

DRAFT

Ord. No. _____

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 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 – Declaration of findings.**
- 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 – Product Stewardship Program 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 – Declaration of findings.

The Board of Supervisors hereby finds and declares the following:

- A. Drugs and sharps are necessary medical technologies which allow us to live longer, healthier and more productive lives;
- B. 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;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired drugs passing through our wastewater treatment centers;

- D. 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;
- E. Consumers dispose of more than 3 billion used needles and syringes and 900 million lancets each year in the United States;
- F. 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;
- G. In Santa Cruz County, volunteers collect more than 3,000 sharps a year from local beaches, rivers, parks and streets;
- H. 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.
- I. 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.
- J. 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.
- K. 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.
- L. 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.
- M. 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.
- N. 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.
- O. 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.
 - P. 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.
 - Q. 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.
 - R. 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.
 - S. 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 April 2011. 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.
 - T. 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 & Mfgs. Assn. v. Cty. of Alameda*, 13-16833, 768 F.3d 1037 (9th Cir. 2014). The U.S. Supreme Court subsequently declined to hear an appeal of this ruling.
 - U. 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.
 - V. There is considerable demand in Santa Cruz County for a permanent drug and sharps stewardship program. Beginning in 2008, the County operated a voluntary County-

funded program. As of May 19, 2015, this program consists of 39 secure drop box locations at County pharmacies, police departments and sheriff stations, which collect both controlled and non-controlled substances, as well as city and county household hazardous waste disposal sites.

- W. 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.
- X. 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.

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.

- a) "Board" refers to the Board of Supervisors of the County of Santa Cruz.
- b) "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.
- c) "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.
- d) "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.
- e) "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; (vi) pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems; and (vii) nonprescription drugs.
- f) "County" means the County of Santa Cruz, California.

- g) "Department" means the Santa Cruz County Department of Public Works.
- h) "Drug Wholesaler" means a business that sells or distributes drugs and covered drugs for resale to an entity other than a consumer.
- 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, or a covered drug contained in or on medical devices or 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 of 1976 (Public Law 94-580), 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 home-generated 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 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.
- s) "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.
- t) "Product Stewardship Program" or "program" means a program financed and operated by producers to collect, transport, and dispose of unwanted products.
- u) "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.
- v) "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.
- w) "Consumer Generators" means single and multiple family residences and locations where household drugs or sharps are unused, unwanted, disposed of, or abandoned. "Consumer 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 nonconsumer source.
- x) "Retailer" means any person that sells drugs or sharps directly to consumers at a business located in the unincorporated area of the county.
- y) "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.
- z) "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.
- aa) "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 apply only to the unincorporated areas of Santa Cruz County. This chapter shall be administered and implemented by the Santa Cruz County Department of Public Works.

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 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 of Santa Cruz, including but not limited to the Department, in the administration and enforcement of their product stewardship program. Exclusive of fines and penalties, the County of Santa Cruz 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 sellers of sharps and drugs in Santa Cruz 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 Santa Cruz 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 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 County of Santa Cruz, 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. Otherwise, controlled substances are expressly excluded from this chapter notwithstanding any other provision contained herein;
 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 and sharps that producer sells in the County of Santa Cruz.
- 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 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 shall update its Product Stewardship Plan and submit the updated Plan to the Department for review and approval.
 5. A Producer who begins to offer a covered Drug for sale in the County of Santa Cruz after July 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.

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 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 consumer generators to separate unwanted products from their original containers, when appropriate, prior to collection or disposal.

7.95.070 - Product stewardship program promotion and outreach.

- A. A product stewardship program must promote the product stewardship program to consumer generators, pharmacists, retailers of covered drugs, and health care practitioners as to the proper and safe method to dispose of unwanted products.
- B. A product stewardship program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of covered drugs. These materials may include, but are not limited to, one or more of the following:
1. Signage that is prominently displayed and easily visible to the consumer.
 2. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
 3. Advertising and/or other promotional materials related to the product stewardship program.
- C. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in 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 Drugs and Sharps in the unincorporated area of the County shall establish a system consistent with the requirements of this chapter for the collection of consumer-generated Drugs and Sharps waste for proper disposal during the Retailer's or Provider's normal hours of operation.
- B. Each system established by a Retailer or provider for the collection and disposal of consumer generated Drugs and Sharps waste shall include, at a minimum, the following elements:
- (1) On-site collection system. Each Retailer or provider shall provide receptacles for the collection of consumer-generated Drugs and Sharps waste within the Retail or Provider establishment. The receptacle shall meet applicable state and federal standards for safe disposal of Drugs or Sharps. The Retailer or Provider shall manage and dispose of all consumer-generated Drugs and Sharps waste that is collected at the retail or provider establishment in a safe manner consistent with all state and federal laws and regulations.
 - (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 Drugs and 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 waste may refuse to accept from a consumer 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 shall be paid or reimbursed by the Producer, group of Producers, or Stewardship Organization as provided in this chapter. Retailers and Providers shall not be expected to incur any costs for participation.

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'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 consumer generators collected at each drop-off site and in the entire county of Santa Cruz and, if applicable, the total amount by weight collected by a mail-back program;
3. A description of the collection system, including the location of each collection site and if applicable, locations where envelopes for a mail-back program are provided;
4. The name and location of disposal facilities at which unwanted products were disposed of and the weight of unwanted products collected from 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, 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, the Product Stewardship Program will conduct a detailed assessment of collected materials at specified locations to help determine effectiveness of the 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 the Producers to cover Santa Cruz County's costs of administering and enforcing this chapter.

7.95.110 - Enforcement.

A. The Department of Public Works shall administer the penalty provisions of this chapter.

B. The Department of Public Works 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 of Santa Cruz 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 of Public Works 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 of Santa Cruz 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 of Public Works. 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 of Public Works 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 of Public Works 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 from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection

does not permit the County of Santa Cruz or any court of competent jurisdiction to restrain the sale of any covered Drug in Santa Cruz 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 in the Santa Cruz County Jail for a period not to exceed six months, or by both such fine and imprisonment.

7.95.120 - Additional provisions.

- A. Disclaimer. In adopting and implementing this chapter, the County of Santa Cruz is assuming an undertaking only to promote the general welfare. Santa Cruz 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 Santa Cruz 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. Santa Cruz 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.
- D. Environmental Findings. The County of Santa Cruz has determined that the actions contemplated in this chapter are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code Section 21000 et seq.).
- E. Nothing in this chapter, or the Program of Stewardship in which Manufacturers of Sharps and Pharmaceutical products who sell Sharps and Drugs in Santa Cruz 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 of California or of the United States.
- F. This chapter shall be construed in accordance with California state law, including but not limited to the Medical Waste Management Act set forth at California Health and Safety Code 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. 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.

SECTION II

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

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

Xxxx
Xxxx
Xxxx
Xxxx