

Alameda County Safe Drug Disposal Ordinance

- *Proposed Ordinance Update Package – BoS Health Subcommittee – January 11 2016*



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Alameda County Environmental Health

BACKGROUND

- June 2012 County passes first in nation Pharmaceutical take-back ordinance
- DEA Controlled Substances – only Law Enforcement could collect!
- Ordinance covers Rx drugs only–not OTC's

ORDINANCE DELAYED

- Pharmaceutical industry trade organizations sue in Federal court
- Ordinance implementation delayed while lawsuit is pending
- County wins, industry appeals, county wins again, industry petitions to the US Supreme Court
- Supreme Court declines to hear case, county ordinance is upheld

IMPLEMENTATION PROBLEMS

- Not including OTC's creates implementation problems
- The public discards both OTC's and RX
- Both can cause public health and environmental problems
- Difficult to sort/separate
- Sorting increases opportunities for diversion



ORDINANCE MOVES FORWARD

- New DEA rules 10/2014 - Controlled Substances may now be collected at Pharmacies
- San Francisco, San Mateo, Santa Clara, Marin and King County WA (Seattle) pass Ordinances based on ours, but are more advanced
- Includes OTC and Controlled Substances
- Ordinance revision package brings Alameda County to a comparable level as San Francisco, San Mateo, Santa Clara, and Marin, and King County

REVISION SPECIFICS

| Current Ordinance | Revised Ordinance |
|---|--|
| Does not cover OTC's | Covers OTC's Eliminates sorting at "One Day Events" |
| Controlled Substances collection at Law Enforcement sites only | Controlled Substances collection at Law Enforcement & DEA Registrants (Pharmacies & Hospitals) |
| Stewardship Organization proposed installing drop-off Kiosks in 110 sites | Stewardship Organization must provide a kiosk to <u>any</u> DEA Registrant even if they have reached the 110 site goal |
| | Minor changes to Definitions to clarify ordinance, and make enforcement easier. |

ORDINANCE NO. _____

AN ORDINANCE AMENDING CHAPTER 6.53 OF THE ALAMEDA COUNTY
GENERAL ORDINANCE, THE SAFE DRUG DISPOSAL ORDINANCE

SECTION I

In enacting the amendments to this Ordinance, the Alameda County Board of Supervisors makes the following 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

WHEREAS, on July 24, 2012, Alameda County Safe Drug Disposal Ordinance was adopted and chaptered as Title 6, Chapter 6.53; and

WHEREAS, the County of Alameda was the first jurisdiction in the country to adopt such an ordinance, and since the Ordinance was passed other local jurisdictions have passed safe drug disposal ordinances; and

WHEREAS, amendments to the Ordinance for to add non-prescription drugs is consistent with other jurisdictions with similar ordinances and better serves the residents of the County; and

WHEREAS, amendment to the Ordinance for to clarify its requirements in light of the with the recent DEA regulations on collection of controlled substances is beneficial.

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

SECTION II

Title 6 of the Alameda County Health and Safety Code, Chapter 6.53, is hereby amended as follows:

6.53.010 (Declaration of Findings) is amended as follows:

The Board of Supervisors hereby finds and declares the following:

- A. ~~Prescription Drugs~~ Legal medicinal drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives;

- B. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription and non-prescription drugs and the illegal re-sale of prescription drugs;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription and non-prescription drugs passing through our wastewater ~~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 6.53.030 (Definitions) is amended as follows:

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, a Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. § 353(b)(1) of the FFDCA~~ sold, offered for sale or dispensed in Alameda County in any form including both prescription and nonprescription drugs, drugs in medical devices and combination products, brand name and ~~Generic Drugs.~~ generic drugs, and drugs for veterinary use.

"Covered Drug" does not include: (i) Vitamins or supplements; (ii) Herbal-based remedies and homeopathic drugs, products, or remedies; (iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and Nonprescription Drugs under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Sec. 301 et seq. (2002)); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1); (v) Drugs that are biological products as defined by 21 C.F.R.

600.3(h) as it exists on the effective date of this Section if the Producer already provides a take-back program; (vi) ~~Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems; and (vii) nonprescription drugs) medical devices or their component parts or accessories if it contains no Covered Drug.~~

4. "Department" means the Alameda County Department of Environmental Health.

5. "Drug Wholesaler" means a ~~business~~ Person that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.

6. "Drugs" means: (i) ~~articles~~ any article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (ii) ~~substances~~ any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) ~~substances~~ any substance, other than food, intended to affect the structure or any function of the body of humans or other animals; (iv) any substance intended for use as a component of any substance specified in (i), (ii), or (iii) of this definition. "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~~ collection method for the return of Unwanted Products from Residential Generators Unwanted Products obtain, utilizing 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. "Manufacture" means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a Repackager wholesaler or practitioner who distributes or dispenses such substance or device in the course of his or her professional practice.

11. "Manufacturer" means a Person engaged in the Manufacture of Drugs.

40. ~~12.~~ 12. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.

44. ~~13.~~ 13. "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal Entity, however organized.

42. ~~14.~~ 14. "Plan" or "Product Stewardship Plan" means a product stewardship plan required under this Chapter that describes the manner in which a Product Stewardship Program will be provided.

43. ~~15.~~ 15. "Prescription Drug" means any drug, including any Controlled Substance, that by federal or state law may be dispensed lawfully only on prescription, or is restricted to use by practitioners only.

44. ~~16.~~ 16. "Producer" means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County. ~~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 and the retailer provides verification and contact information of the Producer; or (ii) a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for direct distribution to a consumer and the pharmacist provides verification and contact information of the Producer; or (iii) a wholesaler and the wholesaler provides verification and contact information of the Producer. For purposes of this section contact information must contain the following: each Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer's participation in the Stewardship Program.

45- ~~17.~~ 17. "Product Stewardship Program" or "Program" means a program financed and operated by Producers to collect, transport, and dispose for the collection, transportation, and disposal of Unwanted Products under this

Ordinance that is: (1) financed, developed, implemented, and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; (3) approved by the Department; and (4) meets the educational and other requirements set forth in this Ordinance.

18. “Repackager” means a Person who owns or operates an establishment that repacks and relabels a product or package containing a Covered Drug for further sale or for distribution without a further transaction.

46. 19. "Residential Generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned. "Residential Generators" do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.

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

48. 21. "Unwanted Product" means any Covered Drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

6.53.050 (Product Stewardship Plan) paragraph A (Plan Content) sections 2, 7, and 11 are amended as follows, with all other sections remaining unchanged:

Section A. 2:

2. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program, including each Drug Producer’s name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer’s participation in the Stewardship Program;

Section A. 7:

7. A description of how the Unwanted Products will be safely and securely tracked and handled from collection through final disposal and a description of the policies and procedures to be followed by Persons handling Unwanted Products collected under the Stewardship Program to ensure security;

Section A. 11:

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~~ collection of Unwanted Products including: (i)

the provision of a collection kiosk with appropriate accessories and signage, (ii) an ability to accept Controlled Substances and other Covered Drugs, (iii) technical support up to and including an appropriate Person to provide on-site assistance ~~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;~~

6.53.050 (Product Stewardship Plan) paragraph A (Plan Content) the following is added as section A. 14:

14. A certification that any patient information on Drug packaging will be promptly destroyed.

6.53.050 – (Product Stewardship Plan) paragraph B (Department Review and Approval; Updates) sections 5 and 6 are amended as follows:

5.
 - a) A Producer who begins to offer a Prescription Covered Drug for sale in the County of Alameda after July 1, 2013, must submit a product stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within 180 days following the Producer's initial offer for sale of a Covered Drug.
 - b) For Producers selling only Non-prescription Covered Drugs, they must meet the requirements of this Ordinance for a Product Stewardship Program no later than February 1, 2017.
 - c) For Producers selling Prescription and Nonprescription Covered Drugs, they must come into compliance for all Non-prescription Covered Drugs no later than March 31, 2016.
 - d) Approved Product Stewardship Programs must immediately begin accepting Nonprescription Drugs.
6. Any proposed changes to a Product Stewardship Plan, other than collection of non-prescription Covered Drugs, must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

6.53.060 (Disposal of Unwanted Product) section C. 3 is amended as follows:

3. Air Reduction or elimination of air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

6.53.070 (Product Stewardship Program promotion and outreach) paragraph A is amended as follows:

A. A Product Stewardship Program must promote the Product Stewardship Program to Residential Generators, pharmacists, retailers of Covered Drugs, and health care practitioners, veterinarians, and veterinary hospitals as to the proper and safe method to dispose of Unwanted Products, so that collection options for Covered Drugs are widely understood and to promote the safe storage of Covered Drugs by Residential Generators.

6.53.070 (Product Stewardship Program promotion and outreach) is amended to add the following paragraphs:

D. Product Stewardship Programs shall not require, conduct or allow any sorting of items brought to collection events or at drop off locations.

E. A Product Stewardship Program shall provide a kiosk at any location in which a Person requests or volunteers to have a kiosk if the following conditions are met:

1. The approved Product Stewardship Plan includes having physical collection sites, such as kiosks (even if the approved number of sites have been accomplished by the Plan);
2. The Person is a law enforcement agency or a registered manufacturer, distributor, reverse distributor or retail pharmacy that is authorized under 21 CFR 1300 et seq to receive a Controlled Substance for the purpose of destruction.

6.53.100 (Regulations and Fees) paragraph A is amended as follows.:

A. The Director of the Department of Environmental Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter. The Director may revise the adopted regulations from time to time after posting the proposed revisions on the Department webpage for not less than ten (10) calendar days with a solicitation for public comments and considering any public comments received.

6.53.120 (Additional Provisions) paragraph H is deleted.

SECTION III

The Alameda County Board of Supervisors declares that it would have adopted each of these ordinance amendments irrespective of the fact that any one or more sections, subsections, clauses, phrases or portions of it be declared invalid or unconstitutional. If, for any reason, any portion of this ordinance is declared invalid or unconstitutional, then all other provisions of it shall remain valid and enforceable.

SECTION IV

This ordinance amendments shall take effect and be in force thirty (30) days from and after the date of its passage and before the expiration of fifteen (15) days after its passage, it shall be published once with the names of the members voting for and against the same in the Inter-City Express, a newspaper published in the said County of Alameda.

Adopted by the Board of Supervisors of the County of Alameda, State of California on _____, 2016, by the following called vote:

AYES:

NOES:

EXCUSED:

Scott Haggerty, President of the Board of Supervisors
County of Alameda, State of California

ATTEST:

Clerk of the Board of Supervisors, County of Alameda,
State of California

Approved as to Form:
DONNA R. ZIEGLER, County Counsel

By: _____
Kathleen Pacheco, Sr Deputy County Counsel