

ORDINANCE NO. NS-517.89

**AN ORDINANCE OF THE BOARD OF SUPERVISORS
OF THE COUNTY OF SANTA CLARA ADDING CHAPTER XX OF DIVISION B11 OF
THE COUNTY OF SANTA CLARA ORDINANCE CODE RELATING TO DISPOSAL
OF COUNTY RESIDENTS' UNWANTED PHARMACEUTICALS**

Summary

This Ordinance adds Chapter XX of Division B11 of the County of Santa Clara Ordinance Code to require pharmaceutical manufacturers to design, implement and fund a program to dispose of County residents' unwanted pharmaceuticals.

**THE BOARD OF SUPERVISORS OF THE COUNTY OF SANTA CLARA
ORDAINS AS FOLLOWS:**

SECTION 1, Findings.

The Board of Supervisors of the County of Santa Clara finds and determines the following:

- (a) Legal medicinal drugs allow us to live longer, healthier, and more productive lives.
- (b) 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.
- (c) The lack of sufficient safe, convenient disposal locations for unwanted drugs creates significant risks to human health and to the environment.
- (d) 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.
- (e) 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. Every day in the United States, 113 people die from a drug overdose, and another 6,748 are treated in emergency departments for misuse or abuse of drugs. 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.
- (f) 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.

- (g) 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.
- (h) 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.
- (i) 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.
- (j) Establishing such a system will reduce the quantity of pharmaceutical compounds that are discharged into the San Francisco Bay and other receiving waters throughout the county.
- (k) 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.
- (l) 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.
- (m) The County of Santa Clara passed an Extended Producer Responsibility Resolution on May 22, 2007 (Resolution No. 25032) expressing support for managing product waste using an EPR system. Many other local and national government bodies support EPR, including CalRecycle, the National Association of Counties, and the National League of Cities.
- (n) California has passed EPR laws applicable to an array of products including mercury thermostats (AB 2347, enacted as Chapter 572 of the statutes of 2008), carpet (AB 2398, enacted as Chapter 681 of the statutes of 2010), paint (AB 1343, enacted as Chapter 420 of the statutes of 2010), and mattresses (SB 254, enacted as Chapter 21 of the statutes of 2013). Each of these laws requires producers to establish and fund product stewardship programs for the products they manufacture.
- (o) 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.
- (p) Mexico, a number of Canadian provinces, 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.
 - (q) 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 & Mfrs. Of Am. v. Cty. of Alameda*, 13-16833, 768 F.3d 1037 (9th Cir. 2014).
 - (r) King County, Washington as well as the City and County of San Francisco and the County of San Mateo have subsequently enacted similar legislation requiring drug manufacturers to design, fund, and operate programs to safely collect and dispose of local residents' unwanted drugs.
 - (s) To date, there is no voluntary or mandatory statewide EPR program to collect and dispose of unwanted household drugs in California.
 - (t) There is considerable demand in Santa Clara County for a permanent drug stewardship program. Since 2008, the County has operated a County-funded program. As of May 19, 2015, this program consists of 13 secure drop box locations at County pharmacies and Sheriff's stations, which collect both controlled and non-controlled substances, as well as two hazardous waste drop-off sites that cannot accept controlled substances. Between April 2014 and April 2015, these 15 sites collected a total of 35,351 pounds of medications.
 - (u) With a limited number of collection locations, these programs do not offer adequate disposal options for the County's 1.86 million residents. Lack of available funds prevents the County program from expanding and from collecting a significant portion of County residents' unwanted drugs. As a result, many residents continue to dispose of drugs in ways that harm aquatic life or heighten the risk of accidental poisonings or death and abuse.
 - (v) A manufacturer-funded collection and disposal program for unwanted drugs 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.

SECTION 2. The Safe Drug Disposal Ordinance is categorically exempt from the California Environmental Quality Act under Title 14 California Code of Regulations sections 15307 and 15308.

SECTION 3. Division B11 of the Ordinance Code of the County of Santa Clara is amended to add Chapter XX to read as follows:

CHAPTER XX. SAFE DRUG DISPOSAL

Sec. B11-539. Purpose.

This Chapter requires drug manufacturers to develop, operate, and fund a program or programs to safely and properly dispose of County residents' unwanted pharmaceuticals.

Sec. B11-540. Definitions.

For the purposes of this Chapter, the following definitions apply:

- (a) "County" means the unincorporated and incorporated areas of Santa Clara County.
- (b) "County residents" means human beings residing in the County. "County residents" does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor's offices, veterinary clinics, pharmacies, or airport security and law enforcement drug seizures.
- (c) "Collector" means a Person that gathers Unwanted Covered Drugs from County residents for the purpose of collection, transportation, and disposal, including, but not limited to, a Retail Pharmacy or law enforcement drop-off site, or a mail-back service.
- (d) "Covered Drug" means a Drug sold in any form and used by County residents, including prescription, nonprescription, brand name, and generic drugs. Notwithstanding the previous sentence, "Covered Drug" does not include: (1) vitamins or supplements; (2) herbal-based remedies and homeopathic drugs, products, or remedies; (3) cosmetics, 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 (Title 21 U.S.C. Chapter 9); (4) drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration-managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1); (5) drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Chapter if the Producer already provides a pharmaceutical product stewardship or take-back program; and (6) medical devices or their component parts or accessories.
- (e) "Agency" means the County of Santa Clara's Consumer and Environmental Protection Agency.
- (f) "Director" means the Director of the County of Santa Clara's Consumer and Environmental Protection Agency, or his or her designee.
- (g) "Drug Wholesaler" means a Person who buys Drugs for resale and distribution to corporations, individuals, or entities other than consumers.
- (h) "Drug" means: (1) any article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States or any supplement of the formulary or those pharmacopoeias as published by the U.S. Pharmacopoeial Convention and the Homeopathic Pharmacopoeia Convention of the

- United States; (2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) any substance, other than food, intended to affect the structure or any function of the body of humans or other animals; or (4) any substance intended for use as a component of any substance specified in (1), (2), or (3) of this definition.
- (i) “Manufacture” means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a Repackager or Wholesaler, or practitioner who distributes or dispenses such substance or device in the course of his or her professional practice or, prepares, compounds, packages, or labels such substance or device.
 - (j) “Manufacturer” means a Person engaged in the Manufacture of Drugs.
 - (k) “Mail-back services” means a collection method for the return of Unwanted Covered Drugs from County residents using prepaid and preaddressed mailing envelopes.
 - (l) “Nonprescription Drug” means a Drug that may be lawfully sold without a prescription.
 - (m) “Person” means a human being, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.
 - (n) “Pharmacy” means a place licensed by the state of California Board of Pharmacy where the practice of pharmacy is conducted.
 - (o) “Plan Operator” means the Person that develops, implements, and operates a Stewardship Plan, including, but not limited to, a Producer or a Stewardship Organization.
 - (p) “Prescription Drug” means any Drug – including any controlled substance – that is required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.
 - (q) “Producer” means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County, including a brand-name or generic Drug. Notwithstanding the previous sentence, “Producer” does not include: (1) a retailer whose store label appears on a Covered Drug or the drug’s packaging if the Manufacturer from whom the retailer obtains the drug is identified under Section B11-541(e) of this Chapter; (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Section B11-541(e) of this Chapter; (3) a pharmacist who compounds or repackages a prescribed individual drug product for a consumer; or (4) a wholesaler who is not also the Manufacturer.
 - (r) “Repackager” means a Person who owns or operates an establishment that repacks and relabels a product or package containing a Covered Drug for further sale, or for distribution without a further transaction.
 - (s) “Retail Pharmacy” means a Pharmacy licensed by the state of California Board of Pharmacy for retail sale and dispensing of drugs.
 - (t) “Stewardship Plan” means a plan for the collection, transportation, and disposal of County residents’ Unwanted Covered Drugs required under Section B11-541 of this Chapter that is: (1) financed, developed, implemented, and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; and (3) approved by the Director.

- (u) “Stewardship Organization” means an organization designated by a Producer or group of Producers to act as an agent on behalf of one or more Producers to develop, implement, and/or operate a Stewardship Plan.
- (v) “Unwanted Covered Drug” means any Covered Drug that the owner has discarded or intends to discard.

Sec. B11-541. Stewardship Plans – Participation.

- (a) Each Producer, shall participate in a Stewardship Plan. Each Producer must:
 - (1) Operate, individually or jointly with other Producers, a Stewardship Plan approved by the Director; or
 - (2) Enter into an agreement with a Stewardship Organization to operate, on the Producer’s behalf, a Stewardship Plan approved by the Director.
- (b) Each Stewardship Plan must be approved by the Director before the Person administering the plan starts collecting and disposing of Unwanted Covered Drugs. Once approved, each Stewardship Plan must have prior written approval of the Director for proposed changes as described under Section B11-544.
- (c) Beginning 60 days after the effective date of this Chapter, each Drug Wholesaler that sells any Covered Drugs in the County must provide a list of the Producers of those Covered Drugs to the Director in a form prescribed by the Director. Wholesalers must update and resubmit the list by January 15 each year.
- (d) Within six months after the effective date of this Chapter, or – if a Producer is not already participating in Stewardship Plan – within six months after a Producer’s Covered Drug is first sold in the County, a Producer must notify the Director in writing of the Producer’s intent to participate in an existing Stewardship Plan or to form a new Stewardship Plan.
- (e) Within six months after the effective date of this Chapter, or within six months after a retailer whose label appears on a Covered Drug or on the Covered Drug’s packaging starts selling the Covered Drug in the County, or within six months after a Covered Drug repackaged by Repackager is first sold in the County, and, thereafter, upon request from the Director, a retailer or Repackager whose label appears on a Covered Drug or the Covered Drug’s packaging must provide:
 - (1) Written notification as to whether the Manufacturer from whom the retailer or Repackager obtains the Covered Drug has provided its written notice of intent to participate in a Stewardship Plan or form a new Stewardship Plan; and
 - (2) The contact information of the Manufacturer from whom the retailer or Repackager obtains the Covered Drug, including the telephone number, mailing address and email address of the retailer’s or Repackager’s point of contact at the Manufacturer.
- (f) A Producer, either individually or jointly with other Producers, shall:
 - (1) Within nine months after the effective date of this Chapter, or nine months after starting sale of a Covered Drug in the County, identify in writing to the Director a Stewardship Plan that is authorized to be the official point of contact for the Stewardship Plan. This notice shall include the Plan Operator’s telephone number, mailing address and email contact information;

- (2) Within nine months after the effective date of this Chapter, or nine months after starting sale of a Covered Drug in the County, notify all Retail Pharmacies and law enforcement agencies in the County of the opportunity to participate as a drop-off site for Covered Drugs in accordance with Section B11-545 of this Chapter and provide a process for forming an agreement between the Stewardship Plan and interested Collectors; and annually thereafter, make the same notification to any nonparticipating or new Retail Pharmacies in the County;
 - (3) Within one year after the effective date of this Chapter, or one year after starting sale of a Covered Drug in the County, submit a proposed Stewardship Plan as described in Section B11-542 to the Director for review;
 - (4) Within three months after the Director's approval of the Stewardship Plan, operate or participate in the Stewardship Plan in accordance with this Chapter; and
 - (5) Pay all costs and fees associated with its Stewardship Plan, as described in Sections B11-549 and B11-550.
- (g) A Producer, either individually or jointly with other Producers, may:
- (1) Enter into contracts and agreements with Stewardship Organizations, other service providers, or other entities as necessary, useful, or convenient to carry out all or portions of their Stewardship Plan; and
 - (2) Perform any other functions as may be necessary or proper to carry out the Stewardship Plan and to fulfill any or all of the purposes for which the plan is organized.
- (h) Pursuant to his or her authority under this Chapter, the Director, at his or her discretion, may promulgate regulations allowing smaller Producers to engage in alternate means for supporting safe disposal of Covered Drugs in lieu of participating in a Stewardship Plan. Those regulations may, among other things, define which Producers may qualify for this alternative. The Director shall provide a report to the Board of Supervisors if and when any such regulations are promulgated.
- (i) The Director may, on a case-by-case basis, approve in writing requests for extensions of time for the submission dates and deadlines in this Section B11-541.
- (j) The Director may audit the records of a Producer, group of Producers, or Stewardship Organization related to a Stewardship Plan or request that the Producer, group of Producers, or Stewardship Organization arrange for the Director to inspect at reasonable times a Stewardship Plan's or a Collector's facilities, vehicles, and equipment used in carrying out the Stewardship Plan.

Sec. B11-542. Stewardship Plans – Components.

Each Stewardship Plan, which must be submitted and reviewed according to Section B11-543, shall include:

- (a) Contact information for all Producers participating in the Stewardship Plan, including each Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Director may direct all inquiries regarding the Producer's participation in the Stewardship Plan;

- (b) A description of the proposed collection system to provide convenient ongoing collection service for all Unwanted Covered Drugs from County residents in compliance with the provisions and requirements in Section B11-545, including a list of all collection methods and participating Collectors, a list of drop-off sites for Unwanted Covered Drugs, a description of how any periodic events to collect Unwanted Covered Drugs will be scheduled and located, a description of how any mail-back services will be provided, and an example of the prepaid, preaddressed mailers the plan proposes to use. The description of the collection service shall include a list of Retail Pharmacies and law enforcement agencies contacted by the Plan Operator under Section B11-541(f)(2) of this Chapter, and a list of all Collectors who agreed to participate;
- (c) A description of the handling and disposal system for Unwanted Covered Drugs, including identification of and contact information for Collectors, transporters and waste disposal facilities to be used by the Stewardship Plan in accordance with Section B11-545 and Section B11-546 of this Chapter;
- (d) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Stewardship Plan, including a description of how all Collectors, transporters and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Drug Enforcement Administration, and how any Pharmacy drop-off site will operate under applicable rules and guidelines of the State of California Board of Pharmacy;
- (e) A description of how any patient information on Drug packaging will be promptly destroyed;
- (f) A description of the public education effort and promotion strategy required in Section B11-547 of this Chapter, including a copy of standardized instructions for County residents, signage developed for Collectors, and required promotional materials the Stewardship Plan proposes to use, and an explanation of how the Stewardship Plan Operator will collaborate with all other Stewardship Plan Operators to develop a single system of promotion for all Stewardship Plans;
- (g) Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education and promotion;
- (h) A description of how the Stewardship Plan will consider:
 - (1) Separating Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and
 - (2) Recycling of Drug packaging to the extent feasible; and
- (i) Any additional information specified in Regulations adopted pursuant to this Chapter.

Sec. B11-543. Stewardship Plans – Agency Review of Proposed and Updated Plans.

- (a) Within one year after the effective date of this Chapter, each Producer, group of Producers or Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review. The Director may, upon request, provide information, counseling,

- and technical assistance about the requirements of this Chapter to assist with the development of a proposed Stewardship Plan.
- (b) The Director shall review any proposed Stewardship Plan and determine whether it meets the requirements of this Chapter. In reviewing a proposed Stewardship Plan, the Director shall provide an opportunity for written public comment on the proposed Stewardship Plan and consider any comments received.
 - (c) After the review under subsection (b) of this Section B11-543 and within 90 days after receipt of the proposed Stewardship Plan, the Director shall either approve or reject the proposed Stewardship Plan in writing and, if rejected, provide reasons for the rejection.
 - (d) If the Director rejects a proposed Stewardship Plan, a Producer, group of Producers, or Stewardship Organization must submit a revised Stewardship Plan to the Director within 60 days after receiving written notice of the rejection. The Director shall review and approve or reject a revised Stewardship Plan as provided under subsections (b) and (c) of this Section B11-543.
 - (e) If the Director rejects a revised Stewardship Plan or any subsequently revised Stewardship Plan, the Director may deem the Producer or group of Producers that submitted the Stewardship Plan out of compliance with this Chapter and subject to this Chapter's enforcement provisions.
 - (f) In approving a proposed Stewardship Plan, the Director may exercise reasonable discretion to waive strict compliance with the requirements of this Chapter that apply to Producers in order to achieve the objectives of this Chapter.
 - (g) At least every four years after a Stewardship Plan starts operations, the Stewardship Plan Operator shall submit an updated Stewardship Plan to the Director explaining any substantive changes to components of the Stewardship Plan required in Section B11-542. The Director shall review updated Stewardship Plans using the process described in this Section B11-543.
 - (h) The Director shall make all Stewardship Plans and proposed plans submitted under this Section B11-543 available to the public.

Sec. B11-544. Stewardship Plans – Prior Approval for Change.

- (a) After the first full year of participation in a Stewardship Plan, a Producer or group of Producers may notify the Director in writing of its intent to form a new Stewardship Plan, and identify a Plan Operator that is authorized to be the official point of contact for the proposed new Stewardship Plan, and shall provide the Plan Operator's telephone number, mailing address, and email contact information. Within three months of such notification, the Producer or group of Producers shall submit a proposed Stewardship Plan as described under Section B11-542 to the Director for review.
- (b) Proposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to, changes to participating Producers, collection methods, achievement of the service convenience requirement described under Section B11-545(b)(1), policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities, must be approved in writing by the Director before the changes are implemented.

- (c) A Producer or group of Producers participating in a Stewardship Plan shall submit to the Director any proposed change to a Stewardship Plan as described under subsection (b) of this Section B11-544 in writing at least 30 days before the change is scheduled to occur.
- (d) The Plan Operator of an approved Stewardship Plan shall notify the Director at least 15 days before implementing any changes in drop-off site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, preaddressed mailers, that do not substantively alter achievement of the service convenience requirement under Section B11-545(b)(1) of this Chapter, or other changes that do not substantively alter plan operations under subsection (b) of this Section B11-544.
- (e) The Plan Operator may request an advance determination from the Director of whether a proposed change would be deemed to substantively alter plan operations. The Director shall provide a determination within 90 days after receipt of the request, and shall provide reasons for the determination.

Sec. B11-545. Stewardship Plans – Collection of Covered Drugs.

- (a) This Section does not require any Person to serve as a Collector in a Stewardship Plan. A Person may offer to serve as a Collector voluntarily, or may agree to serve as a Collector in exchange for incentives or payment offered by a Producer, group of Producers or Stewardship Organization. Collectors may include law enforcement agencies, Pharmacies, mail-back services or other entities operating in accordance with state and federal laws and regulations for the handling and secure storage of Covered Drugs, including but not limited to those of the United States Drug Enforcement Administration, and in compliance with this Chapter. A Pharmacy collection site shall operate under applicable rules and guidelines of the State of California Board of Pharmacy.
- (b) The collection system for each Stewardship Plan shall:
 - (1) Provide reasonably convenient and equitable access for residents in all County of Santa Clara Supervisorial Districts. The system of drop-off sites shall provide at least one drop-off site for every 20,000 County residents, geographically distributed to provide reasonably convenient and equitable access throughout the County, and at no time shall there be less than 10 drop-off sites per County of Santa Clara Supervisorial District. If the service convenience requirement in this subsection (b)(1) cannot be achieved due to a lack of drop-off sites at Retail Pharmacies, law enforcement agencies, or other qualified Collectors in each County of Santa Clara Supervisorial District, then those areas shall be served through periodic collection events and/or mail-back services.
 - (2) Be safe and secure, including providing for the prompt destruction of patient information on Drug packaging.
 - (3) Give preference to having Retail Pharmacies and law enforcement agencies serve as drop-off sites.
 - (4) Include as Collectors any Retail Pharmacy – including Retail Pharmacies operated by the County of Santa Clara – or any law enforcement agency willing to serve voluntarily as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Chapter within three months of its offer to participate, unless the

- Collector requests a longer time frame. A Stewardship Plan may also accept other Collectors willing to serve as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Chapter; and
- (5) Make mail-back services available, free of charge, to disabled and home-bound County residents upon request through the Stewardship Plan's toll-free telephone number and website, and through distribution of prepaid, preaddressed mailers to Persons providing services to such residents.
 - (c) Drop-off sites shall accept all Covered Drugs from County residents during all hours that the Retail Pharmacy, law enforcement agency, or other Collector is normally open for business with the public. In the event that more than one Stewardship Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.

Sec. B11-546. Stewardship Plans – Disposal of Covered Drugs.

- (a) Each Stewardship Plan shall comply with all local, state, and federal laws and regulations applicable to disposal of pharmaceutical waste and controlled substances.
- (b) Each Stewardship Plan shall dispose of collected Covered Drugs by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must possess all required regulatory permits and licenses.
- (c) A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection or equivalent protection at lesser cost than those provided by the disposal technologies in subsection (b) of this Section B11-546. The proposed technology must at a minimum provide equivalent or superior protection in each of the following areas:
 - (1) Monitoring of any emissions or waste;
 - (2) Worker health and safety;
 - (3) Reduction or elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
 - (4) Overall impact on the environment and human health.

Sec. B11-547. Stewardship Plans – Promotion and Surveys.

- (a) All Stewardship Plans shall coordinate with each other and develop a single system of promotion that shall:
 - (1) Promote the Stewardship Plans so that collection options for Covered Drugs are widely understood by County residents, pharmacists, retailers of Covered Drugs and health care practitioners including doctors and other prescribers, veterinarians and veterinary hospitals, and promote the safe storage of Covered Drugs by County residents;
 - (2) Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions for County residents on disposal of Unwanted Covered Drugs in collection bins at drop-off sites and a readily-recognizable, consistent design of collection bins;

- (3) Establish a single toll-free telephone number and single website where collection options and current locations of drop-off sites will be publicized, and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drugs to the Stewardship Plan. These materials must be provided to all Pharmacies, health care facilities, and veterinary facilities in the County, and to other interested parties for dissemination to County residents. Plain language and explanatory images should be used to make use of Drug collection services readily understandable by all residents, including individuals with limited English proficiency;
- (4) Within two years after the first 12-month period of Stewardship Plan operation, and biannually thereafter, conduct a survey of County residents and a survey of pharmacists, veterinarians, and health professionals in the County who interact with patients on use of medicines. The Director shall specify requirements for the survey's content and administration in regulations to be adopted pursuant to this Chapter.
- (b) All surveys, outreach, education, promotion, websites, and toll-free phone service required by this Section B11-547 shall be translated into or conducted in languages specified by the Director.
- (c) The Director shall provide guidance on the development of a single system of promotion for all Stewardship Plans, if there is more than one Stewardship Plan.

Sec. B11-548. Stewardship Plans – Reporting Requirements.

- (a) Within six months after the end of the first 12-month period of Stewardship Plan operation, and annually thereafter, the Plan Operator of a Stewardship Plan shall submit a report to the Director on behalf of participating Producers describing the plan's activities during the previous reporting period. The Director shall specify requirements for the report's content in regulations to be adopted pursuant to this Chapter.
- (b) The Director shall make reports submitted under this Section available to the public.
- (c) For the purposes of this Section B11-548, "reporting period" means the period from January 1 through December 31 of the same calendar year, unless otherwise specified to the Plan Operator by the Director.

Sec. B11-549. Stewardship Plans – Administrative and Operational Costs and Fees.

- (a) A Producer or group of Producers participating in a Stewardship Plan shall pay all administrative and operational costs related to their Stewardship Plan, except as provided under this Section B11-549. Administrative and operational costs related to the Stewardship Plan include but are not limited to the following:
 - (1) Collection and transportation supplies for each drop-off site;
 - (2) Acquisition of all secure collection bins for drop-off sites;
 - (3) Ongoing maintenance or replacement of secure collection bins, as requested by Collectors;
 - (4) Prepaid, preaddressed mailers provided to disabled and/or home-bound residents;

- (5) Operation of periodic collection events, including costs of law enforcement staff time if necessary;
 - (6) Transportation of all collected Covered Drugs to final disposal, including costs of law enforcement escort if necessary;
 - (7) Environmentally sound disposal of all collected Covered Drugs under Section B11-546 of this Chapter;
 - (8) Program promotion under Section B11-547 of this Chapter; and
 - (9) Costs related to any review of a Product Stewardship Plan for purposes of obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.).
- (b) No Person or Producer may charge a point-of-sale fee to consumers to recoup the costs of a Stewardship Plan, nor may they charge a specific point-of-collection fee at the time the Covered Drugs are collected.
 - (c) Producers are not required to pay for costs of staff time at drop-off sites provided by Collectors volunteering to participate in a Stewardship Plan.

Sec. B11-550. Stewardship Plans – Plan Review and Annual Operation Fees.

The Board of Supervisors authorizes the Director to charge Producers or a group of Producers participating in a Stewardship Plan fees to cover all costs the County of Santa Clara incurs in administering and enforcing this Chapter. Fees shall not exceed actual costs to the County of Santa Clara.

Sec. B11-551. Stewardship Plans – Enforcement and Penalties.

- (a) The Director shall administer the enforcement provisions of this Chapter.
- (b) If the Director determines that any Person has violated this Chapter or a regulation adopted pursuant to this Chapter, the Director shall send a written warning, as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter, to the Person or Persons who violated it. The Person or Persons shall have 30 days after receipt of the warning to come into compliance and correct all violations.
- (c) If the Person or Persons fail to come into compliance or correct all violations, the Director may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter. Santa Clara County Ordinance Code Division A37, “Administrative Fines/Penalties,” is hereby incorporated in its entirety and shall govern the imposition, enforcement, collection, and review of administrative fines issued to enforce this Chapter or any regulation adopted pursuant to this Chapter. Each day of non-compliance shall constitute a separate violation for these purposes.
- (d) Any knowing and willful violation of the requirements of this Chapter or of any regulation adopted pursuant to this Chapter is a misdemeanor, and punishable by a fine of five hundred dollars (\$500) for each day per violation, or by imprisonment in the County Jail for a period not to exceed six months, or by both such fine and imprisonment.
- (e) 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) per day per violation. Each day in which the violation continues shall constitute a separate violation.

- (f) In determining the appropriate penalties, the court or the Director 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.
- (g) The County Counsel, a Producer, a group of Producers, a Stewardship Organization, a group of Stewardship Organizations or any organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) may bring a civil action to enjoin violations of or compel compliance with any requirement of this Chapter or any rule or regulation adopted pursuant to this Chapter, as well as for payment of civil penalties and any other appropriate remedy. The court shall award reasonable attorney's fees and costs to the County Counsel, Producer, group of Producers, a Stewardship Organization, a group of Stewardship Organizations or nonprofit organization that brings a civil action to enforce this Chapter under this subsection (g) and is the prevailing party in that action. A Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, or nonprofit organization may institute a civil action under this subsection (g) only if:
 - (1) It has filed a Complaint with the Director;
 - (2) 90 days have passed since the filing of the Complaint;
 - (3) After such 90-day period has passed, the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, or nonprofit organization provides 30-day written notice to the Director and the County Counsel's Office of its intent to initiate civil proceedings; and
 - (4) The County Counsel's Office has not provided notice to the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, or nonprofit organization of the County's intent to initiate civil proceedings by the end of the 30-day period. If the County Counsel's Office provides such notice, the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, or nonprofit organization cannot bring suit under subsection (g) without the express written consent of the County Counsel's Office.
- (h) No criminal, civil or administrative action under this Section B11-551 may be brought more than four years after the date of the alleged violation.

Sec. B11-552. Stewardship Plans – Regulations, Performance Standards, and Report to Board.

- (a) The Director may adopt regulations necessary to implement, administer, and enforce this Chapter.
- (b) The Director may work with a Stewardship Plan Operator to define goals for collection amounts, education, and promotion for a Stewardship Plan.
- (c) The Director shall report as requested to the Board of Supervisors concerning the status of all Stewardship Plans and recommendations for changes to this Chapter.

Sec. B11-553. No Conflict with Federal or State Law.

This Chapter shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. 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. Nothing in this Chapter is intended or shall be construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair competition laws of the State of California or the United States.

Sec. B11-554. Severability.

The provisions of this Chapter are severable. If any section, subsection, paragraph, sentence, clause or phrase of this Chapter is for any reason held unconstitutional or invalid by a decision of any court of competent jurisdiction, the remaining parts of this Chapter shall remain fully effective. If the application of any part of this Chapter to any person or circumstance is held invalid, the application of that part of this Chapter shall not be affected regarding other persons or circumstances

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Sec. B11-555. Effective Date.

The provisions of this Chapter shall be effective 30 days after enactment, unless, prior to the effective date of this Chapter, the United States Supreme Court grants a petition for a writ of certiorari in the case of *Pharmaceutical Research & Manufacturers of America v. County of Alameda*, 13-16833, 768 F.3d 1037 (9th Cir. 2014). If certiorari is granted, this Chapter shall not become operative until 30 days after judgment has been entered in that case. The County Counsel's Office shall notify the Agency once judgment has been entered.

PASSED AND ADOPTED by the Board of Supervisors of the County of Santa Clara, State of California, on _____ by the following vote:

AYES:

NOES:

ABSENT:

ABSTAIN:

DAVE CORTESE, President
Board of Supervisors

ATTEST:

MEGAN DOYLE
Clerk of the Board of Supervisors

APPROVED AS TO FORM AND LEGALITY:



GRETA S. HANSEN
Lead Deputy County Counsel

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