

ORDINANCE NO. \_\_\_\_\_

**SANTA BARBARA COUNTY CODE**

**CHAPTER 18C – ENVIRONMENTAL HEALTH SERVICES**

**ARTICLE II – SECTION 18C-12 THROUGH 18C-30**

**EXTENDED PRODUCER RESPONSIBILITY STEWARDSHIP FOR THE COLLECTION AND DISPOSAL OF UNWANTED COVERED DRUGS**

**WHEREAS**, the United States Drug Enforcement Agency promulgated regulations at, inter alia, 21 CFR § 1317, et seq. in 2014 allowing the collection of controlled substances at collection receptacles, take-back events, and mail-back programs;

**WHEREAS**, to date, there is no statewide product stewardship program for unwanted medicines in California nor is there a product stewardship program within the incorporated or unincorporated areas of Santa Barbara County;

**WHEREAS**, in the state of California, the City and County of San Francisco, Alameda County, and San Mateo County, and in the state of Washington, Seattle King County, have all adopted similar drug stewardship programs that mandate drug manufacturers to design and implement a safe medicine disposal program;

**WHEREAS**, the California Medical Waste Management Act allows local jurisdictions to promulgate more stringent requirements to dispose of medical waste pursuant to Health and Safety Code section 117800.

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

An ordinance amending Chapter 18C of the Santa Barbara County Code, relating to Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs.

**18C-12 TITLE.**

This article may be cited as the Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs.

**18C-13 DEFINITIONS.**

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

- (A) "Collector" means a Person who gathers Unwanted Covered Drugs from County Residents for the purpose of collection, transportation, and disposal and is registered with the United States Drug Enforcement Administration in accordance with Title 21 of the Code of Federal Regulations (C.F.R.). Collector may include, but is not limited to, law enforcement agencies, Pharmacies, or other entities, operating in accordance with state and federal laws and regulations for the handling of Unwanted Covered Drugs.
- (B) "Controlled Substances" means any substance listed under the California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.
- (C) "Cosmetics" means: (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; (2) articles intended for use as a component of any such articles; and (3) cosmetics as defined above with expiration dates.
- (D) "County" means the incorporated and unincorporated areas of the County of Santa Barbara, California.
- (E) "County Resident" means all human beings residing in the County.
- (F) "Covered Drug" means a Drug sold or distributed in any form and used by County Residents, including Prescription, nonprescription, brand name, Generic Drugs, and Controlled Substances. Notwithstanding the previous sentence, "Covered Drug" does not include: (1) vitamins or supplements; (2) herbal-based and homeopathic remedies, or products; (3) cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9); (4) Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration-managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1); (5) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this article if the Producer already provides a pharmaceutical product stewardship or take-back program; and (6) medical devices or component parts or accessories.
- (G) "Department" means the Santa Barbara County Public Health Department.
- (H) "Director" means the Director of the Santa Barbara County Public Health Department or his or her designee.

- (I) “Drop-off Site” means a location where a Collector provides access to one or more Secure Collection Bins pursuant to a Stewardship Plan for County Residents to safely and securely deposit Unwanted Covered Drugs.
- (J) “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. Pharmacopeial 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 animals; or (4) any substance intended for use as a component of any substance specified in (1), (2), or (3) of this definition. For purposes of this article, Drug shall also include Controlled Substances.
- (K) “Generic Drug” means a Drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.
- (L) “Mailer” means packaging specifications in accordance with 21 C.F.R. 1317.70.
- (M) “Manufacture” means the production, preparation, propagation, compounding or processing of a Drug, but does not include a practitioner who, as an incident to his or her administration or dispensing of a Drug in the course of his or her professional practice, prepares, compounds, packages, or labels such Drug.
- (N) “Manufacturer” means a Person engaged in the Manufacture of a Covered Drug.
- (O) “Mail-back Services” means a collection method for the return of Unwanted Covered Drugs from County Residents utilizing prepaid and preaddressed Mailers for shipment to a Person that will dispose of them in accordance with 21 C.F.R. 1317.05(c) and any other applicable rules or regulations.
- (P) “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.
- (Q) “Plan Operator” means the Person that develops, implements, and operates a Stewardship Plan, including, but not limited to a Producer or a Stewardship Organization.

- (R) "Prescription Drug" means any Drug, including any Controlled Substance that is required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.
- (S) "Producer" means: (1) the Manufacturer of a Covered Drug if it is sold or distributed in the County under a brand-name or Generic Drug that the Manufacturer owns, licenses, or otherwise has rights to; or (2) if there is no Person described in clause (1), the owner or licensee of the brand-name or Generic Drug or the Person who otherwise has rights to the brand-name or Generic Drug under which the Covered Drug is sold or distributed in the County; or (3) if there is no Person described in clause (1) or (2), the importer of the Covered Drug into the County. Notwithstanding the previous, "Producer" does not include: (a) Retail Pharmacy whose store label appears on a Covered Drug or the Drug's packaging if the Manufacturer from whom the Retail Pharmacy obtains the Drug is identified under section 18C-14(D) of this article; or (b) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under section 18C-14(D) of this article; or (c) a pharmacist who compounds or repackages a prescribed individual drug product for a consumer; or (d) a wholesaler who is not also a Manufacturer.
- (T) "Repackager" means a Person who owns or operates an establishment in the County that repacks, relabels or does both to a product or package for further sale, or for distribution without a further transaction but does not include a practitioner who, as an incident to his or her administration or dispensing of a Drug in the course of his or her professional practice, prepares, compounds, packages, or labels such Drug.
- (U) "Retail Pharmacy" means a Pharmacy licensed by the State of California Board of Pharmacy for retail sale and dispensing of Drugs within the County.
- (V) "Secure Collection Bin" means a receptacle in compliance with all applicable requirements set forth by, including but not limited to, the United States Drug Enforcement Administration, Title 21 of the Code of Federal Regulations, and the State of California Board of Pharmacy.
- (W) "Stewardship Organization" means an organization designated by a Producer, either individually or jointly with other Producers, to act as an agent on behalf of one or more Producers to develop, implement, and operate a Stewardship Plan.
- (X) "Stewardship Plan" or "Plan" means a plan for the collection, transportation and disposal of Unwanted Covered Drugs required under section 18C-14 of this article that is: (1) financed, developed, implemented and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; and (3) approved by the Director.

- (Y) “Unwanted Covered Drug” means any Covered Drug that the owner or designee has discarded or intends to discard or has otherwise been abandoned.
- (Z) “Wholesaler” means a Person who buys Drugs for resale and distribution to corporations, individuals, or entities other than consumers.

## **18C-14 STEWARDSHIP PLANS – PARTICIPATION.**

- (A) Each Producer shall participate in a Stewardship Plan. Each Producer must: (1) operate, individually or jointly with other Producers, a Stewardship Plan approved by the Director; or (2) enter into an agreement with a Stewardship Organization to operate, on the Producer’s behalf, a Stewardship Plan approved by the Director.
- (B) Each Stewardship Plan must be approved by the Director as described in section 18C-23 before the entity administering the Plan starts collecting Unwanted Covered Drugs. Once approved, each Stewardship Plan must have prior written approval of the Director for proposed changes as described in section 18C-24.
- (C) By six months after the effective date of this article, or by six months after a Producer starts selling or distributing a Covered Drug in the County, a Producer must notify the Director in writing of the Producer’s intent to participate in a Stewardship Plan, or to form a new Stewardship Plan.
- (D) By whichever occurs first, either, six months after the effective date of this article, or by six months after a Retail Pharmacy whose label appears on a Covered Drug, or a Retail Pharmacy’s packaging starts selling the Covered Drug in the County, or by six months after a repackaged Covered Drug is first sold in the County and thereafter, upon request from the Director, a Retail Pharmacy or Repackager whose label appears on a Covered Drug or its packaging must provide to the Director:
  - (1) the contact information of the Producer from whom the Retail Pharmacy or Repackager obtains the Covered Drug, including the telephone number, mailing address, and email address of the Retail Pharmacy’s or Repackager’s point of contact at the Producer; and
  - (2) written notification as to whether the Producer, from whom the Retail Pharmacy or Repackager obtains a Covered Drug, has provided its (Producer’s) notice of intent to participate or to form a new Stewardship Plan; or
  - (3) documentation that the Retail Pharmacy or Repackager made best efforts to meet the requirements of section 18C-14(D)(2) above.

(E) A Producer, either individually or jointly with other Producers, or through a Stewardship Organization shall:

- (1) By whichever occurs first, either, six months after the effective date of this article, or by six months after starting sale of or distributing a Covered Drug in the County, identify in writing to the Director, a Plan Operator, including the telephone number, mailing address and email contact information, that is authorized to be the official point of contact for the Stewardship Plan;
- (2) By whichever occurs first, either, nine months after the effective date of this article, or by nine months after starting sale of or distributing a Covered Drug in the County, notify all Retail Pharmacies and law enforcement agencies in the County of the opportunity to participate as a Drop-off Site in accordance with section 18C-16 and provide a process for forming an agreement between the Stewardship Plan and interested Collectors; and annually thereafter, make the same notification to any nonparticipating or new Retail Pharmacies in the County;
- (3) By whichever occurs first, either, twelve months (one year) after the effective date of this article or twelve months after starting sale of or distributing a Covered Drug in the County, submit a proposed Stewardship Plan to the Director for review as described in section 18C-23 or identify an existing Stewardship Plan in which the Producer will participate;
- (4) Within three months after the Director's approval of a Stewardship Plan, operate or participate in a Stewardship Plan in accordance with this article; and
- (5) At least every three years after a Stewardship Plan starts operations, submit an updated Stewardship Plan to the Director listing any substantive changes. The updated Stewardship Plan shall be accompanied by the applicable fee(s) in accordance with section 18C-26 of this article. The Director shall review updated Stewardship Plans using the process described in section 18C-23.

(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 a Stewardship Plan;

(2) Notify the Director of any Producer selling or distributing Covered Drugs being Manufactured by a Producer(s) in the County that is failing to participate in a Stewardship Plan; and

(3) Perform any other functions as may be necessary or proper to carry out a Stewardship Plan and to fulfill any or all of the purposes for which the Plan is organized.

(G) After the first full year of participation in a Stewardship Plan, a Producer, either individually or jointly with other Producers, or Stewardship Organization may notify the Director in writing of intent to form a new Stewardship Plan, and identify 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 proposed new Stewardship Plan. Within three months of such notification, the Producer, either individually or jointly with other Producers, or Stewardship Organization shall submit a proposed Stewardship Plan as described under section 18C-15 to the Director for review in accordance with section 18C-23.

(H) A Producer must notify the Director within 30 days of any changes to Producer contact information.

(I) The Director may, on a case-by-case basis, approve in writing, requests for extensions of time for the submission dates and deadlines for the submission of Stewardship Plans, Plan revisions and/or Plan changes. An approved extension of time shall not exceed 3 months.

(J) The Director may audit the records of a Producer(s) or Stewardship Organization related to a Stewardship Plan or request that the Producer(s) 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 a Stewardship Plan.

## **18C-15 STEWARDSHIP PLANS – COMPONENTS.**

Each Stewardship Plan, which must be submitted and reviewed according to section 18C-23, shall include:

(A) Current 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 designated person to whom the Director may direct all inquiries regarding the Producer's participation in the Stewardship Plan;

- (B) A description of the proposed collection system to provide convenient ongoing collection service for all Unwanted Covered Drugs from County Residents in compliance with the provisions and requirements in section 18C-16, including a list of all collection methods and participating Collectors, a list of Drop-off Sites, a description of how any periodic collection events will be scheduled and located, a description of how any Mail-back Services will be provided and an example of the prepaid, preaddressed Mailers the Plan will use. The description of the collection service shall include a list of Retail Pharmacies and law enforcement agencies contacted by the Plan under section 18C-14(E)(2), and a list of all Collectors who offered to participate;
- (C) A description of the handling and disposal system, including identification of and contact information for Collectors, transporters and waste disposal facilities to be used by the Stewardship Plan in accordance with section 18C-19;
- (D) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Stewardship Plan, including a description of how all Collectors, transporters and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Drug Enforcement Administration, and how any Retail Pharmacy collection site will operate under applicable rules and guidelines of the State of California Board of Pharmacy;
- (E) A certification that any patient information on Drug packaging will be promptly destroyed;
- (F) A description of the public education effort and promotion strategy required in section 18C-17, including a copy of standardized instructions for County Residents, signage developed for Collectors, and required promotional materials;
- (G) Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education and promotion; and
- (H) A description of how the Stewardship Plan will consider: (1) use of existing providers of waste pharmaceutical services; (2) separating Unwanted Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and (3) recycling of Unwanted Covered Drugs packaging to the extent feasible.



## **18C-16 STEWARDSHIP PLANS – COLLECTION OF UNWANTED COVERED DRUGS.**

(A) This article 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(s) or Stewardship Organization.

(B) The collection system for each Stewardship Plan shall:

- (1) Provide reasonably convenient and equitable access for all County Residents in all Supervisorial Districts through geographically distributed Drop-off Sites. At no time shall there be less than 5 Drop-off Sites per County of Santa Barbara Supervisorial District. If the service convenience goal in this section 18C-16(B)(1) cannot be achieved due to a lack of Drop-off Sites at Retail Pharmacies, law enforcement agencies, or other qualified Collectors throughout the County, then those areas deficient of Drop-off Sites shall be served through periodic collection events or Mail-back Services. Notwithstanding the requirements in this section 18C-16(B)(1), the Director may permit a Producer(s) selling or distributing a Covered Drug to 5 or fewer County Residents to provide Mail-back Services;
- (2) Be safe and secure, including providing for the prompt destruction of patient information on any and all Unwanted Covered Drug packaging;
- (3) Include as Collectors, and give preference to, any Retail Pharmacy or any law enforcement agency willing to serve voluntarily as a Drop-off Site for Unwanted Covered Drugs and able to meet the requirements of this article within three months of the Collector(s) offer to participate, unless the Collector requests a longer time frame. A Stewardship Plan may also accept other Collectors willing to serve as a Drop-off Site for Unwanted Covered Drugs and able to meet the requirements of this article; and
- (4) Make Mail-back Services available, free of charge, to County Residents upon request through the Stewardship Plan's toll-free telephone number and website, and through distribution of prepaid, preaddressed Mailers to Persons providing services to such County Residents. The toll-free telephone number and website required by this section 18C-16(B)(4) shall be in English, Spanish, and other languages as determined by the Department. In the event that more than one Stewardship Plan places a Secure Collection Bin at a Drop-off Site, then each Secure Collection Bin must accept all Unwanted Covered Drugs.

- (C) In addition to the collection system described in section 18C-16(B)(1), all Producers or Stewardship Organizations may jointly or individually operate a Drop-off Site within each County-owned pharmacy or clinic.
- (D) Drop-off Sites shall accept all Unwanted Covered Drugs, during all hours that the Retail Pharmacy, law enforcement agency, or other Collector is normally open for business with the public. Drop-off Sites not operated by a law enforcement agency shall utilize Secure Collection Bins provided in accordance with an approved Stewardship Plan.
- (E) Stewardship Plans shall describe how it will provide support to any law enforcement agencies within the County that have, or later agree to have, a collection program for Unwanted Covered Drugs, including: (1) the provision of a Secure Collection Bin with appropriate accessories and signage; (2) an ability to accept Unwanted Covered Drugs; (3) technical support up to and including an appropriate Person to provide on-site assistance with the sorting and separation of Unwanted Covered Drugs at no cost to a participating law enforcement agency.
- (F) Commercial and institutional establishments, including but not limited to hospitals, clinics, and Pharmacies, are responsible for proper disposal of its Drug waste and may not utilize any collection mechanism developed pursuant to this article or by any public entity designed for use by, County Residents.

## **18C-17 STEWARDSHIP PLANS – PROMOTION AND EDUCATION.**

- (A) Each Producer, either individually or jointly with other Producers, or through a Stewardship Organization shall develop a system of promotion and education that shall:
  - (1) Promote the Stewardship Plan so that collection options for Unwanted Covered Drugs are widely understood by County Residents, pharmacists, Retail Pharmacies of Covered Drugs and health care practitioners including doctors and other prescribers, veterinarians and veterinary hospitals, and promote the safe storage of Covered Drugs;
  - (2) Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions for County Residents on the use of Secure Collection Bins and a readily-recognizable, consistent design of Secure Collection Bins;
  - (3) Develop display materials explaining how and where Unwanted Covered Drugs may safely and lawfully be disposed. These materials shall be legible and easily understood by

the average person. The display materials shall be submitted to and approved by the Director. Thereafter, materials shall be distributed to all Retail Pharmacies;

- (4) Establish a comprehensive and easy-to-use system for public information including, but not limited to, a single toll-free telephone number and single website where collection options and current locations of Drop-off Sites will be publicized, and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drugs to the Stewardship Plan. These materials must be provided to Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County Residents. Plain language and explanatory images should be used to make use of medicine collection services readily understandable by all County Residents, including individuals with limited English proficiency;
- (5) Conduct a biennial survey of County Residents and a survey of pharmacists, veterinarians, and health professionals who interact with patients on use of Drugs and who all operate within the County. Survey questions shall assess: (1) the awareness of the Stewardship Plans by percentage; (2) the extent that Drop-off Sites and other collection methods are convenient and easy to use; and (3) the knowledge and attitudes about risks of abuse, poisonings and overdoses from Drugs and nonprescription medicines used in the home. Draft survey questions shall be submitted to the Director for review and comment at least 30 days prior to initiation of the survey. Results of the survey shall be reported to the Director and made available to the public on the website required in section 18C-17(A)(4) within 90 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 18C-17 shall be in English, Spanish, and other languages as determined by the Department.

## **18C-18 RETURN INFORMATION AT POINT OF SALE.**

Immediately upon receipt of materials referenced in section 18C-17(A)(3), all Retail Pharmacies are encouraged to post display materials in a location visible to the public and adjacent to the area where Drugs are dispensed.

## **18C-19 STEWARDSHIP PLANS – DISPOSAL OF COVERED DRUGS.**

- (A) Unwanted Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 264 and 265.
- (B) The Director may grant approval for a Stewardship Plan to dispose of some or all collected Unwanted Covered Drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if the Director deems the use of a hazardous waste disposal facility described under section 18C-19(A) to be infeasible for the Stewardship Plan based on cost, logistics or other considerations.
- (C) A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in sections 18C-19(A) and 18C-19(B), or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas: monitoring of any emissions or waste, worker health and safety, reduction or elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution, overall impact on the environment and human health.

## **18C-20 STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS.**

- (A) A Producer, either individually or jointly with other Producers, or a Stewardship Organization shall prepare, implement, and operate its Stewardship Plan as required by this article at its own cost and expense, including but not limited to the costs and expenses of:

- (1) Collection and transportation supplies, such as shipping boxes and liners, for each Drop-off Site;
- (2) Acquisition and distribution to Collectors of all Secure Collection Bins for Drop-off Sites;
- (3) Ongoing maintenance or replacement of Secure Collection Bins, as reasonably requested by Collectors;
- (4) Prepaid, preaddressed Mailers upon request;
- (5) Operation of periodic collection events, including costs of law enforcement staff time if necessary;

- (6) Transportation of all collected Unwanted Covered Drugs to final disposal, including costs of law enforcement escort if necessary;
- (7) Disposal of all collected Unwanted Covered Drugs in accordance with Title 21, Code of Federal Regulations;
- (8) Stewardship Plan promotion and education under section 18C-17 of this article;
- (9) Any review of a Stewardship Plan by Director for purposes of obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.); and
- (10) Any review and oversight by Director of a Stewardship Plan for the purpose of obtaining compliance with this article.

(B) No Person, Producer(s) or Stewardship Organization may charge a point-of-sale fee to consumers to recoup the costs of a Stewardship Plan, nor may a Person, Producer(s) or Stewardship Organization charge a specific point-of-collection fee at the time the Unwanted Covered Drugs are collected.

(C) Producers are not required to pay for costs of staff time provided by Collectors volunteering to participate in a Stewardship Plan.

## **18C-21 STEWARDSHIP PLANS – REPORTING REQUIREMENTS.**

(A) Within six 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 the Plan's activities during the previous reporting period. The report must include:

- (1) A list of Producers participating in the Stewardship Plan;
- (2) The amount, by weight, of Unwanted Covered Drugs collected, including the amount by weight from each collection method used;
- (3) A list of Drop-off Sites;
- (4) The number of Mailers provided;
- (5) The Retail Pharmacies where Mailers were provided, if applicable;
- (6) The dates and locations of collection events held, if applicable;

- (7) The transporters used and the disposal facility or facilities used for all Unwanted Covered Drugs;
- (8) Whether any safety or security problems occurred during collection, transportation or disposal of Unwanted Covered Drugs during the reporting period and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and to improve safety and security in the future;
- (9) A description of the public education, outreach and evaluation activities implemented during the reporting period, including the results of the biennial survey pursuant to section 18C-17(A)(5) if applicable for 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;
- (12) The total expenditures of the Stewardship Plan during the reporting period; and
- (13) An Executive Summary.

(B) Any change in Plan Operator or Producers participating in a Plan must be provided to the Department within 30 days of the change.

(C) The Director shall make reports submitted under this section 18C-21 available to the public.

(D) For the purposes of this section 18C-21, "reporting period" means the period from January 1 through December 31 of the same calendar year, unless otherwise specified to the Plan Operator by the Director.

## **18C-22 STEWARDSHIP PLANS – LIST OF PRODUCERS OF COVERED DRUGS.**

Beginning 60 days after the effective date of this article, each Wholesaler that sells, starts to sell, or distributes any Covered Drug in the County must provide a list of the Producers of those Covered Drugs to the Director in a form prescribed by the Director. Wholesalers must update and resubmit the list by January 15 each year.

## **18C-23 STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS.**

- (A) By whichever occurs first, either, twelve months (one year) after the effective date of this article, or twelve months after starting sale of or distributing a Covered Drug in the County, each Producer, either individually or jointly with other Producers, or Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review, accompanied by the applicable fee(s) in accordance with section 18C-26 of this article. The Director may, upon request, provide information, counseling, and technical assistance about the requirements of this article to assist with the development of a proposed Stewardship Plan.
- (B) The Director shall review the proposed Stewardship Plan and determine whether it meets the requirements of this article.
- (C) After the review under section 18C-23(B) and within 90 days after receipt of the proposed Stewardship Plan, the Director shall either approve or reject the proposed Stewardship Plan in writing and, if rejected, provide reasons for the rejection.
- (D) If the Director rejects a proposed Stewardship Plan, a Producer, either individually or jointly with other Producers, or Stewardship Organization must submit a revised Stewardship Plan to the Director within 60 days after receiving written notice of the rejection. The Director shall review and approve or reject a revised Stewardship Plan as provided under sections 18C-23(B) and 18C-23(C).
- (E) If the Director rejects a revised Stewardship Plan, or any subsequently revised Plan, the Director may deem the Producer(s) out of compliance with this article and subject to the enforcement provisions in this article.
- (F) The Director shall make all Stewardship Plans and proposed Plans submitted under this section 18C-23 available to the public.

## **18C-24 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, policies and procedures for handling Unwanted Covered Drugs or education and promotion methods or disposal facilities, must be approved, in writing, by the Director before the changes are implemented. A Producer, either individually or jointly with other Producers, or a Stewardship Organization participating in a Stewardship Plan shall submit to the Director any proposed change to a Stewardship Plan as described under section 18C-24(A) in writing at least 30 days before

the change is scheduled to occur and accompanied by the applicable fee in accordance with section 18C-26 of this article.

(B) The Plan Operator of an approved Stewardship Plan shall notify the Director at least 15 days before implementing any changes to Drop-off Site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, preaddressed Mailers, that do not substantively alter achievement of the service convenience goal under section 18C-16(B) of this article, or other changes that do not substantively alter Plan operations under section 18C-24(A).

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

## **18C-25 STEWARDSHIP PLANS – ENFORCEMENT AND PENALTIES.**

(A) The Director shall administer the penalty provisions of this article. If the Director determines that any Person has violated this article or a regulation adopted pursuant to this article, the violation shall constitute an infraction. Any violation of the provisions of this article by any Person is also subject to administrative fines as provided in Chapter 24A of the Santa Barbara County Code. These remedies are not exclusive of any other remedies available under other federal, state or local laws and it is within the discretion of the Director to seek cumulative remedies.

(B) Any Person who knowingly and willfully violates the requirements of this article or any rule or regulation adopted pursuant to this article is guilty of a misdemeanor and upon conviction thereof is punishable by a fine of not less than fifty dollars (\$50) and not more than one thousand (\$1,000) for each day per violation, or by imprisonment for a period not to exceed six months, or by both such fine and imprisonment.

(C) Any Person in violation of this article or any rule or regulation adopted pursuant to this article shall be liable to the County for a civil penalty in an amount not to exceed one thousand dollars (\$1,000) per day per violation. Each day in which the violation continues shall constitute a separate violation. Civil penalties shall not be assessed pursuant to this section 18C-25(C) for the same violations for which the Director assessed an administrative penalty pursuant to section 18C-25(A).

(D) 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.



## **18C-26 FEES.**

(A) The Board of Supervisors authorizes the Director to charge the fees identified in this article. A Producer, either individually or jointly with other Producers, or Stewardship Organization shall pay to the County the applicable fee(s) to be established for:

- (1) Submittal and review of a proposed Stewardship Plan;
- (2) Review of re-submittal(s) of a proposed Stewardship Plan;
- (3) Review of changes to an approved Stewardship Plan;
- (4) Submittal and review of an updated Stewardship Plan at least every three years under section 18C-14(E)(5) of this article;
- (5) Review of any petition for approval to use alternative final disposal technologies under section 18C-19(C) of this article;
- (6) Notwithstanding (1) through (5) above, other applicable fees that may be recommended by the Director and approved by the County of Santa Barbara Board of Supervisors.

(B) In addition to the above listed fees, each Plan Operator shall pay to the County of Santa Barbara an annual operating fee to be established.

(C) As soon as practicable, the Director shall recommend to the Board of Supervisors a schedule of fees to charge a Producer(s) or Stewardship Organization to cover costs of administering and enforcing this article. The Director shall recommend fees to recover but not exceed actual costs to the County. The Auditor-Controller shall confirm that the fees recommended by the Director do not exceed the actual costs to the County. The Board of Supervisors must approve the schedule of fees for it to become effective.

## **18C-27 UNDERTAKING FOR THE GENERAL WELFARE.**

In adopting and implementing this article, 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 that such breach proximately caused injury.

## **18C-28 NO CONFLICT WITH FEDERAL OR STATE LAW.**

This article shall be construed so as not to conflict with applicable federal or state laws, rules or regulations. Nothing in this article shall authorize any agency or department to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such agency or department action is taken. The County shall suspend enforcement of this article to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted. Nothing in this article 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.

## **18C-29 SEVERANCE.**

If any of the provisions of this article or the application thereof to any Person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this article are severable.

## **18C-30 EXISTING COUNTY CODE.**

This article is meant to supplement, not amend, any existing provision of the County Code. In the event a conflict arises between a provision of the County Code and any provision of this article, this article shall prevail.

This ordinance shall take effect and be in force 30 days from the date of its passage and before the expiration of 15 days after its passage a summary of it shall be published once together with the names of the members of the Board of Supervisors voting for and against the same in the Santa Barbara News-Press, a newspaper of general circulation published in the County of Santa Barbara.

**PASSED, APPROVED AND ADOPTED** Barbara, State of California, this \_\_\_\_\_ day of \_\_\_\_\_ 2016 by the following vote:

AYES:

NOES:

ABSTAIN:

ABSENT:

COUNTY OF SANTA BARBARA

By: \_\_\_\_\_  
CHAIR, BOARD OF SUPERVISORS

ATTEST:  
MONA MIYASATO, COUNTY EXECUTIVE OFFICER  
CLERK OF THE BOARD

By: \_\_\_\_\_  
Deputy Clerk

APPROVED AS TO FORM:  
MICHAEL C. GHIZZONI  
COUNTY COUNSEL

APPROVED AS TO FORM:  
THEODORE A. FALLATI, CPA  
AUDITOR-CONTROLLER

By: \_\_\_\_\_  
Deputy County Counsel

By: \_\_\_\_\_  
Deputy

APPROVED:  
TAKASHI M. WADA, MD, MPH  
DIRECTOR  
PUBLIC HEALTH DEPARTMENT

By: \_\_\_\_\_  
Director