

ORDINANCE NO. 2016-_____

(Safe Drug Disposal)

The Contra Costa County Board of Supervisors ordains as follows:

SECTION I. SUMMARY. This ordinance adds Chapter 418-16 to the Contra Costa County Ordinance Code to establish a stewardship program for the collection and disposal of unwanted prescription drugs.

SECTION II. AUTHORITY. This ordinance is adopted pursuant to Health and Safety Code section 101025 and article XI, section 7 of the California Constitution.

SECTION III. FINDINGS.

- (a) Prescription drugs allow people to live longer, healthier and more productive lives.
- (b) There is a lack of sufficient safe and convenient disposal locations for unwanted prescription drugs in this county.
- (c) As a result, unwanted prescription drugs are often left in homes, where they can be accidentally ingested by children, adults and the elderly, thus increasing their risk of poisoning and death.
- (d) The improper or careless disposal of unwanted prescription drugs can also lead to illegal resales of drugs and drug addiction.
- (e) Nationwide, the drug overdose death rate increased by 137 percent from 2000 to 2014. Nearly 500,000 people died from drug overdoses in that time period. More than 50 percent of those deaths were related to overdoses of prescription drugs, primarily opioids.
- (f) The sales of, and overdose-related deaths from, prescription opioids quadrupled nationwide from 1999 to 2010. From 1999 to 2014, more than 165,000 people died from prescription opioid-related overdoses.
- (g) In Contra Costa County, 75 percent of the 96 accidental drug overdose deaths reported to the Contra Costa County Coroner’s Office in 2014 involved prescription drugs.
- (h) Opioid prescription guidelines have been developed and implemented at emergency rooms throughout Contra Costa County to limit the potential for opioid abuse. However, prescription limitations alone are not enough.
- (i) A survey conducted by the Contra Costa Health Services Public Health Division in 2016 revealed that 73 percent of 1,653 respondents reported having unused or leftover prescription drugs in their homes. Of 1,204 respondents, 43 percent said they hadn’t gotten around to disposing of them, 38 percent said there was no convenient means of proper disposal and 18 percent were uncertain how to properly dispose of them.
- (j) These accumulated drugs pose a serious risk of misuse, abuse and death of residents of Contra Costa County.
- (k) There is currently no mandatory statewide drug stewardship program for unwanted household drugs in California.
- (l) The West Contra Costa Integrated Waste Management Authority, Central Contra Costa Sanitary District and Delta Diablo Sanitation District currently provide collection bins at

locations such as the County hospital, police stations and waste disposal facilities, but only for unwanted drugs that are not controlled substances.

(m) Unused prescription opioids and other controlled drugs, however, may be lawfully collected only by law enforcement and pharmacists, and to date collection options for these types of drugs are very limited. Only two police stations and two pharmacies in Contra Costa County collect unused controlled drugs, and none is located in the unincorporated area. The U.S. Drug Enforcement Administration sponsors take-back events where controlled drugs may be dropped off, but these events are held only a few times each year.

(n) Due to the limitations of these collection options, the above measures do not go far enough to address the risks of misuse, addiction and death from prescription drugs, particularly those drugs that are controlled substances.

(o) Because existing programs to take back unused and unwanted prescription drugs are either too limited or not convenient, establishing the drug stewardship program described in this ordinance is necessary to preserve and protect the health of residents of Contra Costa County.

(p) The drug stewardship program described in this ordinance will benefit the public by significantly increasing convenient disposal options for county residents, enabling collection of larger quantities of unwanted prescription drugs and reducing the above risks to public health.

SECTION IV. Chapter 418-16 is added to the County Ordinance Code, to read:

Chapter 418-16 Safe Drug Disposal

418-16.202 Definitions.

For purposes of this chapter, the following words and phrases have the following meanings:

- (a) “Approved stewardship plan” means a stewardship plan approved by the health officer.
- (b) “Approved stewardship program” means a stewardship program that is described in and operates in accordance with an approved stewardship plan.
- (c) “Collector” means a person or government entity that collects unwanted covered drugs in an approved stewardship program.
- (d) “County residents” means human beings who reside in the unincorporated area of the county.
- (e) “Covered drug” means a prescription drug as defined in subsection 418-16.202(l).
- (f) “Drug” means a drug defined in section 321(g)(1) of title 21 of the United States Code, but does not include any of the following:
 - (1) Vitamins or supplements;
 - (2) Herbal-based remedies and homeopathic drugs, products or remedies;
 - (3) Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.);
 - (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 under section 355-1 of title 21 of the United States Code;

(5) Biological products as defined by 21 Code of Federal Regulations part 600.3(h) (2015) for which a producer provides a pharmaceutical product stewardship or take-back program; and

(6) Medical devices or their component parts or accessories.

(g) “Drug wholesaler” means a person who engages in the sale or distribution of covered drugs to retailers or other entities located in the unincorporated area of the county but not individual consumers.

(h) “Mail-back service” means a collection method for the return of unwanted covered drugs that utilizes prepaid and preaddressed mailing envelopes.

(i) “Manufacturing” means the production, preparation or compounding of a drug, but does not include the repackaging or relabeling of a drug or the preparation, compounding, packaging, labeling, dispensing or distribution of a drug by a practitioner in the course of his or her professional practice.

(j) “Manufacturer” means a person engaged in manufacturing.

(k) “Pharmacy” means a place licensed by the State of California Board of Pharmacy where the practice of pharmacy is conducted.

(l) “Prescription drug” means a drug as defined in subsection 418-16.202(f) that is required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.

(m) “Producer” means the manufacturer of a covered drug that is sold or distributed in any form in the unincorporated area of the county.

(n) “Retail pharmacy” means a pharmacy licensed by the State of California Board of Pharmacy for the retail sale and dispensing of drugs.

(o) “Stewardship plan” means a written document that describes a stewardship program.

(p) “Stewardship program” means a program operated by or on behalf of a producer that provides for the collection, transportation and disposal of unwanted covered drugs generated by county residents.

(q) “Stewardship organization” means a person designated by a producer to develop or implement a stewardship plan or operate a stewardship program on behalf of the producer.

(r) “Unwanted covered drug” means any covered drug that a county resident has obtained and intends to discard, or has discarded, or has abandoned. (Ord. 2016-___ § 4).

418-16.204 Drug wholesalers.

Within 60 days after the effective date of this chapter, and no later than April 1 of every year thereafter, a drug wholesaler shall submit written notification to the health officer of the names and manufacturers of all covered drugs that the drug wholesaler sells or distributes in the unincorporated area of the county. (Ord. 2016-___ § 4).

418-16.206 Producers.

A producer shall satisfy all of the obligations set forth in this section, either individually, jointly with other producers, or by and through a stewardship organization:

(a) Notice of intent.

(1) Within six months after the effective date of this chapter, a producer shall provide written notice to the health officer of the producer’s intent to participate in a stewardship program.

(2) Within six months after the commencement of sale or distribution in the unincorporated area of the county of a covered drug manufactured by the producer, a producer that has not submitted the notice described in subsection 418-16.206(a)(1) shall submit that notice to the health officer.

(b) Identification of operator.

(1) Within nine months of the effective date of this chapter, a producer shall provide written notice to the health officer of the name of, and contact information for, a person who operates or will operate a stewardship program in which the producer intends to participate.

(2) Within nine months of commencement of sale or distribution in the unincorporated area of the county of a covered drug manufactured by the producer, a producer who has not submitted the notice described in subsection 418-16.206(b)(1) shall submit that notice to the health officer.

(c) Notification to retail pharmacies and law enforcement.

(1) Within nine months after the effective date of this chapter, a producer shall provide written notices to all retail pharmacies located in the county and all law enforcement agencies with jurisdiction in the county of the opportunity to participate as collectors. The notice must explain the process for entering into an agreement to participate in the stewardship program.

(2) Within nine months of commencement of sale in the unincorporated area of the county of a covered drug manufactured by the producer, a producer who has not provided the notices described in subsection 418-16.206(c)(1) shall provide those notices to the designated recipients.

(3) Annually after providing the notices required under subsections 418-16.206(c)(1) or 418-16.206(c)(2), a producer shall provide the same notices to all nonparticipating or new retail pharmacies located in the county.

(d) Plan submission; fee.

(1) Within one year after the effective date of this chapter, a producer shall submit to the health officer a stewardship plan that conforms to the requirements set forth in section 418-16.208, together with payment of a fee established by the board by resolution.

(2) Within one year after commencement of sale in the unincorporated area of the county of a covered drug manufactured by the producer, a producer who has not submitted a stewardship plan under subsection 418-16.206(d)(1) shall submit to the health officer a stewardship plan that conforms to the requirements set forth in section 418-16.208, together with payment of a fee established by the board by resolution. If a producer seeks to participate in an existing approved stewardship program in lieu of commencing a new stewardship program, the plan required by this subsection must be an amended stewardship plan, and the amended stewardship plan must be submitted by all of the producers identified in the amended plan.

(e) Plan implementation.

(1) Except as set forth in subsection 418-16.206(e)(2), within 90 days after the health officer's approval of a stewardship plan under subsection 418-16.210(b), a producer shall implement the plan by commencing operation of the stewardship program described in the plan. Commencement of operations of an approved stewardship program must include:

(A) Establishment of the drop-off sites and mail-back services identified in the approved stewardship plan.

(B) Public notice of the availability of unwanted covered drug collection services through postings at collection sites and advertising in local media.

(2) Changes to an approved stewardship program that are set forth in an amended stewardship plan that has been approved by the health officer under subsection 418-16.212(a)(1) must be implemented by the participating producer(s) within 10 business days after the approval.

(f) Program participation. A producer shall participate in an approved stewardship program by providing for the continued operation of an approved stewardship program in accordance with an approved stewardship plan. (Ord. 2016-___ § 4).

418-16.208 Content of stewardship plans.

A stewardship plan must fully describe a stewardship program. The plan must include all of the following:

(a) Identification of and contact information for each participating producer.

(b) Identification of and contact information for the person who will operate the stewardship program.

(c) Description of a collection system that conforms to Section 418-16.214(a), including a list of all collection methods and collectors, a list of drop-off sites, a description of how any periodic take-back events will be scheduled and located, a description of how mail-back services will be provided and an example of the prepaid, preaddressed mailers that may be used.

(d) Description of a system for transporting and disposing of the collected unwanted covered drugs that conforms to section 418-16.216, including identification of, and contact information for, transporters and disposal facilities to be used.

(e) Description of the policies and procedures to be followed by persons handling collected unwanted covered drugs, including a description of (1) how the collected unwanted covered drugs will be safely and securely tracked from collection through final disposal; (2) how all persons participating in the stewardship plan will comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the U.S. Drug Enforcement Administration and State of California Board of Pharmacy.

(f) Description of measures reasonably calculated to result in the use by county residents of the collection services to be offered under the stewardship program, such as public education and promotional materials, signage, standardized instructions and establishment of a toll-free number and website where collection options may be publicized.

(g) The short-term and long-term goals of the stewardship program in terms of collection amounts, education, and promotion.

(h) Description of how the stewardship program will consider:

(1) Use of existing providers of pharmaceutical waste services;

(2) Separation of covered drugs from packaging to the extent feasible to reduce transportation and disposal costs; and

(3) Recycling of drug packaging to the extent feasible. (Ord. 2016-___ § 4).

418-16.210 Inspection, approval and rejection of stewardship plans.

(a) Upon submission of a stewardship plan, the health officer will inspect it for the purpose of determining whether it satisfies the requirements set forth in section 418-16.208.

(b) Within 90 calendar days after submission of a stewardship plan, the health officer will either approve or reject the plan. If the plan conforms to the requirements set forth in section 418-16.208, the health officer will approve the plan and provide written notice to the producer of the approval.

(c) If the health officer rejects a stewardship plan, the health officer will provide to the producer written notice of the rejection that includes the reasons for the rejection.

(d) Within 60 calendar days after the date of the written notice of rejection of a stewardship plan for a new stewardship program, the producer shall submit to the health officer a revised stewardship plan that conforms to the requirements set forth in section 418-16.208, together with payment of a fee established by the board by resolution.

(e) If the health officer rejects a revised stewardship plan, each producer identified in the plan is in violation of this chapter and will remain in violation of this chapter until the producer commences participation in an approved stewardship program. (Ord. 2016-___ § 4).

418-16.212 Changes to existing stewardship programs; new programs.

(a) Changes.

(1) Substantive changes may be made to an existing approved stewardship program only with the prior written approval of the health officer. Substantive changes include changes in the location, number or operating hours of drop-off sites or periodic take-back events; changes in collection methods; changes in mail-back service procedures; changes in the policies or procedures to be followed by persons handling collected unwanted covered drugs; changes required in response to federal, state or local laws or regulations; and changes in stewardship program operators or participating producers. Except as set forth in subsection 418-16.206(d)(2), the participating producers identified in the approved stewardship plan shall submit any proposed substantive changes to the health officer in the form of an amended stewardship plan, along with a written explanation of the change(s) and payment of a fee established by the board by resolution. The health officer will approve an amended stewardship plan if it conforms to applicable requirements set forth in section 418-16.208. If an amended stewardship plan submitted to the health officer under this section is rejected by the health officer for non-conformance with the applicable requirements set forth in section 418-16.208, the approved stewardship program may continue to operate in accordance with the approved stewardship plan.

(2) The following non-substantive changes to an approved stewardship program may be made only with 20 days advance written notification by the program operator to the health officer: Changes in location of a collection kiosk within a retail pharmacy; changes in methods of distribution of prepaid, preaddressed mailers used for the mail-back of unwanted covered drugs; changes in contact information for the program operator and participating producers; and changes in the system described in Subsection 418-16.208(d).

(3) Other than the changes described in subsections 418-16.212(a)(1) and 418-16.212(a)(2), changes may be made to an approved stewardship program without the prior approval of or notification to the health officer.

(4) An approved stewardship plan that is changed in accordance with this section will be deemed an approved stewardship plan. An approved stewardship program that is changed in accordance with this section will be deemed an approved stewardship program.

(b) New programs. After implementation of an approved stewardship program, a participating producer may propose the formation of a new stewardship program by submitting to the health officer a stewardship plan that conforms to the requirements set forth in section 418-16.208, together with payment of a fee established by the board by resolution. (Ord. 2016-___ § 4).

418-16.214 Collection of unwanted covered drugs.

(a) Collection system requirements. A stewardship program's collection system must meet all of the following requirements:

(1) Provide safe and secure collection services within the unincorporated area.

(2) Provide for the operation of at least three drop-off sites in each supervisorial district for the collection of unwanted covered drugs, in locations that allow for convenient and equitable access by residents of the unincorporated areas of those districts, to the greatest extent feasible. If providing for the operation of at least three drop-off sites is not feasible in a supervisorial district, a stewardship program's collection system must provide for the operation of as many drop-off sites in the district as is feasible, in addition to both of the following methods of collection of unwanted covered drugs:

(A) A free mail-back service that allows for convenient and equitable access by all county residents in the district.

(B) Periodic take-back events that are at least six hours in length and held once per quarter of each calendar year in at least three locations in the district.

(3) Give preference to having retail pharmacies and law enforcement agencies serve as collectors.

(4) Include, as collectors, any retail pharmacy or any law enforcement agency that offers to serve as a collector of unwanted covered drugs and is able to meet the requirements of this chapter within three months of the offer.

(5) Make available free mail-back services to county residents who are disabled or homebound, in a manner that allows for convenient and equitable access to these services by these persons.

(b) Collector requirements.

(1) A collector shall operate a drop-off site in accordance with this chapter and all applicable state and federal laws and regulations applicable to the handling of covered drugs.

(2) A collector shall accept all unwanted covered drugs from county residents during all hours that the collector is normally open for business.

(3) A collector that is not a law enforcement agency shall utilize secure collection bins in compliance with all applicable legal requirements.

(c) Commencement. The collection of unwanted covered drugs under a stewardship program under this chapter may commence only after the stewardship plan under which the program will operate has been approved by the health officer.

(d) Nothing in this chapter shall be construed to require any person or government entity to serve as a collector under a stewardship plan. (Ord. 2016-___ § 4).

418-16.216 Transport and disposal.

(a) All unwanted covered drugs that are collected under an approved stewardship program must be transported only by a person who operates under all required permits and licenses.

(b) All unwanted covered drugs that are collected under an approved stewardship program must be disposed of only at a medical waste facility or hazardous waste facility that operates under all required permits and licenses. (Ord. 2016-___ § 4).

418-16.218 Reporting.

Within six months after the end of the first 12-month period of operation of an approved stewardship program, and annually thereafter, the program operator shall submit a report to the health officer that details the following information about program operations during the reporting period:

- (a) A list of all participating producers.
- (b) The weight of all unwanted covered drugs collected, including the weight of unwanted covered drugs collected using each collection method utilized in the program.
- (d) A list of all drop-off sites.
- (e) The number of mailers provided to county residents.
- (f) The locations where mailers were provided, if applicable.
- (g) The dates and locations of collection events held, if applicable.
- (h) A list of all transporters used.
- (i) A list of all facilities to which the collected unwanted covered drugs were transported.
- (j) Any safety or security problems that occurred during collection, transportation or disposal of unwanted covered drugs, and changes made or proposed to alleviate those problems.
- (k) A description of all public education and promotion activities.
- (l) A description of how collected packaging was recycled to the extent feasible; including identification of the recycling facilities used.
- (m) A discussion of the degree of success in meeting the short- and long-term goals of the approved stewardship program, and to the extent goals were not met, plans to achieve those goals in the next reporting period.
- (n) Total expenditures of the approved stewardship program. (Ord. 2016-___ § 4).

418-16.220 Costs and fees.

(a) The administrative and operational costs of an approved stewardship program will be the sole responsibility of the participating producer(s), except as set forth in subsection 418-16.220(c).

(b) No person may charge a point-of-sale fee or point-of-collection fee to recoup any costs of an approved stewardship program.

(c) Nothing in this chapter shall be construed to require a producer to pay for staff time provided by collectors who agree to participate in an approved stewardship program.

(d) Revenues from fees paid under this chapter may be used only to pay for the costs incurred by the health officer in the performance of investigations, inspections and audits under this chapter and the administrative enforcement and adjudication thereof. (Ord. 2016-___ § 4).

418-16.222 Audits, inspections and investigations.

(a) Audits. The health officer may audit the records of stewardship program for the purpose of enforcing the provisions of this chapter. Upon request of the health officer, the operator of the program shall provide the health officer with access to perform audits of the program's records at reasonable times.

(b) Inspections and investigations. Whenever it is necessary to inspect a drop-off site or other property to enforce the provisions of this chapter, or whenever the health officer has cause to believe that there exists on any property any violation of this chapter, the health officer may enter the property to inspect and gather evidence or perform the duties imposed on the health

officer by this chapter. Entry may be made at any reasonable time upon advance notice to the owner or occupant of the property. If entry is refused, the health officer is authorized to proceed pursuant to Code of Civil Procedure section 1822.50 and following, and pursue any and all other remedies provided by law, to secure entry. (Ord. 2016-___ § 4).

418-16.224 Enforcement.

(a) The health officer will enforce the provisions of this chapter.

(b) If the health officer determines that any person has violated any provision of this chapter, the health officer shall provide written notice of the violation to the person who violated it and provide an opportunity to the person to cure the violation before the health officer takes any other enforcement action authorized by this code. The person shall have 30 calendar days after receipt of the notice, or other time agreed to in writing by the person and the health officer, to correct the violation. (Ord. 2016-___ § 4).

418-16.226 Regulations.

The health officer may propose regulations to make more detailed or specific the provisions of this chapter. The regulations are not effective unless adopted by the board by resolution. Effective regulations will be deemed incorporated into this chapter by this reference. (Ord. 2016-___ § 4).

SECTION V. EFFECTIVE DATE. This ordinance becomes effective 30 days after passage, and within 15 days after passage shall be published in the East Bay Times, a newspaper published in this County. This ordinance shall be published in a manner satisfying the requirements of Government Code section 25124, with the names of the supervisors voting for and against it.

PASSED on _____, by the following vote:

AYES:

NOES:

ABSENT:

ABSTAIN:

ATTEST: David J. Twa, Clerk of the Board
of Supervisors and County Administrator

By: _____
Deputy

_____ Board Chair

[seal]