

**AN ORDINANCE OF THE BOARD OF SUPERVISORS OF THE COUNTY OF SONOMA, STATE OF CALIFORNIA, ADDING CHAPTER 14A TO THE SONOMA COUNTY CODE TO ESTABLISH THE SONOMA COUNTY SAFE DRUG AND SHARPS DISPOSAL ORDINANCE**

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The Board of Supervisors of the County of Sonoma, State of California, does ordain as follows:

**SECTION I. Chapter 14A of the Sonoma County Code is added to read:**

**Chapter 14A: Safe Drug and Sharps Disposal**

**Sec. 14A-1 - Purpose.**

Purpose. This Chapter establishes a Safe Drug and Sharps Stewardship Program that: (1) Allows for the safe, convenient and sustainable collection and disposal of Unwanted Covered Drugs and Unwanted Sharps by consumers, and (2) Protects, maintains, restores and/or enhances the environment and its natural resources. This Stewardship Program shall be designed, operated, and funded by the Drug and Sharps industries with oversight by the County Department of Health Services, Environmental Health and Safety Section.

**Sec. 14A-2 - Definitions.**

- (a) "Collector" means a Person that gathers Unwanted Covered Drugs and Unwanted Sharps-from Consumers for the purpose of collection, transportation, and disposal. "Collectors" include, but are not limited to, a Retail Pharmacy, law-enforcement Drop-off Site, Mail-back Service, and hospitals/clinics with an on-site Pharmacy.
- (b) "Consumer" means an individual, residing in the Service Area, who receives or purchases Covered Drugs or Sharps for purposes of personal or family use. "Consumer" does not include receiving or purchasing for purposes of dispensing or sale.
- (c) "County" means the unincorporated territory of the county of Sonoma.
- (d) "Covered Drug" means a Drug sold in any form and used by Consumers, including Prescription, Nonprescription, brand-name Drugs, Generic Drugs, Drugs for veterinary use, and Drugs in medical devices and combination products.
  - (1) Notwithstanding the previous sentence, "Covered Drug" does not include:
    - i. Vitamins or supplements;
    - ii. Herbal-based remedies and homeopathic drugs, products, or remedies;
    - iii. 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 (21 U.S.C. 9);
    - iv. Cannabis or cannabis products; and
    - v. Schedule I drugs as defined by the US Drug Enforcement Agency.

- (2) 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 (21 U.S.C. 355-1); and
  - (3) 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.
- (e) "Department" means the County of Sonoma, Department of Health Services, Environmental Health and Safety Section.
- (f) "Drop-off Site" means the location of a Collector where a secure drop box for all Unwanted Covered Drugs and/or Unwanted Sharps is provided for Consumers.
- (g) "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. Pharmacopoeia 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 subsection (1), (2), or (3) of this definition.
- (h) "Enforcement Agency" means the County of Sonoma, Department of Health Services, Environmental Health and Safety Section.
- (i) "Enforcement Officer" means the Registered Environmental Health Specialist, Environmental Health Specialist Trainee or other as authorized by the Director of Health Services, Health Officer, or Director of Environmental Health.
- (j) "Health Officer" as referred to in this Chapter, means the Sonoma County Health Officer or his/her designee.
- (k) "Hearing Officer" as referred to in this Chapter, means the Sonoma County Health Officer or his/her designee.
- (l) "Household Hazardous Waste Program" means Sonoma County Waste Management Agency's program for the collection of household hazardous waste from Sonoma County residents, including Periodic Collection Events.
- (m) "Mailer" means packaging specifications in accordance with 21 Code of Federal Regulations 1317.70 for Unwanted Covered Drugs. Any "Mailer" used for Unwanted Sharps must be in compliance with the United States Food and Drug Administration (FDA).

- (n) "Mail-back Services" means a collection method for the return of Unwanted Covered Drugs and Unwanted Sharps from Consumers utilizing prepaid and preaddressed mailing envelopes for Unwanted Covered Drugs and prepaid and preaddressed mail-back containers for Unwanted Sharps, with each method meeting all applicable rules or regulations.
- (o) "Manufacture" means the production, preparation, propagation, compounding, or processing of Drugs or Sharps but does not include the repacking and/or re-labeling of a Covered Drug or Sharps, or the activities of a Wholesaler or medical practitioner.
- (p) "Manufacturer" means a person, company, corporation or other entity engaged in the Manufacture of Drugs or Sharps.
- (q) "Nonprescription Drug" means a Drug that may be lawfully sold without a prescription.
- (r) "Participating Jurisdiction" means an incorporated city or town within Sonoma County that authorizes the Department to administer and enforce said requirements.
- (s) "Periodic Collection Event" means an event, not hosted in conjunction with a Household Hazardous Waste Program event and/or a U.S. Drug Enforcement Agency (DEA) take back day event, at which a Collector provides a secure collection receptacle for receiving Unwanted Covered Drugs and/or Unwanted Sharps from Consumers, free of charge.
- (t) "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.
- (u) "Pharmacy" means a place licensed by the State of California Board of Pharmacy where the practice of Pharmacy is conducted.
- (v) "Plan Operator" means the Person that develops, implements, and operates a Stewardship Plan, including, but not limited to, a Producer or Stewardship Organization.
- (w) "Prescription Drug" means any Drug, including controlled substance that are required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.
- (x) "Producer" means one of the following:
  - (1) The Person who Manufactures Covered Drugs or Sharps and who sells, offers for sale, or distributes Covered Drugs or Sharps in Sonoma County under that Person's own name or brand-name.
  - (2) If there is no Person who Manufactures Covered Drugs or Sharps and who sells, offers for sale, or distributes Covered Drugs or Sharps in Sonoma County under the Person's own name or brand-name, then the Producer of a Covered Drug or Sharps is the owner or licensee of a brand-name under which the Covered Drug or Sharps are sold or distributed in Sonoma County.

- (3) If there is no Person who is a Producer of Covered Drugs or Sharps for purposes of paragraphs (u)(1) and (2), then the Producer of that Covered Drug or Sharps is the Person who brings that Covered Drugs or Sharps into Sonoma County for sale or distribution.

Notwithstanding the previous sentence, "Producer" does not include:

- (1) A Retailer that puts its store label on a Covered Drug or Sharps, or
  - (2) A pharmacist who dispenses Prescription Drugs or Sharps to, or compounds a prescribed individual Drug product for a Consumer.
- (y) "Program" or "Safe Drug and Sharps Stewardship Program" means the Sonoma County Program described in this Chapter.
- (z) "Retail Pharmacy" means a Pharmacy licensed by the State of California Board of Pharmacy for retail sale and dispensing of Drugs.
- (aa) "Retailer" means any Person that sells Drugs directly to Consumers at a business located in the Service Area.
- (bb) "Safe Medicine Disposal Program" means the existing program that is a partnership between local agencies, Pharmacies, and law enforcement offices to safely dispose of Unwanted Covered Drugs or Unwanted Sharps.
- (cc) "Service Area" means the unincorporated County and all Participating Jurisdictions.
- (dd) "Sharps" means one or more hypodermic needles, pen needles, intravenous needles, lancets and other devices used to penetrate the skin for drawing blood, or for the delivery of Drugs.
- (ee) "Sharps Container" means a rigid puncture-resistant container meeting the standards of, and receiving approval from, the United States Food and Drug Administration (FDA) as a medical device used for the collection of discarded Sharps.
- (ff) "Sharps-only Collector" means a Person that gathers Unwanted Sharps from Consumers for the purpose of collection, transportation, and disposal, including, but not limited to, household hazardous waste facilities, transfer stations, airports, clinics without Pharmacies, schools, or a Mail-back Services.
- (gg) "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 operate a Stewardship Plan.
- (hh) "Stewardship Plan" means a plan for the collection, transportation, and disposal of Consumers' Unwanted Covered Drugs and Unwanted Sharps required under Section 14A-4 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 Producer; and

- (3) Approved by the Department.
- (ii) "Unwanted Covered Drug" means any Covered Drug that the Consumer wishes to discard. This excludes Covered Drugs disposed of by commercial and institutional sources including, but not limited, to hospitals, clinics, board and care facilities and Pharmacies.
- (jj) "Unwanted Sharps" means any Sharps that the Consumer wishes to discard. This excludes Sharps disposed of by commercial and institutional sources including, but not limited to, hospitals, clinics, board and care facilities, and Pharmacies.
- (kk) "Wholesaler" means a Person who buys Drugs or Sharps for resale or distribution to corporations, individuals, or entities other than Consumers.

**Sec. 14A-3 - Jurisdiction.**

This Chapter shall apply only to unincorporated Sonoma County and to Participating Jurisdictions. Each Participating Jurisdiction may delegate administration and enforcement to the Department as authorized by each Participating Jurisdiction's governing body.

**Sec. 14A-4 - Stewardship Plan - Participation.**

- (a) Each Producer shall participate in a Stewardship Plan. Each Producer shall:
  - (1) Operate, individually or jointly with other Producers, a Stewardship Plan approved by the Department; or
  - (2) Enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Stewardship Plan approved by the Department.
- (b) Each Stewardship Plan must be approved by the Department before the entity administering the Stewardship Plan starts collecting Unwanted Covered Drugs and Unwanted Sharps. Once approved, prior to making any changes, each Stewardship Plan must obtain written approval of the Department as described in Section 14A-7.
- (c) Upon request by the Department, each Wholesaler and/or Retailer that sells any Covered Drug or Sharps within the Service Area shall provide a list of the Producers of those Covered Drugs or Sharps to the Department, in a form prescribed by the Department. The list shall include the telephone number, mailing address, and email address of the Wholesaler's and/or Retailer's point of contact.
- (d) Within thirty (30) calendar days after the effective date of this Chapter, or, if a Producer is not already participating in a Stewardship Plan, within thirty (30) calendar days after a Producer starts the sale of a Covered Drug or Sharps within the Service Area, a Producer shall notify the Department in writing of the Producer's intent to participate in an existing Stewardship Plan or to develop a new Stewardship Plan.
- (e) A Producer, either individually or jointly with other Producers, shall:
  - (1) Within sixty (60) calendar days after the effective date of this Chapter, or sixty (60) calendar days after starting sale of a Covered Drug or Sharps in the Service Area, identify in writing to the Department a Stewardship Plan Operator,

including the Plan Operator's telephone, mailing address and email contact information, that is authorized to be the official point of contact for the Stewardship Plan meeting the requirements under this Chapter;

- (2) Within sixty (60) calendar days after the effective date of this Chapter, or sixty (60) calendar days after starting sale of a Covered Drug or Sharps within the Service Area, notify all Retail Pharmacies, hospitals/clinics with Pharmacies, and law enforcement agencies in the Service Area of the opportunity to participate as a Drop-off Site, in accordance with Section 14A-8 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 Service Area;
  - (3) Within ninety (90) calendar days after the effective date of this Chapter, or ninety (90) calendar days after starting sale of a Covered Drug or Sharps in the Service Area, submit a proposed Stewardship Plan as described in Section 14A-5 to the Department for review;
  - (4) Within ninety (90) calendar days after the Department'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 Section 14A-13.
  - (6) Pay all collection and disposal costs of the existing Safe Medicine Disposal Program until the Stewardship Plan is approved and implemented, as of the date that the ordinance codified in this Chapter becomes effective.
    - i. If the County or Participating Jurisdictions incur any costs due to delays, including approved delays, in establishment of an approved Stewardship Plan, the Producer, group of Producers, or Stewardship Organization shall reimburse the County or Participating Jurisdictions in full for such costs.
- (f) 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;
  - (2) Notify the Department of any Producer selling Covered Drugs or Sharps within the Service Area Manufactured by that Producer or group of Producers that is failing to participate in a Stewardship Plan; and
  - (3) Perform any other functions, as authorized by the Department, that 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.
- (g) Pursuant to his or her authority under this Chapter, the Department, may promulgate regulations allowing smaller Producers to engage in alternate means for supporting safe

disposal of Covered Drugs or Sharps in lieu of participating in a Stewardship Plan. Those regulations may, among other things, define which Producers qualify for this alternative.

- (h) The Department may, on a case-by-case basis, approve in writing requests for extensions of time for the submission dates and deadlines in this Section 14A-4.
- (i) The Department may audit the records of a Producer, group of Producers, and/or Stewardship Organization related to a Stewardship Plan, or request that the Producer, group of Producers, or Stewardship Organization arrange for the Department to inspect at reasonable times a Stewardship Plan's or a Collector's or Sharps-only Collector's facilities, vehicles, and equipment used in carrying out the Stewardship Plan. At request of the Department, Producers and Stewardship Organizations shall make records available and shall allow inspection.

**Sec. 14A-5 - Stewardship Plan - Components.**

Each Stewardship Plan shall be submitted and reviewed according to Section 14A-6, and 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 Department 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 services for all Unwanted Covered Drugs and Unwanted Sharps from Consumers in compliance with the provisions and requirements in Section 14A-8, including a list of all collection methods and participating Collectors and Sharps-only Collectors, a list of Drop-off Sites, a description of how any periodic collection events will be scheduled and located, a description of how Unwanted Covered Drugs and Unwanted Sharps Mail-back Services will be provided, a list of the Mailer distribution locations, and examples of the prepaid, preaddressed Mailers the plan will use. The description of the collection service shall include a list of Retail Pharmacies, hospitals/clinics with Pharmacies, and law enforcement agencies contacted by the Plan Operator under Section 14A-4(e)(2) of this Chapter, and a list of all Collectors and Sharps-only Collectors who offered to participate, and if any Collector or Sharps-only Collector who offered to participate was not included in the plan, an explanation for the reason for such decision;
- (c) A description of the handling and disposal system for Unwanted Covered Drugs and Unwanted Sharps including identification of and contact information for Collectors and Sharps-only Collector, transporters and waste disposal facilities to be used by the Stewardship Plan in accordance with Section 14A-8 and Section 14A-9 of this Chapter, as well as their Drug Enforcement Administration registration number, if any; Environmental Protection Agency identification 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 Unwanted Covered Drugs and Unwanted Sharps collected under the Stewardship Plan, including a description of how all Collectors and Sharps-only Collectors, transporters, and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs and Unwanted Sharps are safely and securely tracked from collection through final disposal, 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, Food and Drug Administration, and how any Pharmacy participating as a Collector 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 or Sharps packaging will be promptly destroyed;
- (f) A description of the public education effort and promotion strategy required in Section 14A-11 of this Chapter and how it will be implemented, including a copy of standardized instructions for Consumers, signage developed for Collectors, Sharps-only Collectors, and distribution sites for Mail-back Services, 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 in the Service Area;
- (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) Use of existing providers of waste pharmaceutical services; and
  - (2) Separating Covered Drug or Sharps from packaging to the extent possible, to reduce transportation and disposal costs; and
  - (3) Recycling of Drug and Sharps packaging to the extent feasible; and
- (i) Any additional information specified in regulations adopted by the Department pursuant to this Chapter.

**Sec. 14A-6 - Stewardship Plan - Approval.**

- (a) Within ninety (90) calendar days after the effective date of this Chapter, each Producer, group of Producers and/or Stewardship Organization shall submit its proposed Stewardship Plan to the Department for review, accompanied by the plan review fee in accordance with Section 14A-13, and any regulations adopted pursuant to this Chapter. The Department 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 Department shall review any proposed Stewardship Plan and determine whether it meets the requirements of this Chapter.



- (c) After the review under subsection (b) of this Section 14A-6 and within ninety (90) calendar days after receipt of the proposed Stewardship Plan, the Department shall either approve or reject the proposed Stewardship Plan in writing.
- (d) If the Department rejects a proposed Stewardship Plan that has been submitted for the first time by a Producer, group of Producers, and/or Stewardship Organization, a revised Stewardship Plan must be submitted to the Department within sixty (60) calendar days after receiving written notice of the rejection. The Department shall review and approve or reject a revised Stewardship Plan as provided under subsections (b), (c), and (d) of this Section 14A-6.
- (e) If the Department rejects a revised Stewardship Plan, the Department may deem the Producer, group of Producers, and/or Stewardship Organization out of compliance with this Chapter and subject to the enforcement provisions in this Chapter.
- (f) In approving a proposed Stewardship Plan, the Department 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 (4) years after the Stewardship Plan starts operations, the Producer, group of Producers, and/or Stewardship Organization shall submit an updated Stewardship Plan to the Department explaining any substantive changes to components of the Stewardship Plan required in Section 14A-5. The Department shall review updated Stewardship Plans using the process described in Section 14A-6 of this Chapter.
- (h) All approved and proposed Stewardship Plans submitted under this Section 14A-6 will be made available to the public.

**Sec. 14A-7 - Stewardship Plan - 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 requirement described under Section 14A-8(b)(1), policies and procedures for handling Unwanted Covered Drugs and Unwanted Sharps, or education and promotion methods or disposal facilities, shall be approved, in writing, by the Department before the changes are implemented.
- (b) After the first full year of participation in a Stewardship Plan, a Producer, group of Producers, and/or Stewardship Organization may notify the Department in writing of intent to form a new Stewardship Plan, and identify a new Plan Operator, including the Plan Operator's telephone, mailing address, and email contact information, that is authorized to be the official point of contact for the proposed new Stewardship Plan. Within ninety (90) calendar days of such notification, the Producer, group of Producers, and/or Stewardship Organization shall submit a proposed Stewardship Plan as described under Section 14A-5 to the Department for review.
- (c) A Plan Operator shall submit to the Department any proposed change to the Stewardship Plan as described under subsection (b) of this Section 14A-7 in writing at least thirty (30) calendar days before the change is scheduled to occur.

- (d) The Plan Operator of an approved Stewardship Plan shall notify the Department at least fifteen (15) calendar days before implementing any changes in Drop-off Site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, pre-addressed Mailers, that do not substantially alter achievement of the service convenience requirement under Section 14A-8(b)(1) of this Chapter, or other changes that do not substantially alter plan operations under subsection (b) of this Section 14A-7.
- (e) The Plan Operator may request an advance determination from the Department of whether a proposed change would be deemed to substantively alter plan operations. The Department shall provide a determination within ninety (90) calendar days after receipt of the request, and shall provide reasons for the determination.

**Sec. 14A-8 - Stewardship Plans - Collection System.**

- (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 Pharmacies, law enforcement agencies, Mail-back Services, or other entities, operating in accordance with state and federal laws and regulations for the handling of Unwanted Covered Drug or Unwanted Sharps, including, but not limited to, those of the United States Drug Enforcement Administration, and in compliance with this Chapter. A Pharmacy participating as a Collector shall operate under applicable rules and guidelines of the State of California Board of Pharmacy.
- (b) The collection system for Stewardship Plans shall:
  - (1) Provide ongoing, reasonably convenient, and equitable access for all Consumers in the Sonoma County's Service Area, regardless of the racial, cultural, or socioeconomic composition of the neighborhoods within which the Collector sites are located, with the goal of all Stewardship Plans collectively meeting the following minimum requirements:
    - i. Unincorporated Sonoma County: There shall be two (2) Collectors for Unwanted Covered Drugs and two (2) Collectors for Unwanted Sharps in the unincorporated area of each Supervisorial District. A single location may have a drop-off site for both Unwanted Covered Drugs and Unwanted Sharps.
    - ii. Participating Jurisdictions: Participating Jurisdictions may select their own convenience standards. The default standard, for those who do not specify an alternative, shall be one (1) Collector for Unwanted Covered Drugs and one (1) Collector for Unwanted Sharps per Participating Jurisdiction with an additional Collector of each type for every twenty thousand (20,000) residents.

- iii. Collector sites shall be geographically distributed and strategically located to ensure that every resident has equal access to sites to the greatest extent feasible;
- (2) If the service convenience goals in this subsection (b)(1) cannot be met collectively, the Stewardship Plan(s) shall set forth the reasons for such failure and provide for and cover full cost of periodic collection events and/or increased Mail-back Services or an alternative method as determined by the Department at no cost to the Consumer. The Department, in coordination with the Participating Jurisdiction, shall have discretion to determine which option(s) provides reasonably convenient and equitable access in the County. Any costs incurred by the County or Participating Jurisdictions during Periodic Collection Events shall be covered by the Stewardship Plan;
  - (3) Be safe and secure, including providing for the prompt destruction of patient information on Drug and Sharps packaging;
  - (4) Give priority to: Retail Pharmacies and hospitals/clinics with Pharmacies serving as Collectors and public buildings serving as distribution sites for Mail-Back Services.
  - (5) Include, as Collectors, any Retail Pharmacy or any law enforcement agency willing to serve voluntarily as a Drop-off Site for Unwanted Covered Drugs and Unwanted Sharps and able to meet the requirements of this Chapter within ninety (90) days of their offer to participate, unless the Collector requests a longer time frame. The Stewardship Organization may not discriminate against small or independent Pharmacies, and shall make best efforts to allow such Pharmacies to serve as Collectors under its Stewardship Plan.
  - (6) A Stewardship Plan may also accept other Collectors and Sharps-only Collectors that are able to meet the requirements of this Chapter; and
  - (7) Include a mechanism for distributing to Consumers Sharps Containers designed for the safe handling of Unwanted Sharps within the Consumer's home that is at no cost to the Consumer. This distribution should preferably occur at the point of sale of the injectable Drug to the Consumer, or at the time the Consumer otherwise receives the Sharps for usage. A Sharps Manufacturer that can demonstrate that its product is designed to be protective of public health and safety and/or the environment, such as by housing the Sharp within a built-in retractable device, may apply to the Department for exemption from this specific requirement. The Department shall make such determinations on a case-by-case basis.
  - (8) Make Mail-back Services available and sent, free of charge, to Consumers, upon request, through the Stewardship Plan's toll-free telephone number and website, and through distribution of prepaid, preaddressed Mailers at convenient locations within the Services Area. The toll-free telephone number and website required by Section 14A-8 (b)(6) shall be in English, Spanish, and

other languages as determined by the Department. Mail-back Services must further provide the Household Hazardous Waste Program with a sufficient quantity of prepaid, preaddressed mail-back containers for Unwanted Sharps and prepaid, preaddressed mailing envelopes for Unwanted Covered Drugs to supply the needs of the County Residents who utilize the Household Hazardous Waste Program, including the Household Hazardous Waste Periodic Collection Events.

- (c) Drop-off Sites shall accept all Unwanted Covered Drugs and Unwanted Sharps from Consumers during all hours that the Collector or Sharps-only Collector is normally open for business with the public. Drop-off Sites not operated by a law enforcement agency shall utilize secure drop boxes in compliance with all applicable requirements, including, but not limited to, those of the United States Drug Enforcement Administration and the State of California Board of Pharmacy. Drop-off Sites shall be emptied and otherwise serviced as often as necessary to avoid creating hazardous conditions, including reaching capacity. In the event that more than one (1) Stewardship Plan operates a Drop-off Site at a particular location, each Drop-off Site shall accept all Unwanted Covered Drugs and Unwanted Sharps. Sharps-only Collectors shall accept all Unwanted Sharps.

**Sec. 14A-9 - Stewardship Plan - Disposal.**

- (a) Each Stewardship Plan shall comply with all local, state, and federal laws and regulations applicable to disposal of pharmaceutical waste, sharps and controlled substances.
- (b) Each Stewardship Plan shall provide for the disposal of Unwanted Covered Drug and Unwanted Sharps obtained through collections by incineration, or by rendering them otherwise non-retrievable, in accordance with 21 Code of Federal Regulations 1300.05. Disposal facilities shall possess all required regulatory permits and licenses. The method of destruction shall be consistent with the purpose of rendering all Covered Drugs or Sharps to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes, protect public health and safety, and protect the environment.

**Sec. 14A-10 - Point of Sale.**

- (a) Any Retailer of Covered Drugs or Sharps shall post display materials approved by the Department explaining how and where members of the public may safely and lawfully dispose of Unwanted Covered Drugs and Unwanted Sharps-at no cost to the Consumer. The materials, which will be made available to Retailers by the Stewardship Organization, shall be in English, Spanish, and other languages as determined by the Department, and shall be legible and easily understandable. The materials shall be posted on the premises of the Retailer's place of business in a location visible to the public, if applicable, and adjacent to the area where Covered Drugs and Sharps are dispensed. Mail-order Pharmacies and on-line Pharmacies selling Covered Drugs or Sharps shall provide such materials at the point of sale or with the order.
- (b) The Department may, at his or her discretion, authorize a Retailer to use alternate means to comply with the requirements of subsection (a). No Retailer may sell, or offer

for sale, Covered Drug or Sharps to the public, using any alternate means of compliance with this Chapter, unless specifically authorized to do so in advance in writing by the Department.

**Sec. 14A-11 - Stewardship Plan - Promotion and Outreach.**

- (a) With the guidance and oversight of the Department, all Stewardship Plans within the Service Area shall coordinate with each other and develop a single system of promotion that shall:
- (1) Promote the Stewardship Plans so that collection options for Unwanted Covered Drugs and Unwanted Sharps are widely understood by Consumers, pharmacists, Retailers of Covered Drugs or Sharps, and health care practitioners, including doctors and other prescribers, veterinarians, and veterinary hospitals, and promote the safe storage and disposal of Covered Drugs and/or Sharps by Consumers;
  - (2) Work with Collectors and Sharps-only Collectors participating in Stewardship Plans to develop clear, standardized instructions for Consumers on the use of secure drop boxes and a readily-recognizable, consistent design of secure drop boxes;
  - (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 and produce Department-approved educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drug and Unwanted Sharps to the Stewardship Plan. These materials shall be provided to the Department, Participating Jurisdictions, Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to Consumers. Plain language and explanatory images should be used to make use of collection services readily understandable by all Consumers, including individuals with limited English proficiency, and materials should be translated into Spanish, and such other languages as determined by the Department; and
  - (4) Conduct a biennial survey of Consumers and a survey of pharmacists, veterinarians, and health professionals in Sonoma County who interact with patients about their medicines, after the first each full year of operation of the Stewardship Plans. Survey questions shall measure percent awareness of the Stewardship Plans, assess to what extent Drop-off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings, and overdoses from Prescription and Nonprescription Drugs used in the home. Draft survey questions shall be submitted to the Department for review and comment at least thirty (30) calendar days prior to initiation of the survey. Results of the survey shall be reported to the Department and made available to the public on the website required in this Section 14A-11 within ninety (90) calendar days of the end of the survey period. The privacy of all survey respondents shall be maintained.
- (b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 14A-11, shall be in translated into and conducted in Spanish and such other languages specified by the Department.

**Sec. 14A-12 - Stewardship Plan - Reporting Requirements.**

- (a) Notification to the Department within three (3) business days if a safety or security problem occurred during collection, transportation, or disposal of Unwanted Covered Drugs or Unwanted Sharps and within thirty (30) days of what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security in the future;
- (b) Within ninety (90) days after the end of the first calendar year following approval of the Stewardship Plan operation (no later than March 30<sup>th</sup>), and annually thereafter, the Plan Operator shall submit a comprehensive annual report to the Department, on behalf of participating Producers, describing the plan's activities during the previous annual reporting period. The report shall include:
  - (1) A list of Producers participating in the Stewardship Plan;
  - (2) The amount, by weight, of Unwanted Covered Drugs and Unwanted Sharps collected, including the amount by weight from each collection method used;
  - (3) A list of current Drop-off Sites;
  - (4) A description of the frequency Drop-off Sites shall be emptied and otherwise serviced;
  - (5) The number of Mailers provided for Consumers per location and Periodic Collection Event;
  - (6) The number of Mailers returned and destroyed;
  - (7) The locations where Mailers were provided, if applicable;
  - (8) The dates and locations of collection events held, if applicable;
  - (9) The transporters used and the disposal facility or facilities used for all Unwanted Covered Drugs and Unwanted Sharps;  
A description of the public education, outreach, and evaluation activities implemented during the reporting period;
  - (10) A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
  - (11) A summary of the Stewardship Plan's goals, the degree of success in meeting those goals in the past year, and, if any goals have not been met, what effort will be made to achieve the goals in the next year; and
  - (12) The total expenditures of the Stewardship Plan during the reporting period.
- (c) Within thirty (30) days after the end of the first quarter following approval of the Stewardship Plan operation, and quarterly thereafter, the Plan Operator shall submit a quarterly summary report to the Department, on behalf of participating Producers, describing the plan's activities during the previous quarterly reporting period. The report shall include:

- 1) Additions or subtractions to the List of Producers, if applicable;
  - 2) The amount, by weight, of Unwanted Covered Drugs and Unwanted Sharps collected, including the amount by weight from each collection method used including the total net and gross weight of drugs shipped from Drop-off Sites;
  - 3) The number of containers shipped and number of shipments from each Drop-off-Site;
  - 4) The number of Mailers provided for Consumers per location and Periodic Collection Event;
  - 5) The number of Mailers returned and destroyed;
  - 6) The number, type and size of packages of Unwanted Covered Drugs and Unwanted Sharps collected at each Periodic Collection Event held;
  - 7) The dates and locations of Periodic Collection Events held, if applicable;
  - 8) The number of participants at each Periodic Collection Event held, if applicable; and
  - 9) A description of the public education, outreach, and evaluation activities implemented during the reporting period;
- (d) Reports submitted under this Section shall be made available to the public.
- (e) The Department shall have the discretion to lessen the frequency or extend the timelines of the reporting periods.
- (f) The Department shall have the discretion to require any other reporting the Department deems necessary.
- (g) For the purposes of this Section 14A-12, "quarterly reporting period" means one-fourth of a year periods: January 1 through March 31; April 1 through June 30; July 1 through September 30; October 1 through December 31., "Annual 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 Department.

**Sec. 14A-13 - Fees.**

- (a) A Producer, group of Producers, and/or Stewardship Organization participating in a Stewardship Plan shall submit to the Department, the fee(s) as established by the Sonoma County Board of Supervisors. The fee shall be calculated so as to recover the reasonable regulatory costs of administration and enforcement of this Chapter for the entire Service Area, including, for example, but not limited to, review and approval of Stewardship Plan, administration of the Program, inspection and compliance checks, documentation of violations, late fees for delinquent submittals, and enforcement proceedings, to the extent not otherwise provided for the Stewardship Plan, which shall not exceed the cost of the regulatory program authorized by this Chapter and California law.
- (b) No Person, Producer, group of Producers, and/or Stewardship Organization 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 Unwanted Covered Drugs or Unwanted Sharps are collected.

- (c) A Producer, group of Producers, and/or Stewardship Organization are not required to pay for costs of staff time at Drop-off Sites provided by Collectors or Sharps-only Collectors volunteering to participate in a Stewardship Plan.
- (d) The Board of Supervisors authorizes the Department to charge a Producer, group of Producers, and/or Stewardship Organization participating in a Stewardship Plan fees to cover all costs the County incurs in administering and enforcing this Chapter.
- (e) A Producer, group of Producers, and/or Stewardship Organization participating in a Stewardship Plan shall pay to the Department plan review fees to be established by the Sonoma County Board of Supervisors.
- (f) A Plan Operator or Stewardship Organization may remit fees on behalf of participating Producers.
- (g) The Board of Supervisors authorizes the Department to set fees pursuant to this Chapter by regulation to recover, but not exceed, actual costs to the County at a rate duly approved by the Board of Supervisors.
- (h) 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 a delay is not excused by the Department in writing, the County may collect and dispose of Covered Drugs and Sharps 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 Covered Drugs and Sharps 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 Department.

**Sec. 14A-14 - Stewardship Plan - Enforcement and Fines.**

- (a) The Department may adopt regulations necessary to implement, administer, and enforce this Chapter.
- (b) The remedies provided by this Chapter are cumulative and in addition to any other remedies available at law or in equity.
- (c) The Department shall administer the enforcement and penalty provisions of this Chapter.
- (d) If the Enforcement Officer makes findings and determines that any Person has violated this Chapter or a regulation adopted pursuant to this Chapter, the Enforcement Officer shall provide a written warning to the Person or Persons who violated it. The Person or Persons shall have thirty (30) calendar days after receipt of the warning to come into compliance and correct all violations.



- (e) If the Person or Persons fail to come into compliance with the written warning and correct all violations, the Enforcement Officer may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter. Upon findings made under subsection (d), the Person or Persons shall be subject to an administrative fine set forth in the regulations adopted pursuant to this Chapter. Each day a violation continues constitutes a separate violation.
- (1) Fine procedures. Notice of the fine shall be provided to the Person or Persons. The notice shall contain an advisement of the right to request a hearing before the Hearing Officer contesting the imposition of the fine and shall follow the hearing procedure as outlined in Section 14A-15.
  - (2) Failure to pay fine. If said fine is not paid within thirty (30) calendar days from the date appearing on the notice of the fine or of the notice of determination of the Department after the hearing, the Department may use any lawful means for collecting the fine, including instituting an action in any court of proper jurisdiction.
- (f) Any Person who violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter, is guilty of a misdemeanor and upon conviction thereof is punishable by a fine of not less than fifty (\$50) dollars and not more than five hundred (\$500) dollars for each day per violation, or by imprisonment in the County jail for a period not to exceed six (6) months, or by both such fine and imprisonment, as set forth in Sonoma County Code, Section 1-7.
- (g) Any Person in violation of this Chapter or any rule or regulation adopted pursuant to this Chapter shall be liable to the County for a civil penalty in an amount not to exceed one thousand (\$1,000) dollars per day per violation. Each day in which the violation continues shall constitute a separate violation.
- (h) The County may elect to seek recovery of its own attorneys' fees as set forth in Sonoma County Code Section 1-7. Under Section 1-7, in any action or proceeding where the County seeks recovery of its attorneys' fees, an award of attorneys' fees may be made available to the prevailing party, provided that the award of attorneys' fees to the prevailing party shall not exceed the amount of reasonable attorneys' fees incurred by the County in the same action or proceeding.
- (i) In determining the appropriate fines, the Enforcement Officer 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.

#### **Sec. 14A-15 – Appeals.**

(a) Appeal of Enforcement Action

A decision of the Department to take enforcement action is appealable to the Hearing Officer and shall be filed within fifteen days of the effective notice of the action. If such appeal is received within the fifteen days, a stay of enforcement of the appealed action shall be considered.

(b) Appeal Hearing Procedures

Whenever this Chapter provides for a hearing or an opportunity to be heard, any such hearing shall be conducted in accordance with this section.

- (1) No later than fifteen (15) calendar days after receipt of the request for a hearing, the Hearing Officer shall set a hearing date at the earliest practicable time and shall give notice of the hearing to the parties at least ten (10) calendar days before the date of the hearing.
- (2) Neither the provisions of the Administrative Procedure Act (Government Code Section 11500 et seq.) nor the formal rules of evidence in civil or criminal judicial hearings shall apply to such hearing. At the hearing, the Hearing Officer may admit any evidence, including witnesses, relevant to the determination of the matter, except as otherwise provided in this Chapter.
- (3) The Hearing Officer may continue the hearing from time to time, in his or her sole discretion, to allow for orderly completion of the hearing.
- (4) After the conclusion of the hearing, the Hearing Officer shall issue a written decision. Notice of the written decision, including findings of facts, conclusions of law, and notification of the time period in which judicial review may be sought pursuant to Code of Civil Procedure Section 1094.6 shall be served upon all parties. Any decision rendered by the Hearing Officer shall be a final administrative decision.

- (c) Judicial Review. The decisions of the Hearing Officer on appeal shall be final, subject to judicial review under the provisions of California Code of Civil Procedure Sections 1094.5 and 1094.6. California Code of Civil Procedure Section 1094.6 governs limitation of time for filing petitions under Section 1094.5, as set forth in Sonoma County Code Section 1-7.5.

**Sec. 14A-16 - General Provisions.**

- (a) 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 or employees, an obligation by which they could be liable in money damages to any Person or entity who claims that a breach proximately caused injury.
- (b) No conflict with state or federal law. This Chapter shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any County agency or Department to impose any duties or obligations in conflict with limitations on authority established by State or federal law at the time such agency or Department action is taken. The County shall suspend enforcement of this Chapter to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently taken. 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.

(c) Severability. If any Chapter, section, subsection, paragraph, sentence, clause, or word of this Chapter is, for any reason, held to be unconstitutional or invalid by a court of competent jurisdiction, such decision shall not affect the validity of the remaining portions of this Chapter. To this end, the provisions of this Chapter and its regulations are severable.

(d) [Exemption.] The adoption of this Chapter is categorically exempt from the provisions of the California Environmental Quality Act under California Code of Regulations, Title 14, Sections 15061(b)(3), 15307 and 15308.

## **Section II.**

If any section, subsection, sentence, clause or phrase of this ordinance is for any reason held to be unconstitutional and invalid, such decision shall not affect the validity of the remaining portion of this ordinance. The Board of Supervisors hereby declares that it would have passed this ordinance and every section, subsection, sentence, clause or phrase thereof, irrespective of the fact that any one or more sections, subsections, sentences, clauses or phrases be declared unconstitutional or invalid.

## **Section III.**

Adoption and implementation of this ordinance is exempt from the California Environmental Quality Act ("CEQA") pursuant to Section 15061(b)(3) of the State CEQA Guidelines because it can be seen with certainty that there is no possibility that this ordinance may have a significant effect on the environment. Adoption and implementation of the standards, permit requirements, and other measures contained in the ordinance will not result in any direct physical change to the environment on their own. In the alternative, the adoption and implementation of this ordinance is exempt from CEQA pursuant to Section 15308 of the State CEQA Guidelines as an action taken to assure the maintenance, restoration, enhancement, and protection of the environment where the regulatory process involves procedures for protection of the environment. The basis for this determination is that this ordinance does not in itself approve any construction activities, but instead establishes standards, permit requirements, and other measures that regulate drug and sharps disposal. These standards, permit requirements, and other measures will assure the protection of human health, which is an aspect of the environment under Public Resources Code section 21083(b)(3), by establishing standards and enforcement measures for regulating drug and sharps disposal. The Director of the Department of Health Services is directed to file a notice of exemption in accordance with CEQA and the State CEQA Guidelines.

## **Section IV.**

This ordinance shall be and the same is hereby declared to be in full force and effect from and after thirty (30) days after the date of its passage. A summary of the ordinance shall be published once before the expiration of fifteen (30) days after passage, with the names of the Supervisors voting for or against the same, in *The Press Democrat*, a newspaper of general circulation published in the County of Sonoma, State of California.

In regular session of the Board of Supervisors of the County of Sonoma introduced on the 11<sup>th</sup> day of September, 2018 and finally passed and adopted this \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_\_, on regular roll call of the members of said Board by the following vote:

**Supervisors:**

Gorin:	Rabbitt:	Zane:	Hopkins:	Gore:
Ayes:	Noes:	Absent:	Abstain:	

**WHEREUPON,** the Chair declared the above and foregoing ordinance duly adopted and

**SO ORDERED.**

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Chair, Board of Supervisors  
County of Sonoma

**ATTEST:**

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Clerk of the Board of Supervisors