



Board of Supervisors

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AGENDA _____ July 10, 2012

July 6, 2012

The Honorable Board of Supervisors
Administration Building
1221 Oak Street, Suite 536
Oakland, California 94612

Dear Board Members:

SUBJECT: ALAMEDA COUNTY'S SAFE DRUG DISPOSAL ORDINANCE

RECOMMENDATIONS:

It is requested that Your Board:

1. Adopt the attached "Alameda County Safe Drug Disposal Ordinance," requiring producers of prescription drugs to develop product stewardship program(s) to collect and dispose of unwanted medications from residential consumers.
2. Adopt the attached "Alameda County Safe Drug Disposal Ordinance," by amending Title 6 of the Alameda County Health and Safety Code, by adding Chapter 6.53.

SUMMARY

On February 28, 2012 the Alameda County Board of Supervisors approved the first reading of a previous version of the Safe Drug Disposal Ordinance. The Board adopted the ordinance by amending Title 6 of the Alameda County Health and Safety Code, by adding Chapter 6.53, Sections 6.53.010 through 6.53.130 requiring producers of prescription and nonprescription drugs to develop product stewardship program(s) to collect and dispose of unwanted medications from residential consumers.

On March 13, 2012 the Safe Drug Disposal Ordinance came before your Board for a second reading and adoption. However, after much discussion and public comment from both the community and the pharmaceutical industry, your Board decided not to vote on the item but continue the matter to a future date, to be no later than June 5, 2012, for second reading. On June 5, 2012, your Board decided

not to have a vote on the item, because a revised version of the ordinance would be submitted for a first reading at this meeting.

DISCUSSION

Unused and expired medications are an increasing concern for public health and safety in Alameda County and nationwide, particularly for senior citizens and youth. Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications. Unintentional poisoning of adults over 60 resulting in hospitalization increased by 43% in Alameda County from 1998 to 2006. Accidental poisoning from ingestion of drugs among children often occurs in homes where medicine is easily accessible. The Partnership for a Drug-Free America released a report in February 2010, indicating that over 60% of teens are able to obtain prescription painkillers free of charge from family and friends.

The environment will be improved by enactment this Ordinance. Pharmaceutical residues have been accumulating in groundwater and drinking water. Drugs enter the environment through multiple sources including flushing toilets or through leaks in landfills. The cost of developing waste treatment for wastewater is extremely high. Thus, many drugs pass through wastewater treatment systems and contaminate receiving waters.

Currently no mandatory state or federal program exists to safely collect unwanted drugs and to properly dispose of them. Yet, safe and convenient medical disposal programs are one of the most effective solutions in preventing negative individual and environmental health impacts. This first-in-the-nation ordinance requires drug producers to dispose of unwanted household medications. Manufacturers and producers of drugs would be required to finance and operate the collection of unwanted prescription medications for proper disposal and pay for all costs associated with complying with this ordinance.

A series of Safe Medication Disposal Ordinance stakeholder meetings were convened by Supervisor Nate Miley's office at the request of the pharmaceutical industry. Another meeting was initiated by pharmaceutical industry representatives and was attended by staff from all members of this board. The meetings were organized to provide the industry with an opportunity to participate and share ideas around improving policy outcomes. In addition, there has been much email and telephone communication with Supervisor Miley's office from a variety of stakeholders including industry representatives. Kay Iwata Associates Inc. facilitated five stakeholder meetings and provided a note taker.

Stakeholder participants came from all over the Bay Area and around the country to attend the meetings. Ginnette Vanasse from the Post Consumer Pharmaceutical Association in Canada also came to a stakeholder meeting to discuss how voluntary and industry funded medication take-back programs work in British Columbia and other provinces.

Below is a listing of the speakers, topics and meetings convened over the last two months:

Industry Initiated Meeting

Monday, April 23, 10 a.m. – noon

Location: Office of the County Counsel 1221 Oak Street, Suite 450 Oakland, California 94612

Topic: Discussion concerning the Safe Drug Disposal Ordinance

Speakers: Marjorie Powell

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Stakeholder Meeting #1

Monday, April 30, 2012 9:30 a.m. – 11:30

Location: Alameda Conference Center 125 12th Street, 4th Floor Oakland CA 94607-6467

Topic: Pharmaceuticals in the Environment, the role of take-back programs

When pharmaceuticals are currently disposed of, where do they end up and what evidence do we have that this is safe?

Speakers: Melody Labella, Central Contra Costa Sanitation, Andria Ventura, Clean Water Action/Clean Water Fund

Topic: Why does Alameda County need a pharmaceutical take-back program?

Speakers: Linda Pratt, CommPre, Carolina Guzman, Prevention Institute

Topic: What are the issues with controlled substances and take-back programs?

Speaker: Nancy O'Malley, Alameda County District Attorney

Stakeholder Meeting #2

Wednesday, May 9, 2012 11:30 a.m. – 1:30 p.m.

Location: Alameda Conference Center 125 12th Street, 4th Floor Oakland CA 94607-6467

Topic: Producer Responsibility and Take-back Programs

What is extended producer responsibility (EPR)?

Speaker: Heidi Sanborn, Executive Director of the California Product Stewardship Council

Topic: What are ways others have safely and effectively disposed of drugs?

Speaker: Ginette Vanesse, Executive Director of the Post-Consumer Pharmaceutical Stewardship Association (PCPSA)

Stakeholder Meeting #3

Wednesday, May 16, 2012 2:00 p.m. – 4:00 p.m.

Location: Alameda Conference Center 125 12th Street, 4th Floor Oakland CA 94607-6467

Topic: Alameda County Safe Medication Disposal Ordinance in Detail

Review and Presentation of Ordinance Language

Speaker: Alameda County Deputy County Counsel, Robert D. Reiter
Topic: Bay Area Medication Disposal Study and Implication for the Ordinance
Speaker: Dr. Joel Kreisberg, Teleosis Institute

Stakeholder Meeting #4

Wednesday, May 23, 2012 10:00 a.m. – noon

Location: Alameda Conference Center 125 12th Street, 4th Floor Oakland CA 94607-6467

Topic: Moving Forward

Educational and Social Media Campaigns to Curb Medicine Abuse

Speaker: Chelsea Crucitti Associate Director, State Government Affairs Consumer Healthcare Products Association

Topic: Other Programs and the Ordinance

Speaker: Open Forum

Stakeholder Meeting #5

Wednesday, June 27, 2012

Location: Alameda Conference Center 125 12th Street, 4th Floor Oakland CA 94607-6467

Topic: Revisions to the Ordinance

Speaker: Robert D. Reiter, Deputy County Counsel with open forum.

FINDINGS

Throughout the stakeholder meeting series many questions were raised about the Ordinance, its complexity and how it can be used to address health, public safety and environmental issues. Stakeholder participants shared their feedback on how to improve the Ordinance. Supervisor Miley applauded the healthy debate on the issues and emphasized that the goal of the stakeholder meetings was to try and write a sustainable Ordinance, address concerns, and build consensus in a way that is effective. Stakeholder participants received summary notes and presentations of all the speakers after each meeting.

The stakeholder meetings culminated on May 23rd, when participants agreed that Alameda County Safe Drug Disposal Ordinance needed to be revised based on the feedback and input given during the stakeholder meetings. As a result, the revisions of the ordinance were shared with the industry at a meeting on June 27, during which they had an opportunity to review the revised Ordinance and provide final input before the item returns to the board of Supervisors.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Robert D. Reiter', written over the typed name 'Robert D. Reiter'.

ORDINANCE NO. _____

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 _____, 2012, by the following called vote:

AYES:

NOES:

EXCUSED:

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