Generators to obtain information about Collection Points, educational materials and other aspects of the Plan.

iv. **Other.** All information required by the Ordinance.

B. **Collection Measurement and Goals.** A Plan must contain an estimate for the quantity of Unwanted Products that will be collected under the Plan and how the quantity of collected Unwanted Products will be measured.

C. **Implementation Description.** A Plan must contain a discussion of how and when the Plan will be implemented, including but not limited to:

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- i. The number of initial Collection Points and Collection Points that will be phased in over time.
- ii. The dates on which Unwanted Products will begin to be collected at each Collection Point, which must be within 90 days of Department approval of the Plan. Collection Points may include established Collection Points for which the Plan will assume responsibility.

D. Multiple Collection Components. A Plan may have multiple collection components, which may include:

- i. Collection Points with secure drop-off kiosks at hospitals, pharmacies and other convenient locations;
- ii. A mail-back program, such as providing consumers with a container in a prepaid self-addressed package for mailing Unwanted Products to be destroyed;
- iii. Public collection events, including at senior citizen facilities, health fairs, and recycling events. Plan Owners and Producers are encouraged to coordinate with community organizations, public entities, and local government regarding the Plan.

E. Transporter Information. Transportation from the Collection Points to the disposal facility must be performed by a Transporter. The Plan must include the following information for each Transporter to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of Transporter;
- iv. Environmental Protection Agency identification number;
- v. Permit status;
- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Transporter will be utilized under the Plan .

F. Disposal Facility Information. The Plan must include the following information for each Disposal Facility to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of facility;
- iv. Environmental Protection Agency identification number;
- v. Permit status;

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- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Disposal Facility will be utilized under the Plan.

A list of eligible Disposal Facilities that are properly permitted to dispose of Unwanted Products and information regarding such sites located in California may be obtained from the California Department of Public Health (CDPH). Information is available on its website located at www.cdph.ca.gov.

- G. **Copies of Materials.** A Plan should include copies of any educational or public outreach materials that are proposed to be used under the Plan, including a copy of any signage, with the dimensions of the proposed actual sign.
- H. **Plan Goals.** A Plan should include a proposal as to the short term and long term goals under the Plan for collection, education and public outreach. The Department may modify Plan goals as a condition of approval. As set forth below, Plan goals shall be reviewed in each Annual Report, at which time the Department, working with the Plan Liaison, will set the goals for the next reporting period.
- I. **Public Document:** Any Plan submitted to the Department or Board of Supervisors or any other governmental agency under the Ordinance or Regulations will be considered a public record. No part of the Plan should be marked as confidential or proprietary. This provision is not intended to require the disclosure of records that are exempt from disclosure under the California Public Records Act (Government Code section 6250, et seq.). If any Plan Owner or Producer participating in a Plan contends that information it is required to provide is exempt from disclosure under the California Public Records Act, such information must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether the documents or information are exempt from the California Public Records Act.

Section 8 – Plan Evaluation

- A. Plans will be evaluated by the Department based on the following:
 - i. **Adequate Collection.** Whether the Plan's collection program is adequate to serve the needs of Alameda County residents, including but not limited to:

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- a. Whether the Plan provides for adequate collection of Unwanted Product for each area of the County where the Covered Drugs of the participating Producer(s) are offered for sale, sold, or distributed; and
 - b. Whether residents who procure their medications outside of physical pharmacies, such as online, will be adequately served by the Plan.
- ii. **Adequacy Of Collection Points.** Whether the Plan has an adequate number of Collection Points and whether these Collection Points are accessible and located throughout Alameda County. Possible Collection Points can include, but are not limited to pharmacies, medical and veterinary offices, clinics, hospitals, law enforcement agencies, and governmental buildings. The Department encourages Plan Liaisons to contact the Department before Plans are due if they are having difficulty identifying suitable or sufficient Collection Point locations.
- iii. **Management Practices.** Whether the Plan includes adequate management and administrative practices, including but not limited to:
- a. Training to be provided at the Collection Points;
 - b. General security procedures;
 - c. Procedures for pickup and disposal of Unwanted Products;
 - d. Frequency of pickup from Collection Points and disposal;
 - e. Procedures if a collection vessel is full prior to scheduled pick-up and disposal; and
 - f. Management and administration of alternative collection methods, such as mail-back containers.
- iv. **Tracking.** Whether the Plan provides for the collected Unwanted Products to be safely and securely tracked and handled from collection through disposal.
- v. **Controlled Substances.** Whether the Plan adequately addresses collection of Controlled Substances.
- vi. **Education and Public Outreach.** Whether the Plan complies with the public education and outreach requirements of the Ordinance, including but not limited to whether the Plan adequately provides for education regarding the safe collection and disposal of Unwanted Products for:
- a. Medical providers and their patients;
 - b. Veterinary providers and animal owners;
 - c. Pharmacies, including education for dispensers of Covered Drugs and their patients; and
 - d. The general public.

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- vii. **Educational Materials.** Whether the Plan adequately incorporates educational materials for the public and whether such materials adequately address:
- a. The importance of promptly and properly disposing of Unwanted Products;
 - b. How to find and use Collection Points;
 - c. Alternative methods of returning Unwanted Products under the Plan (such as mail-back programs);
 - d. How to properly dispose of Unwanted Products; and
 - e. Privacy issues, such as removing Unwanted Products from labeled prescription containers, which may disclose private information, and placing them in unlabeled bags or containers.
- viii. **Public Outreach.** Whether the Plan provides for adequate public outreach, including but not limited to sufficient use of print and social media, radio, television, signage, and public events.
- ix. **Cost.** The Plan does not need to include an itemized cost breakdown for the Plan or the charges to, or financial contributions from, any Producer, so long as a statement is provided from each Producer that it is their reasoned opinion that the proposed Plan meets the criteria of Section 6.53.040(B) of the Ordinance.
- B. When considering a Plan for approval, the Department assumes the truth and accuracy of all information provided in connection with the Plan. Plan Owners and all Producers participating in a Plan are jointly and severally responsible for the truth and accuracy of their representations. If the Department determines that any information provided to it in connection with a Plan is false or inaccurate, the Plan Owner(s) and Producer(s) participating in the Plan shall, at the discretion of the Department, be subject to the penalty provisions of the Ordinance and Regulations.

Section 9 – Petitioning For Alternative Method Of Disposal

A Plan Liaison may petition for a method of disposal other than incineration as required by Section 6.53.060 (B) of the Ordinance by submitting a written petition to the Department Liaison by e-mail. The following information must be included in the petition:

- A. An explanation as to how the proposed alternative method of disposal adequately meets the requirements of the Ordinance, including Section 6.53.060 (C), and Regulations;
- B. A deposit for the estimated cost to the County to review, consider and respond to the petition, based on the Fee Schedule.

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The Department will contact the petitioner if additional information is required to make a determination on the petition. The Department shall have discretion to grant or deny any petition filed under this Section.

Section 10 – Review, Public Hearing and Approval of Plan

- A. **Review:** Following receipt of a Plan by the Department, the Department Liaison may review the Plan with the Plan Liaison. If the Department Liaison does not recommend approval of the Plan as submitted, a Revised Plan may be submitted by a date set by the Department Liaison. It is within the discretion of Department to continue a noticed public hearing to allow for submission of a Revised Plan.
- B. **Public Hearing.**
- i. **Public Hearing:** A Public Hearing shall be noticed and conducted by the Department to determine if a Plan complies with the Ordinance and Regulations
 - ii. **Availability of Plan:** Within 10 days of the Department providing notice of the public hearing, the proposed Plan will be made available to the public by the Department at no cost on the Department website. A copy will also be made available for public viewing at the Department office.
- C. **Approval of Plan.** Within 30 days following the public hearing, the Department will notify the Plan Liaison by e-mail whether the proposed Plan has been approved or denied, whether any changes to the Plan are required for approval and/or whether additional time, information, and/or documents are needed for the Department to make a determination on the Plan. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations.
- D. **Posting of Approved Plan.** All approved Plans shall be posted by the Department on its website within fifteen (15) days of notification to the Plan Liaison of approval.
- E. **Rejection of a Plan.** If a Plan is rejected by the Department, the Plan Liaison must submit a Revised Plan to the Department within 60 days after receiving notice of the rejection. If a Revised plan is not timely submitted and approved, Producers participating in the rejected plan may have an Alternative Plan imposed on them.
- F. **Alternative Plan.** At the Department's discretion, an Alternative Plan may be, but is not limited to, a Plan developed by the Department, or a Plan submitted by another Plan Owner(s) or Producer(s).

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- i. All costs incurred by the County relating to an Alternative Plan shall be paid by the Producer(s) participating in the Plan. Such costs shall be determined in accordance with the Fee Schedule, Ordinance and Regulations, and shall not exceed the actual costs of the County.
- ii. The Department in its discretion may contract with a third party to create an Alternative Plan. Any fees or costs for such a consultant shall be paid by the Producer(s) participating in the Plan.
- iii. Producer Contact(s) will be sent notification of the imposition of an Alternative Plan by e-mail and first class mail, which will include a webpage where a copy of the Alternative Plan may be downloaded.

G. Appeal. A Plan Liaison or Participating Producer may appeal an Alternative Plan, or a portion of an Alternative Plan, to the Board of Supervisors within ten (10) calendar days after receiving notice of imposition of the Alternative Plan.

- i. The appeal may be initiated by filing a Notice of Appeal with the Clerk of the Board of Supervisors. A courtesy copy of the Notice of Appeal shall be sent to the Department Liaison.
- ii. The Notice of Appeal shall specify the grounds for the appeal, the specific changes requested to the Alternative Plan, and the appellant's contact information.
- iii. The appeal process before the Board of Supervisors for an Alternative Plan shall follow the procedures set forth for administrative citations in Section 6.53.110 (J) of the Ordinance. If the Board of Supervisors cannot attain a majority vote as to whether to grant or deny an appeal of an Alternative Plan, the Alternative Plan shall be upheld.

Section 11 – Request To Modify an Approved Plan

- A. Only a Plan Liaison may request modifications to an approved Plan. All such requests must be made in writing and submitted to the Department Liaison with a Modification Request Fee, as set forth on the Fee Schedule. No material modifications may be made to a Plan without prior Department approval, including but not limited to:
- i. Collection Point changes;
 - ii. Changes to collection methods or collection events;
 - iii. Material changes to educational or public outreach efforts.

The Department must be promptly notified, in writing, of any non-material changes to the Plan, including a change in Plan Liaison, but prior Department approval is not required for such non-material changes.

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- B. The Department will notify the Plan Liaison within 30 days of receipt of a request to modify an approved Plan as to whether the requested modification has been approved, denied, approved in part, or if additional information, documents and/or time are needed to make a determination. The Department shall have discretion to determine whether to allow modifications of an approved Plan.

Section 12 – Plan Compliance

The Department may, but is not required to, monitor Plan compliance, including but not limited to visiting Collection Points or educational events or engaging a third party to do so. Costs incurred by the County in monitoring Plan compliance shall be borne by Producers participating in a Plan.

Section 13 – Enforcement and Penalties

- A. **Written Warning.** If the Department Liaison determines that a Plan is in violation of the Ordinance or Regulations or is not being implemented as approved, the Department Liaison shall send by e-mail a written warning to the Plan Liaison. Since Producers are the parties responsible for payment of all fines and penalties, all Producers participating in a Plan shall be sent a copy of the written warning at the address identified on the Plan for their Producer Contact. The written warning will be deemed received the day after it is sent by e-mail.
- B. **Recommendation for Administrative Citation.** If any violation(s) identified in the written warning is not corrected within 30 days, a recommendation will be made by the Department Liaison that the Department issue an Administrative Citation to the offending Producer(s).
- C. **Administrative Citation.** An Administrative Citation issued by the Department shall include a description of the violation, the section of the Ordinance or Regulation that has been violated, the date the warning was issued, and the administrative fines and civil penalties to be assessed against the Producer(s). The fines and penalties shall begin accruing on the 31st calendar day after the written warning. The Department has discretion as to when to issue an Administrative Citation.
- D. **Per Day Violation and Penalties.** Each day a Plan is in violation of the Ordinance or Regulations after the 30 day cure period shall constitute a separate and distinct violation, and penalties may, at the Department's discretion, be assessed on a daily basis until the violation is cured. The amount of the penalty for each violation shall be determined at the discretion of the Department, up to a maximum amount of one

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thousand dollars (\$1,000) per day per violation. Any civil penalty is separate and distinct from any fines imposed in connection with any criminal conviction.

- E. **Payment of Penalties.** All penalties shall be paid within 30 days of the date the Administrative Citation was issued. Any penalty amounts that are not paid within the 30 day period shall accrue interest at the rate of 10% per annum. Penalties shall be payable to the Department.

Section 14 – Appeal of Administrative Citations

- A. **Submission of Appeal.** Any appeal of an Administrative Citation shall follow the process set forth in the Ordinance at Section 6.53.110.
- B. **Department Review.** Appeals shall be sent to the Department Liaison for review to determine if the appeal is complete according to the requirements of Section 6.53.110 of the Ordinance.
- C. **Contact Information.** The appeal must set forth the contact person for purpose of the appeal and the appellant's telephone number, e-mail and mailing addresses.
- D. **Incomplete Appeal.** If any appeal is determined by the Department Liaison to be incomplete, it shall be returned to the appellant with the basis for the determination.
- E. **Notification of Hearing.** If the Department Liaison determines that an appeal is complete, a hearing officer will be designated, and the Department will provide written notice of the hearing as set forth in Section 6.53.110 (G) of the Ordinance.
- F. **Appeal to Board of Supervisors.** A Producer or the Department may appeal the Hearing Officer Decision to the Board of Supervisors by following the process set forth at section 6.53.110 (J) of the Ordinance. A copy of any appeal filed with the Clerk of the Board of Supervisors shall be sent by the appellant to the Department Liaison or, if filed by the Department, to the Plan Liaison.

Section 15 – Annual Reports

- A. **Submission of Reports.** An Annual Report must be submitted to the Department Liaison for each Plan on or before the annual report date set by the Department at the time the Plan is approved.
- B. **Report Format:** The Annual Report shall be in two parts: a Report Narrative section containing a narrative description of the activities under the Plan for that year and a Report Data section containing the data described below. In addition to elements

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required in the Ordinance and below, the Annual Report shall contain any changes to contact information for any Plan Owner or Producer participating in a Plan.

- C. **Report Narrative.** The narrative section of the Annual Report shall include the following brief subsections:
- i. **Executive Summary.** The purpose of the Executive Summary is to provide a broad understanding of the Plan as a whole and context for the data and information that will follow. This summary should include a brief description of collection and disposal efforts during the reporting period. The executive summary should also include a description of proposals to improve collection efforts and challenges encountered during the reporting period, and how they will be addressed. (Security issues must be addressed separately as set forth below.)
 - ii. **Reporting on Goals.** The Report Narrative should include a summary of the Plan goals and the degree of success in meeting those goals in the past year. The discussion should include a summary of the efforts to meet the goals, any difficulty in meeting the goals, and if any goals have not been met, what effort will be made to achieve such goals in the next year.
 - iii. **Future Goals.** The Report Narrative should include proposed goals to be accomplished in the upcoming year. If the proposed goals differ from the original Plan goals, the Annual Report should include a discussion of the reasons for the suggested change(s).
 - iv. **Collection Practices.** The Report Narrative shall include a brief description of the collection efforts over the past year. .
 - v. **Educational Efforts and Public Outreach Activities.** The Report Narrative shall include a brief description of education and public outreach efforts over the past year.
 - vi. **Safety and Security Report:** This section shall be provided on a separate page and clearly marked "Safety and Security Report". This section shall:
 - a. Identify any known security or safety incidents at Collection Points, events and during transportation or disposal. For each such incident, the report must include the following:
 1. What, if any, corrective or other action was taken in response to the incident;

REGULATIONS

2. Any law enforcement or regulatory agencies involved in the incident; and
3. Any litigation, arbitrations or other legal proceedings arising out of, or involving, the incident.

b. If the Plan Owner or a Producer participating in a Plan contends that information it is required to provide in the Safety and Security Report is exempt from disclosure under the California Public Records Act, this section of the Annual Report may be submitted conditionally under seal. It must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. Submission of a written claim that the document, or information contained in a document, is exempt from disclosure under the California Public Records Act does not in itself create an exemption. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether documents or information are exempt from the California Public Records Act.

D. **Report Data:** The data section of the annual report must contain all items required by the Ordinance and the following information:

- i. All Producers participating in the Plan;
- ii. For each Collection Point:
 - a. Location, host site name, and address;
 - b. Collected Unwanted Products by weight over the past year; and
 - c. Number of times Unwanted Products was picked up for transportation per location.
- iii. For any mail-back program:
 - a. The number of mail-back containers distributed;
 - b. The number of mail-back containers returned; and
 - c. Collected Unwanted Products by weight.
- iv. For each Disposal Facility:
 - a. The facility name, address and telephone number; and
 - b. The total weight of collected products disposed of at each Facility.

REGULATIONS

E. Failure to Submit Adequate Annual Report.

- i. If the Department finds any Annual Report to be inadequate, it may request additional information or a revised report.
- ii. If a Plan Owner does not provide an adequate Annual Report after a request by the Department for additional information or a revised report, any Producers participating in the Plan may be subject to enforcement actions and penalties under the Ordinance and Regulations.

Section 16 – Plan Renewal

Once a Plan is approved it is valid for three (3) years, unless the Department specifically sets forth a different term, which is within the Department's discretion Plan Liaison should set up an appointment with the Department Liaison six (6) to eight (8) months prior to the end of the three (3) year term, and no later than 60 days prior to the expiration of the term of the existing Plan, to discuss renewal of the Plan and how the Plan may be improved or modified. The Department will advise the Plan Liaison within 30 days following this meeting as to whether the Plan will need to be revised prior to renewal.

The Department shall have discretion to determine whether a public hearing will be held prior to renewal of a Plan.

Section 17 – Request for Exception

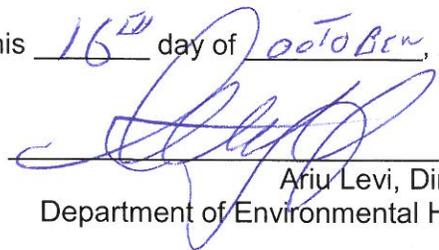
- A. **Petitions for Exception.** A Plan Liaison or a Producer may make a request of the Department for an exception, exemption, or allowance from any requirement of the Ordinance or Regulations.
- B. **Petition Content.** Any Petition for Exception must be made in writing to the Department Liaison and contain all of the following:
 - i. The name and contact information of the Plan Liaison or Producer seeking the exceptions;
 - ii. The Ordinance section or Regulation to which the request relates;
 - iii. The reason and justification for the request; and
 - iv. A deposit for the estimated cost to the County of review, consideration and response to the Petition based on the Fee Schedule.
- C. **Department Discretion.** The Department shall have the discretion to grant or deny any Petition for Exception.

REGULATIONS

Section 18 – General Provisions

- A. **Severability.** If any part or provision of these Regulations or the application thereof to any person or circumstances is held invalid, the invalid provision(s) shall be severed, and the remainder of the Regulations, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect.
- B. **Compliance with all Laws and Regulations.** Plan Owners and Producers participating in a Plan, and not the Department, are jointly and severally responsible for creating and maintaining a Plan that is in compliance with all federal and California laws and all city and county ordinances and regulations. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations. Any statement by the County, including the Department Liaison, that the Plan may contain a component that violates any federal, state, city, or county law, ordinance, or regulation shall not be interpreted as an opinion that any other component of the Plan is in compliance with any federal, state, city, or county laws, ordinances or regulations.
- C. **Separate and Distinct Compliance.** Adherence to the Ordinance and Regulations is not meant to replace or meet the requirements of any other federal, state, city, or county laws, ordinances, or regulations. Any review or approval pursuant to the Ordinance or Regulations is not meant to and shall not be indicative of compliance with or violations of any other federal, state, city, or county laws, ordinances or regulations.

These Regulations, as amended, are hereby adopted this 16th day of October, 2013.


Ariu Levi, Director
Department of Environmental Health

Alameda County Safe Drug Disposal

FEE SCHEDULE / COST RECOVERY

The approved hourly rate for cost recovery, effective July 1, 2015, is \$246.

The following is a schedule of estimates of the minimum amount of time that each type of activity will take a staff person. When the Ordinance or Regulations require a deposit of the estimated cost, the following schedule may be used as a base line to estimate the deposit amount.

ACTIVITY	ESTIMATED HOURS
Petition for Exemption (Section 5B)	3.00
Preliminary Review of Plan- pre-formal submittal (Section 6)	4.00
Plan Evaluation (Section 6)	16.00
Petition for Late Submission Date for a Plan (Section 6)	1.00
Review of Revised Plan (Section 10E)	8.00
Request to Modify an Approved Plan (Section 11)	2.00
Petition for alternative method of disposal (Section 9)	2.00
Public Posting, Hearing and Noticing (Section 10)	4.00
Appeal Hearing of Alternative Plan (Section 10G)	2.00
Request for Exception (Section 17)	3.00
Alternative Plan Developed (Section 10F)	32.00
Monitoring Plan Compliance (Section 12)	8.00
Appeal of Administrative Citations (Section 14)	6.00
Review of Annual Report (Section 15)	2.00

General work such as assistance with educational outreach, training, meetings, website management, complaints, and inspections shall be estimated at the time that work is requested or completed.

This schedule is an estimate and the actual time and amount will vary depending on the complexity of the petition, or matters at issue, size of the Plan and other individual factors. At the time the activity is requested, the Department may request a deposit in excess of the estimated hours on this schedule, if it believes the actual time will exceed the estimated hours.

The amount ultimately charged will be that of the actual time spent, whether it is more or less than the time estimated.

July 2015