ORDINANCE NO. NS-517.92

AN ORDINANCE OF THE BOARD OF SUPERVISORS OF THE COUNTY OF SANTA CLARA ADDING CHAPTER XXI TO DIVISION B11 OF THE COUNTY OF SANTA CLARA ORDINANCE CODE RELATING TO DISPOSAL OF CONSUMER-GENERATED SHARPS WASTE

Summary

This Ordinance adds Chapter XXI to Division B11 of the County of Santa Clara Ordinance Code to require manufacturers of medicinal sharps products, as well as manufacturers of pharmaceuticals requiring the use of sharps in their administration, to design, implement, and fund a program to dispose of consumer-generated sharps waste.

Adopted: 03/06/2018

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

SECTION 1. The Board of Supervisors of the County of Santa Clara finds and determines the following:

(a) "Sharps"—medical devices with sharp points or edges that can cut or puncture the skin, which include needles, pen needles, syringes, lancets, auto-injectors, infusion sets, intravenous catheters, connection needles/sets, and other devices—are a necessary medical technology used by consumers outside of healthcare settings to treat medical conditions including diabetes, multiple sclerosis, allergies, infertility, arthritis, hepatitis, HIV, blood clotting disorders, migraines, and cancer.

(b) Consumers dispose of more than 3 billion used needles and syringes and 900 million lancets each year in the United States.

(c) In 2008, California enacted Health & Safety Code section 118286, which requires consumers to dispose of their sharps waste in sharps containers or other containers authorized by the relevant local enforcement agency, and prohibits the loose disposal of consumer-generated Sharps waste.

(d) Many people remain unaware of the change in the law and continue to dispose of contaminated Sharps waste in a manner that increases the risk that others will be harmed by that waste.

(e) Improper disposal of Sharps waste puts people at risk of injury and serious infection.

(f) There are frequent reports of waste pick-up route drivers, landfill workers, recycling center workers, employees of hotels, health clubs, parks and recreation departments, transportation organizations (including Caltrans, Bay Area Rapid Transit, airlines and airports), janitorial workers, police, and restaurant and laundry workers finding and being injured in the workplace by Sharps waste that has been disposed of improperly.

(g) Flushed consumer-generated Sharps waste can make its way to beaches and streams, creating a risk of injury and illness to a broader cohort of individuals, including children.

(h) Because they penetrate the skin, Sharps may become contaminated with blood-borne pathogens and can transmit diseases, including HIV and Hepatitis B and C, to others who unintentionally come into contact with contaminated Sharps.

(i) Because of the severity of the infections that may be spread through consumer-generated Sharps waste, standard practice is to treat all used consumer-generated Sharps waste as though it were contaminated with pathogens such as HIV and Hepatitis B and C; even if a Sharps injury does not cause infection, it can have significant psychological, social, and financial impacts on the victim who has to be tested and must wait from days to months to know if he or she has contracted a communicable and life-threatening disease.

(j) 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.

(k) The County of Santa Clara passed an EPR Resolution on May 22, 2007 (Resolution No. 25032) expressing support for managing product waste using an EPR system, and in 2015, it passed an ERP ordinance requiring pharmaceutical manufacturers to facilitate and fund proper disposal of their products within the County. Many other local and national government bodies support EPR, including CalRecycle, the National Association of Counties, and the National League of Cities.

(l) 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.

(m) Various California jurisdictions have passed EPR laws applicable to Consumer-Generated Sharps Waste, including the Counties of Alameda, Santa Cruz, and Tulare, and the Cities of Capitola, Galt, Sacramento, Scotts Valley, Tulare, Visalia, and Watsonville; and the San Luis Obispo Integrated Waste Management Authority.

(n) In recent years, the County of Santa Clara's Household Hazardous Waste Program has collected an average of 5,000 pounds of consumer-generated Sharps waste.

(o) It is therefore necessary and desirable to establish a Product Stewardship Program to ensure the safe and environmentally sound disposal of consumer-generated Sharps waste and to ensure the costs associated with the handling and disposal of consumer-generated Sharps waste are the responsibility of those who produce sharps and pharmaceuticals requiring the use of Sharps in their administration.

SECTION 2. The Safe Sharps 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 relating to Environmental Health is hereby amended by adding a new Chapter to be numbered and titled and to read as follows:

Chapter XXI – SAFE SHARPS DISPOSAL

Sec. B11-560. Purpose.

This Chapter requires manufacturers of Sharps and Sharps-Administered Medications to develop, operate, and fund a program or programs for the safe, proper, and convenient disposal of Consumer-Generated Sharps Waste, and to encourage use of such program or programs while discouraging improper disposal of Consumer-Generated Sharps Waste.

Sec. B11-561. Definitions.

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

(a) "Agency" means the County's Consumer and Environmental Protection Agency.

(b) "Collector" means a Person that gathers Consumer-Generated Sharps Waste for the purpose of collection, transportation, and/or disposal. "Collectors" may include Drop-Off Sites, entities providing Mail-Back Services, and other entities facilitating the collection of Consumer-Generated Sharps Waste in compliance with this Chapter and in accordance with state and federal laws and regulations for the handling and secure storage of such waste.

(c) "Collection System" means a Stewardship Plan's system for collecting Consumer-Generated Sharps Waste including Drop-Off Sites, Take-Back Events, and Mail-Back Services.

(d) "Consumer-Generated Sharps Waste" means Sharps that have been used by a Consumer outside a healthcare setting, such as in a home, at work, at school, in an establishment open to the public, or while travelling.

(e) "Consumer" means any Person who uses Sharps outside a healthcare setting or any Person who assists another Person in using Sharps outside a healthcare setting in Santa Clara County. "Consumer" includes any Person who uses Sharps to treat a pet or other animal outside a healthcare setting in Santa Clara County.

(f) "County Residents" means human beings residing in Santa Clara County. "County Residents" does not include business generators of Sharps waste, such as hospitals, clinics, doctor's offices, veterinary clinics, pharmacies, or airport security and law enforcement drug seizures.

(g) "Director" means the Director of the County's Consumer and Environmental Protection Agency or her or his designee.

(h) "Drop-Off Site" means a physical location with a secure collection receptacle for receiving Consumer-Generated Sharps Waste from Consumers, free of charge. "Drop-Off Sites" may include, but are not limited to, Retail Pharmacies, the County's Household Hazardous Waste facilities, transfer stations, law enforcement, transportation hubs, hotels, clinics, hospitals, schools, offices, recreation facilities, apartment buildings with 50 or more units, and workplaces with 100 or more employees.

(i) "Entity" means an agency, cooperative, collaboration, corporation, partnership, company, or other group arrangement other than a natural Person.

(j) "Mail-Back Distribution Site" means a convenient distribution site providing for free, prepaid, preaddressed mail-back containers to County Residents as part of Mail-Back Services.

(k) "Mail-Back Services" means a collection method providing for the disposal of Consumer-Generated Sharps Waste by County Residents using prepaid and preaddressed mail-back containers.

(l) "Plan Operator" means the Person authorized to be the official contact for a Stewardship Plan.

(m) "Producer" means a manufacturer who engages in the manufacture of Sharps or Sharps-Administered Medications that are sold or distributed in Santa Clara County. "Producer" specifically includes at a minimum all pharmaceutical manufacturers subject to the reporting requirements of Public Resources Code section 47115 *et seq*. (SB 486) that sell or distribute their Sharps or Sharps-Administered Medications in Santa Clara County. "Producer" does not include:

(1) A retailer whose store label appears on the Sharps, Sharps-Administered Medications, or packaging, if the retailer does not manufacture the Sharps or Sharps-Administered Medications;

(2) A pharmacist who compounds or repackages a prescribed individual product for direct distribution to a Consumer; or

(3) A wholesaler or distributor who does not manufacture the Sharps or Sharps-Administered Medications.

(n) "Promotion System" means the system of education and outreach required under Section 568 of this Chapter.

(o) "Retail Pharmacy" means a pharmacy licensed by the California Board of Pharmacy for retail sale and dispensing of pharmaceutical products.

(p) "Reporting Period" means, for the first report, the 12-month period since the Stewardship Plan's approval, and, for all subsequent reports, the 12-month period since the previous report was due to be submitted to the Agency, unless otherwise specified by the Safe Sharps Disposal Liaison.

(q) "Safe Sharps Disposal Liaison" means the Agency contact designated by the Director for all communications relating to this Chapter.

(r) "Santa Clara County" means the unincorporated and incorporated areas of Santa Clara County.

(s) "Service Convenience Goal" means the required amount of Drop-Off Sites, Mail-Back Services, and Take-Back Events as described in Section 566 of this Chapter.

(t) "Sharps" means devices with a sharp point or edge that can cut or puncture the skin, including a needle, pen needle, syringe, lancet, auto-injector, infusion set, intravenous catheter, connection needle/set, or other device.

(u) "Sharps-Administered Medication" means a medication that is usually intended to be injected outside a healthcare setting.

(v) "Sharps Container" means a rigid puncture-resistant container meeting the standards of, and receiving approval from, the United States Food and Drug Administration as a medical device used for the collection of discarded Sharps.

(w) "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.

(x) "Stewardship Plan" means a plan for the collection, transportation, and disposal of Consumer-Generated Sharps Waste required under Section 562 of this Chapter that is:

(1) Financed, developed, implemented, and participated in by one or more Producers; and

(2) Operated by the participating Producers or a Stewardship Organization.

(y) "Survey" means a survey of County Residents, pharmacists, veterinarians, and health professionals in the County who interact with patients on use of Sharps, which must be conducted within two years after the first year of an approved Stewardship Plan's operation and biennially thereafter.

(z) "Take-Back Event" means an event, not hosted in conjunction with a County Household Hazardous Waste Program event, at which a Collector provides a secure collection receptacle for receiving Consumer-Generated Sharps Waste from County Residents, free of charge.

Sec. B11-562. Stewardship Plans—Participation.

(a) Each Producer shall participate in a Produce 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—or, if applicable, conditionally approved—by the Director before the Person administering the Stewardship Plan starts collecting, transporting, and disposing of Consumer-Generated Sharps Waste for purposes of compliance with this Chapter. Once the Stewardship Plan is approved, prior written approval from the Director must be obtained before any changes that substantively alter the Stewardship Plan can be made.

(c) Within three months after the effective date of this Chapter or becoming a Producer, whichever is later, a Producer must notify the Safe Sharps Disposal Liaison in writing of:

(1) All Sharps or Sharps-Administered Medications it sells or distributes in Santa Clara County; and

(2) The Producer's intent to participate in an existing approved Stewardship Plan, or to form a new Stewardship Plan.

(d) Within four months after the effective date of this Chapter or becoming a Producer, whichever is later, a Producer must, either individually or jointly with other Producers, provide the Safe Sharps Disposal Liaison the name of the Producer's designated Stewardship Plan Operator and the Plan Operator's telephone, mailing address, and email contact information.

(e) A Producer shall either:

(1) Participate in an existing Stewardship Plan in compliance with this Chapter, within five months of the effective date of this Chapter or becoming a Producer, whichever is later, or:

(2) Either individually or jointly with other Producers:

(A) Within five months after the effective date of this Chapter or becoming a Producer, whichever is later, notify an appropriate and diverse pool of potential Collectors in the County of the opportunity to participate as a Mail-Back Distribution Site or Drop-Off Site and provide a process for forming an agreement between the Stewardship Plan and interested Collectors;

(B) Within six months after the effective date of this Chapter or becoming a Producer, whichever is later, submit a proposed Stewardship Plan as described in Sections 562 and 563to the Director for review, accompanied by the Stewardship Plan review fee in accordance with Section 570 of this Chapter;

(C) Within two months after the Director's final approval of the Stewardship Plan, operate and implement the Stewardship Plan in accordance with this Chapter;

(D) At least every four years after the Stewardship Plan is approved, submit an updated Stewardship Plan to the Director identifying and explaining any substantive changes to components of the existing Stewardship Plan required in Section 563 of this Chapter. The updated Stewardship Plan shall be accompanied by a plan review fee in accordance with Section 570 of this Chapter; and

(E) Pay all administrative and operational costs and fees associated with its Stewardship Plan.

(f) A Producer, either individually or jointly with other Producers, may:

(1) Enter into agreements with Stewardship Organizations, other service providers, or other entities, as necessary, to carry out all or portions of their Stewardship Plan;

(2) Notify the Safe Sharps Disposal Liaison of any Producer or group of Producers in the County that is failing to comply with its obligations to participate in a Stewardship Plan; and

(3) 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 Stewardship Plan is organized.

(g) After the first year of participation in an approved Stewardship Plan, a Producer, group of Producers, or Stewardship Organization may notify the Director in writing of its intent to form a new Stewardship Plan, identify a Plan Operator that is authorized to be the official point of contact for the proposed new Stewardship Plan, and provide the Plan Operator's telephone number, mailing address, and email address. Within three months of such notification, the Producer, group of Producers, or Stewardship Organization shall submit a proposed Stewardship Plan, as described under Section 563 of this Chapter, to the Director for review. Any Producer, group of Producers, or Stewardship Organization forming a new Stewardship Plan under subsection (a) shall continue to participate in an approved Stewardship Plan until a new Stewardship Plan has been approved by the Director.

(h) The Director may promulgate regulations allowing smaller Producers to engage in alternate means for supporting safe disposal of Consumer-Generated Sharps Waste in lieu of participating in a Stewardship Plan. Those regulations may, among other things, define which Producers may qualify for this alternative.

(i) The Director may, on a case-by-case basis and based on a showing of good cause, approve requests for extensions of time for the submission dates and deadlines in this Section.

(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. B11-563. Stewardship Plans—Components.

Each Stewardship Plan must include:

(a) Contact information for all Producers participating in the Stewardship Plan, including each Producer's name, mailing address, phone number, and email address, and the name, mailing 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 Consumer-Generated Sharps Waste from County Residents in compliance with Section 566 of this Chapter, including a list of all collection methods and participating Collectors, a list of proposed Mail-Back Distribution Sites and Drop-Off Sites, a description of how any Take-Back Events will be scheduled and located, a description of how any Mail-Back Services will be provided, and an example of the prepaid, preaddressed mail-back containers the Stewardship Plan proposes to use. The description of the collection service shall include a list of Retail Pharmacies and law enforcement agencies contacted by the Stewardship Plan under Section 566 of this Chapter, and a list of all Collectors who offered or agreed to participate.

(c) A description of the handling and disposal system, including identification of and contact information for Collectors, transporters and disposal facilities to be used by the Stewardship Plan in accordance with Sections 566 and 567 of this Chapter, as well as the United States Department of Transportation, the United States Drug Enforcement Administration, or the United States Environmental Protection Agency number, if any; permit status, as applicable; and record of any penalties, violations, or regulatory orders received in the previous five years.

(d) A description of the policies and procedures to be followed by Persons handling Consumer-Generated Sharps Waste collected under the Stewardship Plan, including a description of how all Collectors, transporters, and disposal facilities used will ensure that the Consumer-Generated Sharps Waste is 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 Food and Drug Administration, the United States Occupational Safety and Health Administration, the United States Department of Transportation, the United States Environmental Protection Agency, and the United States Drug Enforcement Administration, and how any

Pharmacy collection 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 Sharps packaging will be kept confidential and a certification that any such patient information on Sharps packing shall be promptly destroyed in compliance with all privacy laws.

(f) A description of the Promotion System and how it will be implemented, a copy of standardized instructions for Consumers, signage developed for participating Collectors and Mail-Back Distribution Sites, a copy of required promotional materials the Stewardship Plan proposes to use, and an explanation of how the Plan Operator will collaborate with all other Plan Operators to develop a single Promotion System for all Stewardship Plans.

(g) Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education, and outreach.

(h) A description of how the Stewardship Plan will consider the use of existing household hazardous waste, transfer stations, and recycling facilities within the County.

(i) A certification that the Stewardship Plan will accept all Sharps regardless of who produced them, unless excused from this requirement by the Director as part of the approval of the Stewardship Plan.

(j) A description of how the Stewardship Plan will provide collection services for Sharps throughout Santa Clara County, will be convenient to Consumers, and will be adequate to meet the needs of the Consumer population in the area being served.

(k) The targeted location of each Mail-Back Distribution Site and Drop-Off Site.

(l) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years for each transporter and disposal facility proposed to participate in the Stewardship Plan.

(m) A description of how the scope and extent of the Stewardship Plan are reasonably calculated to allow for the collection of the amount of Consumer-Generated Sharps Waste generated in Santa Clara County.

(n) A starting date for collection of Consumer-Generated Sharps Waste.

(o) A description of how Drop-Off Sites for Consumer-Generated Sharps Waste will be located throughout Santa Clara County, and a description of how the Drop-Off Sites will be managed in a safe and secure manner.

(p) If more than one Producer will be involved in a proposed Stewardship Plan, then the Stewardship Plan must set forth a fair and reasonable method for allocating the costs among the participants in that program, such that the

portion of costs paid by each Producer is reasonably related to the amount of Sharps or Sharps-Administered Medications that it sells or distributes in Santa Clara County.

(q) Any additional information specified in regulations adopted pursuant to this Chapter.

Sec. B11-564. Stewardship Plans—Review of Proposed and Updated Stewardship Plans.

(a) The Agency may, upon request, provide information and technical assistance about the requirements of this Chapter to assist with the development of a proposed Stewardship Plan.

(b) The Director, or authorized designee, shall review proposed and updated Stewardship Plans, and shall make the final determination, in the Director's reasonable discretion, whether such plans meet 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, except as provided under subsection (d) of this Section.

(c) After the review under subsection (b) of this Section and within two months after receipt of the proposed Stewardship Plan, the Director shall approve, conditionally approve, or reject the proposed Stewardship Plan in writing. If the Director conditionally approves or rejects the proposed Stewardship Plan, the Director shall provide specific changes needed for final approval of a conditionally approved Stewardship Plan or reasons for the rejection.

(d) If the Director conditionally approves a proposed Stewardship Plan, the Plan Operator must submit a revised Stewardship Plan conforming to the required changes. This revised Stewardship Plan must be submitted within one month after receiving written notice of the conditional approval. The Director shall provide final approval or rejection of a revised, conditionally-approved Stewardship Plan submitted under this subsection within one month after receipt, without further written public comment.

(e) If the Director rejects a revised Stewardship Plan, the Director may deem the submitting Producer, group of Producers, and/or Stewardship Organization 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) The Agency shall make all Stewardship Plans submitted under this Section available to the public.

Sec. B11-565. Stewardship Plans—Prior Approval for Change.

(a) 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 Goal under Section 566 of this Chapter, policies and procedures for handling Sharps, disposal facilities, or the Promotion System must be approved in writing by the Director before the changes are implemented. Such changes shall be submitted in writing at least one month before the change is scheduled to occur.

(b) Proposed changes to an approved Stewardship Plan must be submitted to the Director within six months of notice from the Agency of a change to the population of a Supervisorial District requiring an increase in services to satisfy the Service Convenience Goal under Section 566 of this Chapter. Such changes must be submitted in writing at least one month before the change is scheduled to occur.

(c) The Plan Operator of an approved Stewardship Plan shall notify the Director at least fifteen days before implementing any changes in Mail-Back Distribution Site or Drop-Off Site locations, methods for scheduling and locating Take-Back Events, or methods for distributing prepaid, preaddressed mail-back containers, that do not substantively alter achievement of the Service Convenience Goal under Section 566 of this Chapter, or other changes that do not substantively alter plan operations under subsection (b) of this Section.

(d) The Plan Operator may request in writing an advance determination from the Director of whether a proposed change would be deemed to substantively alter plan operations.

Sec. B11-566. Sharps Collection.

(a) This Chapter does not require any Person to serve as a Collector. 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. Producers, groups of Producers, or Stewardship Organizations must consider using any potential Collector interested in participating in Sharps collection, unless the Producer, group of Producers, or Stewardship Organization determines that

the use of such potential Collector would negatively impact the efficiency or scope of collection.

(b) Service Convenience Goal. The Collection System for each Stewardship Plan must provide reasonably convenient and equitable access for County Residents in all County Supervisorial Districts. The Director shall have discretion to determine whether a Stewardship Plan's Mail-Back Services, Drop-Off Sites, and Take-Back Events provide reasonably convenient and equitable access for County Residents. Each Stewardship Plan shall:

(1) Provide, free of charge, comprehensive Mail-Back Services to all County Residents. Mail-Back Services must be provided upon request through the Stewardship Plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mail-back containers to Persons providing caretaker services to County Residents, without limitation to how many mail-back containers can be requested at any given time. Mail-Back Services must further provide at least ten Mail-Back Distribution Sites that offer prepaid, preaddressed mail-back containers at no charge to County Residents for every 20,000 County Residents, geographically distributed to provide reasonably convenient and equitable access throughout each County Supervisorial District. Mail-Back Services must further provide the County's Household Hazardous Waste Program with a sufficient quantity of prepaid, preaddressed mail-back containers to supply the needs of County Residents who attend the County's periodic Household Hazardous Waste drop-off events.

(2) Provide, free of charge, one Drop-Off Site for every 20,000 County Residents, geographically distributed to provide reasonably convenient and equitable access throughout each County Supervisorial District, and at no time shall there be fewer than ten Drop-Off Sites per County Supervisorial District. If the Service Convenience Goal cannot be achieved due to a lack of Drop-Off Sites at qualified Collectors in any County Supervisorial District, then convenient and equitable access for that Supervisorial District shall be achieved by providing at least one reasonably convenient Take-Back Event per year in lieu of each Drop-Off Site needed to meet the Service Convenience Goal in that Supervisorial District. Take-Back Events shall provide for secure collection of Consumer-Generated Sharps Waste at no charge to Consumers, and may be held in conjunction with take-back events for unwanted medicines under Chapter XX of the County Ordinance Code.

(3) Be safe and secure, including providing for the prompt destruction of any patient information on packaging.

(4) Provide for adequate pick-up frequency from Drop-Off Sites, which must (i) minimize any disruption in the Drop-Off Site's ability to collect Consumer-Generated Sharps Waste, (ii) minimize the potential of a full and locked collection bin by continuously adjusting the pick-up frequency based on demand, and (iii) for Drop-Off Sites that operated prior to participation in an approved Stewardship Plan, initially maintain the Drop-Off Site's existing pickup frequency and then adjust according to demand.

(5) Give preference to having: (i) Retail Pharmacies, law enforcement agencies, and high-traffic areas serve as Drop-Off Sites; (ii) high-traffic areas and public buildings serve as Mail-Back Distribution Sites; and (iii) community events serve as Take-Back Events.

(6) Include, as Collectors, any Retail Pharmacy or any law enforcement agency willing to serve as a Drop-Off Site for Consumer-Generated Sharps Waste and able to meet the requirements of this Chapter.

(c) Drop-Off Sites shall accept all Consumer-Generated Sharps Waste from Consumers during all hours normally open for business with the public. Drop-Off Sites shall utilize secure collection bins in compliance with all applicable requirements, including but not limited to those of the United States Food and Drug Administration and the United States Occupational Safety and Health Administration. Drop-Off Sites must accept all Consumer-Generated Sharps Waste.

Sec. B11-567. Stewardship Plans—Disposal of Consumer-Generated Sharps Waste.

(a) Each Stewardship Plan must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations applicable to the transportation and disposal of medical waste.

(b) Each Stewardship Plan must dispose of all Consumer-Generated Sharps Waste by incineration at a medical waste or hazardous waste facility in compliance with all federal, state, and local laws. The medical waste or hazardous waste facility must be in possession of all required regulatory permits and licenses.

(c) Plan Operators may petition the Director 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 Sharps if and when those technologies are proven and available. The Director shall have discretion to grant or deny any petition

submitted under this subsection. To be approved by the Director, 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.

Sec. B11-568. Stewardship Plan—Promotion and Surveys.

(a) All Plan Operators shall coordinate with each other and develop to provide a single Promotion System that is consistent with the intent and purpose of this Chapter to provide convenient and equitable access to proper disposal options for all Consumers and that shall:

(1) Promote the Stewardship Plans so that Sharps collection options are widely understood by Consumers, pharmacists, retailers of Sharps-Administered Medications and Sharps, and healthcare practitioners including doctors, veterinarians, and other prescribers in hospitals, clinics, and veterinary hospitals;
(2) Promote the safe disposal of Sharps by Consumers;
(3) Work with participating Collectors to develop clear, standardized instructions for Consumers on the use of secure collection bins and a readily-recognizable, consistent design of secure collection bins;
(4) Establish a single, County-specific toll-free telephone number and a single, County-specific web site—which, in the Director's discretion, may be required to be routed through a URL secured by the County— where information about the Collection System(s) and current locations of Drop-Off Sites, Mail-Back Distribution Sites, and Take-Back Events will be publicized;
(5) Prepare and widely distribute, at least on an annual basis and more frequently as requested by the Director, educational and outreach materials promoting safe storage of used Sharps and describing where and how to dispose of Sharps through the Collection System(s). These materials must be provided to pharmacies, healthcare facilities, veterinary facilities, apartment buildings with 50 or more units, workplaces with 100 or more employees, and other interested parties for dissemination to Consumers;
(6) Undertake targeted advertising of Take-Back Events at least one month in advance of the Event; and

(7) Collaborate with home healthcare providers to promote the use of Mail-Back Services by disabled and homebound County Residents and provide metrics on how such collaboration will be effective.

(b) Plain language and explanatory images should be used to make use of the Collection System readily understandable to all County Residents, including individuals with limited English proficiency. Information in these materials must be included on the website required by subsection (a)(4) of this Section.

(c) Within two years after the first 12-month period of Stewardship Plan operation, and biennially thereafter, all approved Stewardship Plans must conduct a survey of County Residents, pharmacists, veterinarians, and health professionals in the County who interact with patients on use of Sharps. The Director shall specify requirements for the survey's content and administration in regulations to be adopted pursuant to this Chapter.

(d) The outreach, education, website, toll-free telephone number, and surveys required by this Section shall be accessible and usable by everyone and shall be translated into languages in an effective and functionally equivalent version as in the English language, in addition to any further requirements specified by the Director in regulations adopted pursuant to this Chapter.

(e) The Safe Sharps Disposal Liaison shall provide guidance on the development and requirements of a single Promotion System.

Sec. B11-569. Stewardship Plans—Annual Report.

(a) Within four months after the end of the first 12-month period of operation, and annually thereafter, the Plan Operator of a Stewardship Plan shall submit a report to the Director on behalf of participating Producers describing their plan's activities during the reporting period. The Director shall specify requirements for the report's content in regulations to be adopted pursuant to this Chapter.

(b) The Agency shall make reports submitted under this Section available to the public, except for any portion marked "Safety and Security Report."

(c) For the purposes of this Section, "reporting period" means the 12-month period since the Stewardship Plan's approval for the first report, and for all subsequent reports, the 12-month period since the previous report.

Sec. B11-570. Stewardship Plans—Administrative and Operational Costs and Fees.

(a) A Producer, group of Producers, or Stewardship Organization participating in a Stewardship Plan shall pay all administrative and operational costs

related to its Stewardship Plan, unless specifically excluded by this Chapter. 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 and replacement of secure collection bins, as requested by Collectors;
(4) Prepaid, preaddressed mail-back containers provided to County Residents;
(5) Operation of periodic Take-Back Events, including costs of law enforcement and Agency staff time if necessary;
(6) Transportation of all collected Sharps to final disposal, including costs of law enforcement escort if necessary;
(7) Environmentally sound disposal of all collected Sharps under this Chapter; and
(8) The Promotion System.

(b) No Person may charge a point-of-sale fee to Consumers to recoup the costs of a Stewardship Plan and compliance with this Chapter, nor may they charge a specific point-of collection fee at the time Consumer-Generated Sharps Waste is collected or Mail-Back Services are provided.

(c) Producers are not required to pay for costs of a Collector's staff time at Drop-Off Sites provided by participating Collectors. However, nothing in this Chapter shall be construed to prohibit such payment, or other compensation to a Drop-Off Site.

Sec. B11-571. Stewardship Plans—County Fees.

(a) The Director is authorized to charge fees to any Producer, group of Producers, or Stewardship Organization participating in a Stewardship Plan to cover all costs that the County incurs in administering and enforcing this Chapter. Fees shall not exceed actual costs to the County of Santa Clara.

(b) If there is any delay in implementation of any component of an approved Stewardship Plan beyond the timelines provided for in this Chapter and such delay is not excused by the Director in writing, the County may collect and dispose of Consumer-Generated Sharps Waste and/or implement any other component of the approved Stewardship Plan on behalf of the Producer, group of Producers, and/or Stewardship Organization participating in the Plan. The Producer, group of Producers, and/or Stewardship Organization participating in the Plan shall be jointly and severally liable for any and all costs the County incurs in collecting and

disposing of Consumer-Generated Sharps Waste and/or implementing any other component of the approved Stewardship Plan on their behalf, and must reimburse the County in full for such costs in a timely manner as provided by the Director.

Sec. B11-572. Stewardship Plans—Enforcement and Penalties.

(a) The Director shall administer the penalty provisions of this Chapter.

(b) For any information required to be submitted by a Producer, group of Producers, or Stewardship Organization, the Director may request that additional information be provided. A Producer, group of Producers, or Stewardship Organization must provide any requested information by the date specified by the Director.

(c) The Producer(s) and Stewardship Organization participating in a Plan are jointly and severally responsible for the truth and accuracy of their representations. If any information provided to the County in connection with a Stewardship Plan is false or inaccurate, the Producer(s) and Stewardship Organization participating in the Stewardship Plan shall, at the discretion of the Director, be subject to the enforcement provisions of this Section.

(d) 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(s) who violated it. The Person(s) shall have thirty (30) days after receipt of the warning to come into compliance and correct all violations.

(e) If the Person(s) fail(s) 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. Division A37 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 noncompliance shall constitute a separate violation for these purposes.

(f) 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 $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.

(g) 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 $1,000 per day per violation. Each day in which the violation continues shall constitute a separate violation.

(h) 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.

(i) 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 against a Producer to enjoin violations of or compel compliance with any requirement of this Chapter imposed on Producers, or any rule or regulation adopted pursuant to this Chapter that creates a requirement imposed on Producers, 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 (i) 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 (i) only if:

(1) It has filed a complaint with the Director;

(2) Ninety (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 of its intent to initiate civil proceedings; and

(4) The County Counsel 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 provides such notice, the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, or nonprofit organization cannot bring suit under this subsection (i) without the express written consent of the County Counsel.

(j) No criminal, civil or administrative action under this Section may be brought more than four years after the date of the alleged violation.

Sec. B11-573. Stewardship Plans—Regulations, Performance Standards, and Report to the Board.

(a) The Director may adopt rules and regulations necessary to clarify, implement, administer, and enforce this Chapter. All regulations adopted under this Chapter shall be first reviewed and approved by the Office of the County Counsel as to form and legality.

(b) The Safe Sharps Disposal Liaison may work with the Plan Operator to define goals for collection amounts, the Promotion System, and other elements of 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. B11-574. Undertaking for the General Welfare.

In adopting and implementing this Chapter, the County is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any Person who claims such breach proximately caused injury.

Sec. B11-575. No Conflict with Federal or State Law.

(a) 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.

(b) Any Producers and/or Stewardship Organizations participating in a Stewardship Plan are jointly and severally responsible for creating and maintaining a Stewardship Plan that complies with all applicable federal, state, and local laws, ordinances and regulations. The County is not responsible in any way for a Stewardship Plan's compliance with any federal, state, or local laws, ordinances, and regulations other than this Chapter. Approval of a Stewardship Plan by the Director does not constitute an opinion on compliance with any other federal, state, or local laws, ordinances, or regulations. Any statement by the Director or any

County official shall not be interpreted as an opinion that any component of a Stewardship Plan is in compliance with any federal, state, or local laws, ordinances or regulations.

(c) Adherence to this Chapter is not meant to replace or satisfy the requirements of any other federal, state, or local laws, ordinances, or regulations. Any review or approval pursuant to this Chapter or regulations is not meant to and shall not be indicative of compliance with or violations of any other federal, state, or local laws.

PASSED AND ADOPTED by the Board of Supervisors of the County of Santa Clara, State of California, on MAR 0 6 2018, 2018 by the following vote:

AYES: CHAVEZ, YEAGER, CORTESE

NOES: NONE

ABSENT: NONE

~~ABSTAIN~~: WASSERMAN, SIMITIAN
RECUSE

S. JOSEPH SIMITIAN, President
Board of Supervisors

ATTEST:

MEGAN DOYLE
Clerk of the Board of Supervisors

APPROVED AS TO FORM AND LEGALITY:

JAVIER SERRANO
Deputy County Counsel

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