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County of Santa Cruz

DEPARTMENT OF PUBLIC WORKS

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JOHN J. PRESLEIGH DIRECTOR OF PUBLIC WORKS

AGENDA: NOVEMBER 10, 2015

November 2, 2015

SANTA CRUZ COUNTY BOARD OF SUPERVISORS 701 Ocean Street Santa Cruz, California 95060

SUBJECT: SAFE DRUG AND SHARPS DISPOSAL ORDINANCE

Members of the Board:

On September 1, 2015, your Board directed Public Works to: 1) Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from county residents; 2) To initiate stakeholder engagement with the pharmaceutical industry and other stakeholders to solicit feedback on the ordinance, communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste, and generate awareness about the collection program that will be created; and 3) To return to the Board on or before November 3, 2015, with a recommended ordinance for Board consideration.

Public Works has conducted extensive research on similar existing and proposed ordinances as well as relevant state and federal laws and regulations. There has been comprehensive outreach to the industry and other stakeholders, including a Public Stakeholder Meeting held here in the Board Chambers on October 8, 2015. The attached Proposed Ordinance draws from the best of existing ordinances while at the same time taking into account local conditions.

It is therefore recommended that the Board of Supervisors take the following actions:

1. Accept this report and the Proposed Ordinance.

- 2. Hold Public Hearing for the first reading on the Proposed Safe Drug and Sharps Disposal Ordinance.
- 3. Direct the Clerk of the Board to place the Proposed Ordinance on the December 8, 2015 agenda for a Final Reading and adoption.

Yours truly,

JOHN J. PRESLEIGH Director of Public Works

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Attachment

Recommended for Approval:

SUSAN A. MAURIELLO

County Administrative Officer

Copy to:

Public Works

HSA

Integrated Waste Management Local Task Force

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ORDINANCE ADDING CHAPTER 7.95 TO THE SANTA CRUZ COUNTY CODE REQUIRING THE SAFE DISPOSAL OF DRUGS AND SHARPS

The Board of Supervisors of the County of Santa Cruz hereby finds and declares the following:

WHEREAS, drugs and sharps are necessary medical technologies which allow us to live longer, healthier and more productive lives and reduce suffering at the end of life;

WHEREAS, the public, particularly children, the elderly and public employees, are at significant and unnecessary risk of poisoning and injury due to improper or careless disposal of drugs and sharps;

WHEREAS, our groundwater and drinking water are being contaminated by unwanted, leftover or expired drugs passing through our wastewater treatment centers;

WHEREAS, there is no mandatory statewide stewardship program for unwanted drugs or sharps in California, and manufacturers and producers have not offered any support for a permanent collection program to date;

WHEREAS, consumers dispose of more than 3 billion used needles and syringes and 900 million lancets each year in the United States;

WHEREAS, although state law (Health and Safety Code Section 118286) now requires consumers to dispose of sharps in sharps containers or other containers authorized by the local enforcement agency, and prohibits the loose disposal of sharps, many people continue to dispose of contaminated sharps in a manner that increases the risk that others will come into contact with them;

WHEREAS, in Santa Cruz County, volunteers collect more than 3,000 sharps a year from local beaches, rivers, parks and streets;

WHEREAS, according to the Centers for Disease Control and Prevention (CDC), nearly 50 percent of Americans take one prescription drug. Among adults age 65 and older, more than half take at least two prescription drugs, and two in five take five or more prescription drugs. The CDC also found that health care providers in the United States wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of these pills;

WHEREAS, the lack of sufficient safe, convenient disposal locations for unwanted drugs creates significant risks to human health and to the environment. As a result, unwanted drugs are often left in homes where they can be accidentally ingested or abused by children, adults, and the elderly, increasing the risk of poisoning, addiction, and death;

WHEREAS, each year, more than 9,000 young children are hospitalized after accidentally ingesting prescription drugs. And drug overdose deaths have been rising steadily over the past two decades. Nearly nine out of 10 poisoning deaths are caused by drugs. In 2011, 80 percent of the 41,340 drug overdose deaths in the United States were unintentional;

WHEREAS, unwanted drugs are also often flushed down toilets or sinks. But municipal wastewater treatment plants are not designed to remove the complex compounds in the drugs that end up in the sewer system. As a result, drugs can pass through wastewater treatment systems and contaminate receiving waters;

WHEREAS, an Environmental Protection Agency report on drinking water released in December 2013 tested effluent samples from 50 large wastewater treatment plants for active pharmaceutical ingredients and metabolites. Out of the 63 total compounds tested for, 43 were detected in at least one of the samples and all samples were found to contain at least one pharmaceutical compound. The presence of pharmaceuticals in surface water is well documented to have ecological impacts, including negative effects on fish and other aquatic life;

WHEREAS, establishing a safe, convenient collection system for unwanted drugs will reduce unintentional poisonings and drug overdose deaths by making drugs less accessible to persons who might accidentally ingest them;

WHEREAS, establishing such a system will also reduce the number of people who misuse and become addicted to prescription drugs. Results from the 2013 National Survey on Drug Use and Health indicate that about 15.3 million people aged 12 or older used prescription drugs non-medically in the past year, and 6.5 million did so in the past month. Seventy percent of those addicted to prescription drugs say they first accessed drugs from friends and family;

WHEREAS, establishing such a system will reduce the quantity of pharmaceutical compounds that are discharged into the Monterey Bay National Marine Sanctuary and other environmentally sensitive waters throughout the County;

WHEREAS, by 2020, California Assembly Bill No. 341 requires diversion of 75% of waste that would otherwise go to landfills statewide. Local jurisdictions are responsible for increasing diversion of solid waste, including pharmaceutical waste;

WHEREAS, extended Producer Responsibility (EPR) laws, sometimes referred to as Product Stewardship laws, place responsibility for end-of-life management of consumer products on the manufacturers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle;

WHEREAS, in 2010, Congress passed the "Secure and Responsible Drug Disposal Act of 2010," Public Law No. 111-273, which authorized the Attorney General to expand the methods through which pharmaceuticals classified as controlled substances may be collected, including through collection at pharmacies. The goal of the bill was to increase opportunities for drug collection in order to reduce substance abuse, accidental poisoning, and the release of harmful substances into the environment. On October 9, 2014, the Drug Enforcement Agency promulgated regulations implementing the bill. These regulations authorize retail pharmacies to maintain secure collection bins for controlled substances;

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WHEREAS, Mexico, a number of Canadian provinces, much of Europe and several other countries already have active, well-established EPR drug disposal programs in place. British Columbia has had a manufacturer-funded drug collection program in place since 1996. Ontario began a program in July 2010. And Manitoba began its program in April2011. France, Spain, and Portugal, among other countries, have national collection programs, which are paid for by drug companies and operated by product stewardship associations on their behalf. Many of the same drug companies that participate in these programs manufacture drugs sold in the United States;

WHEREAS, in 2012, Alameda County became the first local government in the United States to pass legislation requiring pharmaceutical companies to design, fund, and operate a program to safely collect and dispose of unwanted drugs, similar to the take-back programs in Canada's pharmacies. On September 30, 2014, the Ninth Circuit Court of Appeal rejected a legal challenge to Alameda County's ordinance brought by pharmaceutical trade associations. *Pharm. Research & lvlfrs. Of Am. v. Cty. of Alameda*, 13~16833, 768 F.3d1037 (9th Cir. 2014). The U.S. Supreme Court subsequently declined to hear an appeal of this ruling;

WHEREAS, King County, Washington as well as the City and County of San Francisco and the Counties of San Mateo, Santa Clara, San Luis Obispo and Marin have subsequently enacted similar ordinances requiring drug manufacturers to design, fund, and operate programs to safely collect and dispose of local residents' unwanted drugs and/or sharps. Other Counties including Los Angeles and Santa Barbara have begun the process;

WHEREAS, there is considerable demand in Santa Cruz County for a permanent drug and sharps stewardship program. Beginning in 2008, the County has operated a voluntary County-funded collection program. As of October 23, 2015, this program consists of 46 locations at pharmacies, police departments, sheriff's stations, which collect both controlled and non-controlled substances, as well as city and county household hazardous waste disposal sites;

WHEREAS, on August 5, 2014, the Santa Cruz County Board of Supervisors passed an ordinance requiring the establishment of a sharps waste management program by all businesses selling or dispensing sharps within the unincorporated County. Participation in collection and disposal of unwanted drugs is still voluntary, resulting in a patchwork of businesses participating in one or both programs, leading to confusion among consumers and sometimes improper disposal in the wrong containers;

WHEREAS, a manufacturer-funded collection and disposal program for unwanted drugs and sharps would significantly increase convenient disposal options for County residents' unwanted drugs, enabling collection of larger quantities of unwanted drugs and reducing risks to public safety, health, and the environment.

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

SECTION I

The Santa Cruz County Code is hereby amended by adding Chapter 7.95 to read as follows:

Chapter 7.95 SANTA CRUZ COUNTY SAFE DRUG AND SHARPS DISPOSAL

7.95.010 – Purpose and Intent.

7.95.020 - Title

7.95.030 – Definitions.

7.95.040 - Product Stewardship Program.

7.95.050 - Product Stewardship Plan.

7.95.060 - Disposal of Unwanted Products.

7.95.070 - Product Stewardship Program Promotion and Outreach.

7.95.075 – Retailer Participation.

7.95.080 – Reporting.

7.95.085 - Program Assessment and Collection of Data.

7.95.090 - List of Producers.

7.95.100 - Regulations and Fees.

7.95.110 - Enforcement.

7.95.120 – Additional Provisions.

7.95.010 - Purpose and Intent.

The purpose of this chapter is to protect the health, safety and welfare of the public and of the environment by providing for the safe and orderly collection and disposal of drug and sharps waste; and by placing responsibility for end-of-life management of drug and sharps products on the manufacturers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle.

7.95.020 - Title.

This chapter may be cited as the "Santa Cruz County Safe Drug and Sharps Disposal Ordinance."

7.95.030 - Definitions.

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

- A. "Board of Supervisors" refers to the Board of Supervisors of the County of Santa Cruz.
- B. "Consumer Generators" means residents of single and multiple family residences or other locations who possess, dispose of or abandon household drugs or sharps. "Consumer generators" does not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonconsumer source.
- C. "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.

- D. "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.
- E. "Covered Drug" means all drugs as defined in 21 U.S.C. Section 321 (g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. Section 353(b)(1) of the FFDCA, including both brand name and Generic Drugs, and Nonprescription Drugs.
- F. "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. Section 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. Section 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.
- G. "County" means the County of Santa Cruz, California.
- H. "Department" means the Santa Cruz County Department of Public Works.
- I. "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.
- J. "Entity" means a Person other than an individual.
- K. "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.
- L. "Hazardous Waste" means pharmaceutical waste that falls under the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 USCA Sec. 6901 et seq.). This waste includes bulk chemotherapy drugs, P-listed waste, U-listed waste and characteristic hazardous waste.
- M. "Manufacture" means the production, preparation, propagation, compounding, or processing of Drugs or Sharps but does not include the activities of a repackager, wholesaler or medical practitioner.
- N. "Manufacturer" means a Person, company, corporation or other Entity engaged in the manufacture of Drugs or Sharps.
- O. "Mail-back Program" means a system whereby Consumer 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.

- P. "Medical Waste" means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended; Sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of homegenerated Sharps; and waste generated in the cleanup of trauma scenes.
- Q. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.
- R. "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.
- S. "Pharmacy" means a place licensed by the State of California Board of Pharmacy where the practice of pharmacy is conducted.
- T. "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.
- U. "Plan Operator" means the Person, Company or Organization that develops, implements and operates a Product Stewardship Plan, including but not limited to a Producer or Stewardship Organization.
- V. "Prescription Drug" means any Drug that by federal or state law may be dispensed lawfully only on prescription.
- X. "Producer" shall be determined, with regard to Covered Drugs and Sharps that are sold, offered for sale, or distributed in Santa Cruz County as meaning one of the following:
 - 1. The Person who Manufactures Covered Drugs or Sharps and who sells, offers for sale, or distributes Covered Drugs or Sharps in Santa Cruz County under that Person's own name or brand.
 - 2. If there is no Person who sells, offers for sale, or distributes Covered Drugs or Sharps in Santa Cruz County under the Person's own name or brand, the Producer of Covered Drugs or Sharps is the owner or licensee of a trademark or brand under which the Covered Drugs or Sharps are sold or distributed in Santa Cruz County, whether or not the trademark is registered.
 - 3. If there is no Person who is a Producer of Covered Drugs or Sharps for purposes of paragraphs (1) and (2), the Producer of Covered Drugs or Sharps is the Person who brings the Covered Drug into Santa Cruz 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.
- Z. "Product Stewardship Program" or "Program" means a program financed and operated by Producers to collect, transport, and dispose of Unwanted Products.

- AA."Provider" means any Person that sells or otherwise furnishes Drugs or Sharps to consumers at a medical or veterinary office, clinic, hospital or approved needle-exchange program located in the unincorporated area of the County.
- BB. "Public Hearing" means any hearing held by the Department or the County which is open to the public for the purposes of collecting public comment. It does not necessarily refer to meetings of the Board of Supervisors.
- CC. "Retailer" means any Person that sells Drugs or Sharps directly to consumers at a business located in the unincorporated area of the County.
- DD. "Sharps" means one or more hypodermic needles, pen needles, intravenous needles, lancets and other devices used to penetrate the skin for drawing blood, or for the delivery of medications or Drugs.
- EE. "State" means the State of California.
- FF. "Unicorporated County" means the unicorporated portions of the County of Santa Cruz.
- GG. "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.
- HH."Unwanted Products" means Covered Drugs or Sharps no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

7.95.040 - Product Stewardship Program.

- A. Requirement for Sale. This chapter shall apply only to Producers whose Covered Drugs or Sharps are sold or distributed in Santa Cruz County and to Retailers who sell Covered Drugs or Sharps in Santa Cruz County. This chapter shall be administered and implemented by the Department:
 - 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.
 - 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 Consumer 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 and expenses associated with obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code Section 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 Consumer Generators or delivered for disposal.
 - 4. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the County, including but not limited to the Department, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the County shall only recover its actual costs of administration and enforcement under this chapter and shall not charge any amounts under this chapter in excess of its actual administrative and enforcement costs.

5. A Producer, group of Producers, or Stewardship Organization must pay all collection and disposal costs as of the date that this Ordinance becomes effective. If the County incurs any costs due to delays in establishment of an approved Stewardship Plan, the Producer, Group of Producers, or Stewardship Organization must reimburse the County in full for such costs.

7.95.050 - 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 Consumer Generators will be collected at all retail sale facilities of Sharps and Drugs in Unincorporated County, including a description of bins to be used and collection methods.
 - 4. A description of the methods by which Unwanted Products from Consumer Generators will be collected at all public health facilities in Unincorporated County, as well as at such other locations as designated by the Department, including a description of bins to be used and collection methods.
 - 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 Waste 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 and Sharps that are sold in the Unincorporated County, 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 Santa Cruz 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.

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12. 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 Unincorporated County.

B. Department Review and Approval—Updates.

- 1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with this chapter until it has received written approval of its Product Stewardship Plan from the Department. The County may continue collection on an interim basis if there is any delay in establishing a Stewardship Program as required.
- 2. Product Stewardship Plans must be submitted to the Department for approval. The initial Plans must be submitted by March 1, 2016, or at a later date as approved in writing by the Department.
- 3. Within sixty (60) days after receipt and review of a Product Stewardship Plan, the Department will determine whether the Plan complies with the requirements of this chapter and of any regulations adopted pursuant to this chapter. The Department may at its sole discretion conduct a noticed Public Hearing as part of this process.
 - 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 thirty (30) days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, at 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 chapter. The imposed Plan will be presented at a Public Hearing. The Department is not required, and nothing in this chapter 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 shall be 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 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 or Sharps for sale in the County of Santa Cruz after March 1, 2016, must submit a Product Stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within sixty (60) 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.

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7. Required Plan Amendment. Within 60 days of the final promulgation of rules by the California Board of Pharmacy regarding collection of controlled substances by retail pharmacies in conformity with the U.S. Drug Enforcement Agency regulations resulting from the Secure and Responsible Drug Disposal Act of 2010, each Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall submit to the Department for review and approval an update to its Product Stewardship Plan that describes how the Plan will, within 120 days, include collection of Controlled Substances at all collection locations on the premises of Retailers and Providers of Covered Drugs.

7.95.060 - 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 treatment and disposal of Unwanted Products.
- B. Treatment and Disposal. Each Product Stewardship Program must treat Sharps waste by high heat sterilization and dispose of all unwanted Covered Drugs by incineration at a Medical Waste or Hazardous Waste facility. Each treatment or disposal facility utilized must be in possession of all required regulatory permits and licenses.
- C. New Technologies. Producers with Product Stewardship Programs may petition the Department for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current Medical Waste disposal technologies for Sharps and 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 Consumer Generators to separate Unwanted Products from their original containers and packaging, when appropriate, prior to collection or disposal.

7.95.070 - Product stewardship program promotion and outreach.

- A. A Product Stewardship Program must promote the Program to Consumer Generators, pharmacists, Retailers of Covered Drugs and Sharps, 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 for use by Retailers of Covered Drugs and Sharps. These materials may include, but are not limited to, two 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.

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C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Santa Cruz 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 Consumer Generators can call to find nearby collection locations and understand how the program works.

7.95.075 – Retailer participation

- A. Every Retailer and every Provider of Covered Drugs and Sharps in the Unincorporated County shall establish a system consistent with the requirements of this chapter for the collection of consumer-generated Covered Drugs and Sharps waste for proper disposal during the Retailer's or Provider's normal hours of operation, except that:
 - 1. A Retailer or Provider who does not sell or provide Sharps to consumers is not required to establish a collection system for Sharps waste; and
 - 2. A Retailer or Provider who does not sell or provide Covered Drugs to consumers is not required to establish a collection system for Covered Drugs waste.
- B. Each system established by a Retailer or Provider for the collection and disposal of consumer generated Covered Drugs and Sharps waste shall include, at a minimum, the following elements:
 - 1. Each Retailer or Provider shall provide one of the following:
 - a) On-site collection system. Receptacles for the collection of consumer-generated Covered Drugs and Sharps waste within the Retailer or Provider establishment. The receptacle shall meet applicable state and federal standards for safe disposal of Drugs or Sharps. The Retailer or Provider shall provide for the management and disposal of all consumer-generated Covered Drugs and Sharps waste that is collected at the Retailer or Provider establishment in a safe manner consistent with all state and federal laws and regulations; or
 - b) Mailback collection system. Prepaid mailback envelopes in sufficient capacity for safe disposal of Drugs or Sharps waste, as required by a consumer.
 - 2. Signage prominently displayed within five feet of every public entrance to the Retailer or Provider establishment and easily visible to the consumer, indicating that the Retailer or Provider establishment collects consumer-generated Covered Drugs and/or Sharps waste from consumers.
- C. A Retailer or Provider of Sharps must provide at no additional cost to the consumer an approved Sharps disposal container or containers sufficient to dispose of all Sharps purchased. A Retailer or Provider of Sharps may refuse to accept from a consumer Sharps waste that is not properly contained in an approved container. In the event of a refusal to accept Sharps waste, the Retailer or Provider shall provide the consumer with an appropriate container for proper disposal of said Sharps waste.
- D. Sharps disposal containers shall be either a rigid puncture-resistant container with a sealable lid approved by the U.S. Food and Drug Administration for the purpose of transporting Sharps for disposal or a pre-paid mailback container approved by the U.S. Food and Drug Administration for the purpose of transporting Sharps for disposal.
- E. All costs of participation by Retailers and Providers shall be paid or reimbursed by the Producer, group of Producers, or Stewardship Organization as part of its Program as provided in this chapter. Retailers and Providers shall not be expected to incur any costs for participation.

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7.95.080 - Reporting.

- A. On or before July 1, 2017 (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 activities during the previous reporting period. The report must include, at minimum, the following:
 - 1. A list of Producers participating in the Product Stewardship Program;
 - 2. The amount, by type and by weight, of Unwanted Products collected from Consumer Generators collected at each drop-off site and in the entire County of Santa Cruz and, if applicable, the total amount by type and 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 by type of Unwanted Products collected from Consumer 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 and their effectiveness, 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.

7.95.085 - Program Assessment and Collection of Data

- A. At least once per year, at a time to be determined by the Department, each Product Stewardship Program will conduct a detailed characterization study of Unwanted Products collected at specified locations to help assess effectiveness of the Product Stewardship Program.
- B. Assessments shall be conducted in a secure location with proper supervision, in full compliance with federal and state laws and regulations, and in accordance with guidelines issued by the Department.
- C. Data collected from Program assessments shall be shared with the Department and other relevant agencies in a timely manner.
- D. The Department may require additional assessments as needed to address problems or to help determine Program needs.

7.95.090 - 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.

7.95.100 - Regulations and fees.

- A. The Director of the Department of Public Works 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 Producers to cover the County's costs of administering and enforcing this chapter.

7.95.110 - Enforcement.

- A. The Department shall administer the penalty provisions of this chapter.
- B. The Department may issue an administrative citation to a Producer, Plan Operator or Product Stewardship Organization for violation of this chapter or any regulation adopted pursuant to this chapter. The Department shall first send a written warning to the Producer, Plan Operator or Product Stewardship Organization as well as a copy of this chapter and any regulations adopted pursuant to this chapter. The Producer, Plan Operator or Product Stewardship Organization shall have thirty (30) days after receipt of the warning to comply and correct any violations.
- C. If the Producer, Plan Operator or Product Stewardship Organization 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 for a civil penalty in an amount not to exceed one thousand dollars (\$1,000.00) 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 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, Plan Operator or Product Stewardship Organization receiving an administrative citation under this chapter or any regulation adopted pursuant to this chapter may appeal it within twenty-one (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 twenty-one (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. Written notice of the time and place for the hearing will be served by first class mail or personal service at least twenty-one (21) days prior to the date of the hearing to the Producer, Plan Operator or Product Stewardship Organization appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.
- H. Failure of any Producer, Plan Operator or Product Stewardship Organization to file an appeal in accordance with the provisions of this section shall constitute waiver of that Producer's, Plan Operator's or Product Stewardship Organization'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, Plan Operator or Product Stewardship Organization requesting the appeal may request the Director of the Department 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.
- J. The Department may establish appropriate administrative rules for implementing this chapter, conducting hearings, and rendering decisions pursuant to this section.
- K. 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 Santa Cruz 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 or Entity 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 the Unincorporated County.
- L. 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 Santa Cruz 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 (\$50.00) and not more than five hundred (\$500.00) for each day per violation, or by imprisonment for a period not to exceed six months, or by both such fine and imprisonment.

0271

7.95.120 - Additional provisions.

- A. Disclaimer. In adopting and implementing this chapter, the County 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 chapter 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.
- E. Nothing in this chapter, or the Program of Stewardship in which Manufacturers of Sharps and Pharmaceutical products who sell Sharps and Drugs in the Unincorporated County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this chapter be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State or of the United States.
- F. This chapter shall be construed in accordance with State law, including but not limited to the Medical Waste Management Act set forth at California Health and Safety Code Section 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. Environmental Findings. This chapter is entitled to a categorical exemption of the California Environmental Quality Act ("CEQA") pursuant to 14 California Code of Regulations sections 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.

0272

SECTION II

This ordinance shall take effect on the 31st day after the date of final passage.

PASSED AND ADOPTED this eighth day of December, 2015, by the Board of Supervisors of the County of Santa Cruz by the following vote:

AYES:

SUPERVISORS:

NOES:

SUPERVISORS:

ABSENT:

SUPERVISORS:

ABSTAIN:

SUPERVISORS:

Attest:

Clerk of the Board

APPROVED AS TO FORM:

Office of County Counsel
T. Brooke Miller

bl safedrugandsharpsyv.doc



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OCT 29 2015

BOARD OF SUPERVISORS COUNTY OF SANTA CRUZ

October 22, 2015

The Honorable Members of the Board of Supervisors County of Santa Cruz 701 Ocean Street Santa Cruz, CA 95060

RE: Ordinance Requiring Manufacturers and Producers of Prescription and

Nonprescription Drugs and Sharps to Develop Product Stewardship Take-Back Programs to Collect and Dispose of Unused/Unwanted Pharmaceutical and Sharps Waste

Members of the Board,

On behalf of the Central Water District I want to offer support for the recommendation of Supervisors Leopold and Coonerty regarding the drafting of an ordinance that requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship programs. The District is also in support of the process outlined by the Supervisors to engage stakeholders to gain feedback on the ordinance.

The District sees this as a critical health and public safety issue and appreciates the time and effort of the County of Santa Cruz officials and staff spent on addressing this concern.

Sincerely

Ralph Bracamonte District Manager

CENTRAL WATER DISTRICT 400 Cox Road P.O. Box 1869 Aptos, California 95001-1869 831-688-2767 (telephone) 831-688-2774 (fax) cenwtr@yahoo.com

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Thursday, November 05, 2015 5:34 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Nancy B. Macy

Email: nbbm@cruzio.com

Address: 15485 Bear Creek Rd.,

Boulder Creek, CA 95006

Phone: 831-338-6578

Comments:

As former Director of the SLV Redemption/Recycling Centers, and current Co-chair of the Valley Women's Club's Environmental Committee, I strongly support this ordinance. Sharps have appeared a the recycling centers in the past, posing a safety hazard. Also, over the 29 years of the annual River & Road Clean-up, there have been far too many run-ins with sharps by those picking up debris along the road and in the waterways. Having drop-off point locally, like Boulder Creek Drugs, has helped, but it doesn't go far enough. Veterinarians subscribe medications needing sharps and should be included in the ordinance. Kudos to the staff in Public Works for their efforts in behalf of public safety.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 9:19 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Hollie Locatelli

Email: hloco@aol.com

Address: 629 Miramar Dr

Phone: 831-426-5567

Santa Cruz, Ca 95060

Comments:

I am in favor of having pharmacies provide disposal of medicine including sharps and required reporting to the public.

I would also like to have the number of illegally disposed sharps found by city/county workers and private citizens tracked and reported in order to truly measure the success of our disposal/collection efforts. Too many are still being found in public spaces. (11 sharps found by the levee this month by Santa Cruz Waste Water Maintenance Workers).

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 8:56 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Don Honda

Email: Not Supplied

Address: Not Supplied

Phone: Not Supplied

Comments:

This would seem a no-brainer. Please advocate for businesses in unincorporated sections of Santa Cruz County who sell Rx Drugs to be responsible and take back used sharps and no longer needed medications. This is a must to keep them out of our environment, waterways while preventing a public health hazard.

Thank you.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 8:39 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Gabrielle Korte

Email: Not Supplied

Address: Not Supplied

Phone: Not Supplied

Comments:

I am writing to express my support for the drug & sharps pharmacy "take-back" ordinance. I have had the frustrating experience of trying to figure out how to dispose of my son's unused epi-pens. It makes sense to require the pharmacy that sold them to us also be responsible for their disposal. Thank you.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 8:23 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Diogenes Arnold Jasso

Email: Not Supplied

Address: Not Supplied

Phone: Not Supplied

Comments:

I find this ordinance as nothing but helpful towards the community. Those that sell these 'sharps' and meds should take responsibility for what they continue to profit off of.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 11:33 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Kate Williams

Email: krgarton@gmail.com

Address: 117 May Ave Santa Cruz, CA 95062

Phone: 717-880-0008

Comments:

Passing this will help keep our children safe, our waterways straight, and dirty needles off of our streets.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 12:59 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Jessica Conner

Email: Not Supplied

Address: Not Supplied

Phone: Not Supplied

Comments:

I am 24, my boyfriend and I are planning to get married next year and hope to start a family right away, and I want to be raising my children in the type of Santa Cruz I was raised in. I don't feel as safe in my town as I once did, I don't want my children to feel the same way I do.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 1:24 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type : County Board of Supervisors

Item Number: 39.00

Name: David Giannini

Email: giannini.david@hotmail.com

Address: 412 Stanford

Phone: 8314589147

Ave.

Santa Cruz CA 95062

Comments:

I am in favor of an official county policy on the safe disposal of prescription drugs and hazardous medical waste (used sharps). I also favor more transparency in accounting for the number and locations of publicly discarded used sharps.



From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 1:39 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: James Burtnett

Email:

jamesburtnett@ymail.com

Address: 12655 Flat Street Unit B

Boulder Creek, Ca. 95006

Phone: 831-227-8105

Comments:

I am in favor of the ordinance.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 3:20 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board

of Supervisors

Item Number: 39.00

Name: Barry Kane

Email: sfobayguy@gmail.com

Address: 1780 46th Ave

Phone: 8315157220

Comments:

I strongly urge passage of this item (#39) to prevent unused prescription drugs from: ending up in children's hands, disposed of improperly, including into our sewage systems and waterways. Improperly disposed of sharps waste creates a hazard for the public and sanitation workers. By creating a disposal system for drugs and sharps waste, this ordinance will help improve public safety and the environment. Its a win win for everyone! Thank you so much for looking into this, its a great idea!

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 6:11 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board

of Supervisors

Item Number: 39.00

Name: Tom Abbott

Email: imaham@prodigy.net

Address: 1315 Hames Road

Aptos, 95003

Phone: 408-489-1389

Comments:

I would ask that the board strongly endorse this ordinance. It is no secret that we are continuing to see more and more needles and other drug items left on our streets and other property and I would hope that providing more places to dispose of these items would reduce public exposure to these items. I am not naive enough to think that this will be some kind of panacea to the problem but at this point I would support anything that would help. It is a good place to start.

Thank you

39

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Monday, November 09, 2015 6:46 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: David Zeltser and Dr. Fiona

Dulbecco

Email: Not Supplied

Address: 114 Phelan Court

Santa Cruz, CA 95060

Phone: Not Supplied

Comments:

We are writing in strong support the Santa Cruz County Safe Drug & Sharps Disposal Ordinance. Please pass this important law to protect our community.

David Zeltser and Dr. Fiona Dulbecco

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Sunday, November 08, 2015 11:41 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board of

Supervisors

Item Number: 39.00

Name: Mark S. Wilson

Email: Not Supplied

Address: 1731 Foster Court

Santa Cruz, CA 95062

Phone: Not Supplied

Comments:

This ordinance starts with some good WHEREAS's but the most important WHEREAS is that the Cnty has operated a voluntary County funded collection program for over 8 years. Our program just needs a cash flow from prescription, OTC, and sharps producers to help offset costs.

Our program does not need producers to operate or producers to pay a stewardship organization to act as their agent. Our county has done a terrific job and will continue to do so without their help.

A cash flow from prescription producers can be collected in a fair & reasonable manner. It starts with requesting the CA DOJ to allow our county to extract/share data from CURES (a PDMP prescription drug monitoring program), pursuant to Health & Safety Code section 11165(c)(2), CURES data is available to appropriate state, local, and federal public agencies, law enforcement, and regulatory boards for disciplinary, civil, or criminal purposes. The Department of Justice (DOJ) may also provide data to other agencies and entities for educational, peer review, statistical, or research purposes, provided that patient identity information is not disclosed. So it possible that our local ordinance can request to share CURES data. Requesting just a sorted list of drug NDC's tied to our county zip codes identifies how many prescriptions each producer's products were dispensed to county residents over a period of time. Multiply each producer's total by a prescription stewardship fee (a few cents for each prescription), send the bill to the producer, and you have established a partial cash flow.

To capture data from mail order pharmacy that arrives in Santa Cruz County, the next step would be to request data sharing from other states PDMP's where large PBM's like Express Scripts, CVS Caremark, Medco, Catalyst, Argus, Restat, MEdimpact & Envision have large mail order

service centers. Again, just requesting the NDC's with a Santa Cruz county destination for the same purpose of collecting a prescription stewardship fee.

There are no OTC monitoring programs like CURES for OTC meds. Perhaps, our county could apply for a grant to develop one. It would be based on point of sale scanning of OTC bar codes. The bar code identifies the OTC's NDC or UPC. Scanning at the register is how retailers track sales of an item over a period of time. Retailers would submit their sales reports to a monitoring program for the purpose of collecting the number of certain UPC's and NDC's sold. The number of each producer's sales would be multiplied by a stewardship fee and again, you have established a fair and reasonable cash flow from OTC sales.

There are a lot less sharps producers than prescription and OTC producers. The ordinance is requesting that sharps containers be provided by sharps producers at no charge which I feel they will work directly with our county and be obliged to do so in the spirit of stewardship. Sharp producers will also contribute to offset the cost to properly dispose of sharps.

As to other suggestions related to the Santa Cruz County Safe Disposal of Meds and Sharps, home generators of meds and sharps need to better understand what needs to be properly disposed of and what is just garbage. Too often, the entire bathroom cabinet and vanity are emptied and thrown into a bag or box and brought to a participating facility for disposal. Also size and weight can be significantly reduced if prescriptions vials, containers and other packaging was recycled and just the drugs were returned for proper disposal

Lastly, the problem of littered used syringes by injection drug users needs to be better handled by pharmacies who sell syringes to injection drug users and to the needle exchange staff. Diabetics are very conscientious about proper disposal of their syringes and every year, more diabetics are switching from syringe dependent insulin vials to pen needle dependent insulin pens.

From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Monday, November 09, 2015 8:52 AM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date:

11/10/2015

Meeting Type: County Board of Supervisors

Item Number: 39.00

Name: Katherine O'Dea

Email: katherine@saveourshores.org

Address: Save Our

Shores

345 Lake Avenue

Santa Cruz, CA 95062

Phone: 831 462 5660

Comments:

Speaking for the organization, Save Our Shores, I would like to express support for the Safe Disposal of Drugs and Sharps and the inclusion of over-the-counter medicines. Keeping pharmaceuticals and OTC drugs our of our National Sanctuary and sharps off our shores and watershed areas is essential to the health of our natural ecosystem/resources and the safety of everyone living or visiting our beautiful community.



From:

cbdbosmail@co.santa-cruz.ca.us

Sent:

Monday, November 09, 2015 2:35 PM

To:

CBD BOSMAIL

Subject:

Agenda Comments

Meeting Date: 11/10/2015

Meeting Type: County Board

of Supervisors

Item Number: 39.00

Name: Andria Ventura

Email: aventura@cleanwater.org

Address: Clean Water Action/Clean Water Fund 350 Frank H. Ogawa Plaza, Suite 200, Oakland, CA 94612 **Phone:** 415.369.9166

Comments:

Dear Supervisors:

On behalf of our combined organizations and our county constituents, we commend the Santa Cruz Board of Supervisors' leadership on the issues of household drug waste and proper disposal of sharps. We support a model, which the Board is now considering, that requires pharmaceutical and sharps manufacturers to develop, implement, and fund safe and convenient programs for the disposal of their products at the end of their useful lives. Such industry supported programs will keep tons of pharmaceutical waste out of our waterways each year, reduce inappropriate access to drug products, protect waste workers from the dangers of being stuck by used needles, and help protect both public and environmental health.

Pharmaceutical Waste

Pharmaceutical chemicals are regulated because of their impacts on humans and other living organisms. They do not belong in our waterways, yet depression, anti-anxiety, anti-epileptic, tranquilizing, and other types of drugs are being detected in the state's drinking water sources and aquatic habitats. Pharmaceuticals have been found, for example, in the Colorado River which is a drinking water source for 3 states. Nor is the problem specific to prescription medications. Since over the counter drugs are the most commonly used medications, they are also detected in the highest quantities, which is why it is important to prevent their improper disposal. Ibuprofen is, for instance, one of the most widely detected medications in water.

One cause of pharmaceutical pollution is the improper disposal, either down the drain or in the trash, of household medications. Wastewater treatment plants are not meant to address complex chemicals, and some pharmaceuticals can get through the system and end up in water sources and even in treated drinking water. When drugs are thrown in the trash, pharmaceutical chemicals can end up in landfill effluent. That effluent can either leach into groundwater or are siphoned off and put through the wastewater treatment process, with the same result as flushing.

The known environmental effects of pharmaceuticals are sobering. Reproductive failure in aquatic species due to changes to sex organs, endocrine disruption, sex reversal, and impaired eggs and sperm density can be linked to synthetic estrogens in oral contraceptives. Antidepressants and anti-anxiety drugs at levels found in water can reduce sociability, reduce reaction to predators, and alter foraging habits. Some drugs bioaccumulate up the food chain, potentially impacting species that humans eat.

While human exposure to drugs through drinking water or eating contaminated food are generally below therapeutic levels, the ultimate effect of continued long-term exposure to chemical mixtures, the development of antibiotic resistant bacteria, and the impacts on vulnerable populations such as fetuses and infants are poorly understood. Studies that show how exposure to small amounts of various drugs can effect embryonic kidney cells, as well as blood and breast cancer cells, demonstrate the need to take action now to reduce the medications entering water resources, before rising rates of pollution cause serious public health problems.

Without proper disposal options, people often stockpile medications in their homes. This has been linked to greater access by teens and the elderly and a rise in accidental poisonings. While part of this problem is due to improper prescribing practices, the Office of National Drug Control Policy has stated that developing "convenient and environmentally responsible prescription drug disposal programs to help decrease the supply of unused prescription drugs in the home" is an essential strategy in reducing prescription drug abuse. In other cases, elderly patients are mistakenly taking out of date or no longer appropriate medications which they find in their homes because they weren't disposed of. In less than ten years, Alameda County saw a 43 percent jump in drug related hospitalizations of the elderly.

Sharps

Disposal of needles and other medical sharps in the trash or down the toilet has been illegal in California since 2008, but the law left it up to local communities to figure out disposal solutions. Without adequately accessible and affordable options, many people do dispose of them improperly with serious consequences. Flushing can block or do other damage to sewage treatment systems and pollute waterways when they get through the system. More chilling is the track record of needle sticks

to sanitation and wastewater workers. Needle-stick injuries occur even through protective shoes and gloves, requiring immediate medical care because of the alarming threat of infection and the need for immediate medical care.

Santa Cruz County's pilot program currently collects about 1,000 pounds of pharmaceutical waste per month (63,000 pounds since the program's inception), as well as sharps. While this represents a significant record of pollution prevention and public health protection, the Board has recognized the programs are not accessible to all county residents. EPR is a sustainable way to make such programs more successful and permanent and more successful. What's more, it is a fair model. Local communities and some retailers have provided collection sites and education and the public has demonstrated the willingness and desire to bring toxic products for proper disposal. It is time for those who profit from the sales of medications and sharps to take responsibility for the products that provide them with those profits.

Pharmaceutical companies support collection programs in other nations, including Mexico, despite the fact that consumers often pay a much smaller percentage of their income on medications than do U.S. residents. This has proven to be both a beneficial public service and a cost effective strategy. When companies work together, the cost is so low (usually pennies per returned medication) they have not raised drug prices.

Our local constituents support an EPR model to keep pharmaceuticals and sharps out of our environment and the hands of those who may abuse them. Again, we thank the Board for its leadership on this important issue and look forward to what we hope are industry implemented and supported disposal programs.

Sincerely,

Andria Ventura, Toxics Program Manager Clean Water Action

