GAIL FARBER, CHAIR
MARGARET CLARK, VICE - CHAIR

LOS ANGELES COUNTY
SOLID WASTE MANAGEMENT COMMITTEE/
INTEGRATED WASTE MANAGEMENT TASK FORCE
900 SOUTH FREMONT AVENUE, ALHAMBRA, CALIFORNIA 91803-1331
P.O. BOX 1460, ALHAMBRA, CALIFORNIA 91802-1460
www.lacountyiswmtf.org

July 3, 2012

The Honorable Alameda County
Board of Supervisors
1221 Oak Street, Suite 536
Oakland, CA 94612

Dear Supervisors:

ALAMEDA COUNTY SAFE MEDICATION DISPOSAL ORDINANCE

On behalf of the Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force (Task Force), I am pleased to advise that the Task Force at its meeting on June 21, 2012, voted unanimously in favor of the proposed Alameda County Safe Medication Disposal Ordinance (copy enclosed). We understand that the proposed ordinance is tentatively scheduled for your Board's consideration on July 24, 2012, and the Task Force strongly encourages its adoption.

Pursuant to Chapter 3.67 of the Los Angeles County Code and the California Integrated Waste Management Act of 1989 (Assembly Bill 939 [AB 939], as amended), the Task Force is responsible for coordinating the development of all major solid waste planning documents prepared for the County of Los Angeles and the 88 cities in Los Angeles County with a combined population in excess of ten million. Consistent with these responsibilities and to ensure a coordinated, cost-effective, and environmentally sound solid waste management system in Los Angeles County, the Task Force also addresses issues impacting the system on a countywide basis. The Task Force membership includes representatives of the League of California Cities-Los Angeles County Division, County of Los Angeles Board of Supervisors, City of Los Angeles, waste management industry, environmental groups, the public, and a number of other governmental agencies.

The presence of pharmaceutical waste in the environment is an issue of growing concern, but the level of risk that it poses to human beings and the environment remains largely unknown. Major national studies have found that an alarming percentage of streams (as high as 80 percent of the streams surveyed) had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Exposure, even at low levels, to medications threatens the marine environment and public health. The presence of these medications in surface waters across the nation has been associated with increased bacterial resistance to antibiotics, as well as interference with growth and reproduction in aquatic organisms such as fish and frogs.

Medications enter surface waters through various sources, including wastewater treatment plants. When unused/expired medications are thrown down the toilet or drain they enter the sewer system and wind up in a wastewater treatment plant. However, wastewater treatment plants are not designed (and therefore are unable) to remove these pollutants from the water. Therefore, measures are urgently needed to prevent these pollutants from entering the water stream. Failure to take appropriate action can have grave consequences for public health and safety, as well as the environment.

Also, safe disposal of pharmaceuticals is a shared societal burden, the costs of which should not fall on local government alone. We hope that the pharmaceutical companies share in this responsibility and work with Alameda County and its many constituencies eager to support a robust program.

For these reasons, the Task Force **supports** the Alameda County Safe Medication Disposal Ordinance. If you have any questions, please contact Mr. Mike Mohajer of the Task Force at MikeMohajer@yahoo.com or (909) 592-1147.

Sincerely,

Margaret Clark

Margaret Clark, Vice-Chair
Los Angeles County Solid Waste Management Committee/
Integrated Waste Management Task Force and
Council Member, City of Rosemead

CM:fr
P:\eppub\ENGPLAN\TASK FORCE\SupportofAlamedaCounty7-3-12MM

Enc.

cc: Each City Mayor and City Manager in the County of Los Angeles
Each Member of the Los Angeles County Board of Supervisors
Each Member of the Los Angeles County Integrated Waste Management Task Force
Gateway Cities Coucil of Governments
San Fernando Valley Council of Governments
San Gabriel Valley Council of Governments
South Bay Cities Council of Governments
Westside Cities Council of Government

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 having a drug stewardship program; and

WHEREAS, the County of Alameda has chosen to exercise its police power to have a drug stewardship program; and

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 does hereby declare the following:

A. Drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives.

B. Total healthcare spending on pharmaceuticals in the US was $320 billion in 2011. The rise in consumption was 3.7 percent.

C. One half million children under the age of five are exposed to accidental poisoning from pharmaceuticals each year. Emergency Department visits for young children due to medication poisonings exceeded injuries from motor vehicles. The recent study published in the Journal of Pediatrics suggests this is due to the rise of the number of medications in the home. Overall, there has been a 22% increase in pediatric pharmaceutical-related calls to poison centers. Poisonings remain the second leading cause of injury death in the United States for several years. Most fatal poisonings come from unintentional drug overdoses. In Alameda County, nonfatal hospitalized injuries for unintentional poisonings for adults over 65 increased by 88% from 2000 to 2010.

D. In 2010 1.9 million teens abused prescription drugs. Teens ages 12-17 have the second-highest annual rates of prescription drug abuse after young adults (18-25). In 2007, approximately 27,000 unintentional drug overdose deaths occurred in the United States, one death every 19 minutes. Prescription drug abuse is the fastest growing drug problem in the United States.

E. Pharmaceutical residues have been proven to be accumulating in ground water and drinking water. Studies revealing concentrations of a variety of common drugs in ground and surface water continue to mount: including the 2001 US Geological Survey Report, the report for the San Francisco Estuary Institute, and investigative research by the Associated Press.

F. Drugs enter the environment through multiple sources, but primarily through human excretion disposed into the environment through municipal wastewater systems by flushing down toilets, or through leachate leaks in landfills. Municipal wastewater treatment plants were designed to treat biological pollutants in wastewater. Costs to develop waste treatment through wastewater treatment are extremely high; thus, drugs pass through wastewater treatment systems and contaminate receiving waters.

G. Properly disposing of leftover, expired and unwanted drugs would be a significant step forward in preventing unintentional poisoning deaths attributable to drugs, as well as both abuse related to access to pharmaceuticals and dangerous concentrations of medicines contaminating our drinking water.

H. California Senate Bill 966, enacted as Chapter 542 of the Statutes of 2007, required CalRecycle to survey existing drug collection programs, evaluate them for several factors including cost effectiveness, and make recommendations for implementation of statewide programs. Recommendations have been returned to the state legislature for further action.

I. Extended Producer Responsibility (EPR) is a mandatory type of product stewardship that includes, at a minimum, the requirement that the producer's responsibility for their product extends to post-consumer management of that product. Two related features of EPR policy: 1) shifting financial and management responsibility, with government oversight, upstream to the producer and away from the public sector; and 2) providing incentives to producers to incorporate environmental considerations into the design of their product and packaging. EPR policies put the primary responsibility with the producers, or brand owners, who make the design and marketing decisions.

J. In 2009 and 2010, California passed three significant EPR bills for mercury thermostats, carpet, and paint. All three bills require producers to establish and fund product stewardship programs for their waste stream. To date, 128

resolutions have been passed by California local jurisdictions and organizations supporting EPR.

K. There is no permanent drug collection program in Alameda County, but there is considerable demand for it. In 2009, Bay Area residents disposed of over 60,000 Ibs of unwanted pharmaceuticals at 128 currently available sites. Alameda County citizens returned just roughly 4000 Ibs, compared to Santa Clara County which disposed of almost 19,000 Ibs and San Mateo which disposed of close to 18,000 pounds

L. United States Senate Bill 3397, the "Secure and Responsible Drug Disposal Act of 2010," which was signed into law on October 12, 2010, authorizes the Attorney General to increase the methods, currently restricted to law enforcement, by which controlled substances may be collected. This includes collection at pharmacies. The goal of the bill is to increase opportunities for drug collection programs in order to reduce the instances of diversion and release of harmful substances into the environment.

M. A number of states introduced drug product stewardship bills since 2009, including Maine, Maryland, Minnesota, Rhode Island, Florida, New York, Oregon, Washington, and most recently Pennsylvania.

N. Several Canadian provinces and many other countries have active, well-established drug product stewardship programs in place: British Columbia has had a manufacturer-funded drug collection program in place since 1996; Manitoba began its program in April 2011. France, Spain and Portugal, among others, have national, well-established, manufacturer-funded drug collection programs.

O. There is no voluntary or 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.

References

B. 1. The Use of Medicines in the United States: Review of 2010, Report by the IMS Institute for Healthcare Informatics http://www.imshealth.com/imshealth/Global/Content/IMS%20Institute/Documents/IHII_UseOfMed_report%20.pdf

2. U.S. prescription drug sales hit $300 bln in 2009 Thu Apr 01 17:34:08 UTC 2010 Reuters Bill Berkrot http://www.reuters.com/article/2010/04/01/us-drug-sales-idUSTRE6303CU20100401

C. 3. The growing impact of pediatric pharmaceutical poisoning. Bond GR, Woodward RW, Ho M. *J Pediatr.* 2012 May;160(5):888-9.

D. 4. Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings (NSDUH) http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm#2.2

5. Incidence and Age at Initiation of Prescription Drug Misuse SAMSA, US Department of Health and Human Services. 4. http://www.oas.samhsa.gov/prescription/Ch4.htm

6. CDC. Policy impact: prescription painkiller overdoses. Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at http://www.cdc.gov/homeandrecreationalsafety/rxbrief/index.html. Accessed January 9, 2012.

E. 7. Kolpin, Dana et al. (2002) Pharmaceuticals, hormones and other organic wastewater contaminants in U.S. Streams, 1999-2000: A National Reconnaissance, Environmental Science and Technology v. 36: 1202-1211.

8. Oros, Daniel and David, Nicole (2002). Identification and Evaluation of Unidentified Organic Contaminants in the San Francisco Estuary, San Francisco Estuary Regional Monitoring Program for Trace Substances, SFEI

9. Donn, J, Mendoza, M & Pritchard, J. (2008) AP Probe Finds Drugs in Drinking Water.

H. 10. SB 966

J. 11. Paint ab_1343_bill

12. Carpets AB-2398

13 Thermostats ab_2347

K. 14. Bay Area Medication Disposal Study 2009: An Inventory of Household Pharmaceutical Waste Final Report, Kreisberg, Ruhoy, Zheng, October 26, 2010 Teleosis Institute

L. 15. SB 3397

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

4. "Department" means the County’s Department of Environmental Health.

5. "Drug wholesaler" means a business that sells or distributes 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" 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" means a person or entity that: (i) has a physical presence in the United States and manufactures a covered drug for

sale as a generic drug or under a brand, brand name, or co-brand; (ii) has legal ownership of a generic drug or a brand, brand name, or co-brand under which a covered drug is sold; (iii) imports a covered drug branded or manufactured by a person or entity that has no physical presence in the United States but is sold in Alameda County, or (iv) a retailer that puts its store label on a covered drug.

"Producer" does not include a pharmacist who compounds a prescribed individual drug product for a patient.

15. "Product stewardship 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 fee to cover the costs of a product stewardship program at the time of sale to a consumer of the covered product or when unwanted products are collected from residential generators or delivered for disposal.

6.53.050 - Product stewardship plan.

A. Plan content. Each product stewardship program shall have a product stewardship plan that must contain 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 all producers participating in the product stewardship program;

3. A description of the methods by which unwanted products from residential generators will be collected in the County and an explanation of how the collection system will be convenient and adequate to serve the needs of County residents;

4. Provide collection services for covered drugs in all areas of the County that are reasonably convenient to the public and adequate to meet the needs of the population in the area being served.

5. If applicable, include the location of each collection site and locations where envelopes for a mail-back program are available;

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 transporter 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 effort 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 stewardship program are consistent with the scope and extent of the sales of covered drugs within the County by the producer or group of producers; and,

10. A starting date when collection of unwanted products will begin.

11. Provide support to any law enforcement agencies within Alameda County that have, or later agree to have, a collection program for controlled substances, that shall include: (i) 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. Collection sites for unwanted drugs may be placed at appropriate retail stores in Alameda County, but retailers are not required or mandated to host collection sites.

B. Department review and approval; updates.

1. No producer, group of producers, or stewardship organization may begin collecting unwanted products 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 by the Department.

3. Within 180 days after receipt of a 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. As part of its approval, the Department may set reasonable performance goals for the program. If the Department approves a plan, it shall notify the applicant of its approval in writing. If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. 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. If the Department rejects the revised 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.

4. At least every three years, a producer, group of producers or stewardship organization operating a product stewardship program must 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 plan 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 approved by the Department in writing.

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 drugs 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 products, and health care practitioners as to the proper and safe method to dispose of unwanted drugs.

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 or other promotional materials, or both.

C. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in the 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 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 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 and the total amount by weight collected by a mail-back program, if applicable;

3. A description of the collection system, including the location of each collection site and locations where envelopes for a mail-back program are provided, if applicable;

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 any 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 the 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 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 appointed 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. The failure of any producer to receive notice of the hearing shall not affect the validity of any proceedings under this Chapter. 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.

I. A hearing officer shall be designated by the Director of the Department of Environmental Health for hearings under this Chapter. 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. All testimony shall be by declaration under penalty of perjury;

3. The producer responsible for the violation or any other interested person may present testimony or evidence concerning the violation.

4. 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.

5. The hearing officer shall make findings based on the record of the hearing and make a written decision based on the findings. The decision shall be served by first class mail on all parties. The decision of the hearing officer affirming or dismissing the administrative citation is final, unless a timely notice of appeal is filed for hearing by the board of supervisors.

J. A second appeal may be filed with the board of supervisors within ten calendar days after the date of service of the decision by the hearing officer.

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 make available to the board 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 hearing any appeal filed pursuant to this section to the appellant, the Department and the producer at issue.

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 may make such findings and decisions as are consistent with state law and county ordinances; provided that, if no motion relative to the 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, said order 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 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 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. The 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 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. The 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 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. Except as provided in this subsection, any action by a manufacturer or producer of drugs or any product stewardship organization formed under this Chapter or its members that relates to any of the following is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code: (1) The creation, implementation, or management of a product stewardship plan approved by the department pursuant to this Chapter and the types or quantities of drugs being collected or otherwise managed as described in this Chapter. (2) The cost and structure of an approved product stewardship plan. (3) The establishment, administration, or disbursement of a product stewardship assessment as described in this Chapter.

F. Except as provided in this subsection, any action by a manufacturer or producer of drugs or any product stewardship organization formed under this Chapter or its members that relates to any of the following is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code: (1) The creation, implementation, or management of a product stewardship plan approved by the department pursuant to this Chapter and the types or quantities of drugs being collected or otherwise managed as described in this Chapter. (2) The cost and structure of an approved product stewardship plan. (3) The establishment, administration, or disbursement of a product stewardship assessment as described in this Chapter.

G. This Chapter shall be in effect for a period of ten (10) years following enactment and no longer.

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:

CRYSTAL K. HISHIDA-GRAFF, Clerk
Board of Supervisors, County of Alameda

By:_____

APPROVED AS TO FORM:

DONNA R. ZIEGLER
County Counsel

By:_____
ROBERT D. REITER
Deputy County Counsel