

## Chapter 418-16 - SAFE DRUG DISPOSAL

**Sections:**

## 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 drug as defined in subsection (f), except for 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.
- (f) "Drug" means a drug defined in section 321(g)(1) of Title 21 of the United States Code.
- (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) "Producer" means the manufacturer of a covered drug that is sold or distributed in any form in the unincorporated area of the county.
- (m) "Retail pharmacy" means a pharmacy licensed by the State of California Board of Pharmacy for the retail sale and dispensing of drugs.
- (n) "Stewardship plan" means a written document that describes a stewardship program.
- (o) "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.
- (p) "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.
- (q) "Unwanted covered drug" means any covered drug that a county resident has obtained and intends to discard, or has discarded, or has abandoned.

(Ord. No. 2016-24, § IV, 12-20-16)

#### 418-16.204 - Drug wholesalers.

Within sixty 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. No. 2016-24, § IV, 12-20-16)

#### 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 (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 (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 (c)(1) shall provide those notices to the designated recipients.
  - (3) Annually after providing the notices required under subsections (c)(1) or (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 (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 (e)(2), within ninety 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 ten 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. No. 2016-24, § IV, 12-20-16)

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. No. 2016-24, § IV, 12-20-16)

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 ninety 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 sixty 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. No. 2016-24, § IV, 12-20-16)

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 twenty 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 (a)(1) and (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. No. 2016-24, § IV, 12-20-16)

#### 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. No. 2016-24, § IV, 12-20-16)

#### 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. No. 2016-24, § IV, 12-20-16)

#### 418-16.218 - Reporting.

Within six months after the end of the first twelve-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.
- (c) A list of all drop-off sites.
- (d) The number of mailers provided to county residents.
- (e) The locations where mailers were provided, if applicable.
- (f) The dates and locations of collection events held, if applicable.
- (g) A list of all transporters used.
- (h) A list of all facilities to which the collected unwanted covered drugs were transported.
- (i) 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.
- (j) A description of all public education and promotion activities.
- (k) A description of how collected packaging was recycled to the extent feasible; including identification of the recycling facilities used.
- (l) 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.
- (m) Total expenditures of the approved stewardship program.

(Ord. No. 2016-24, § IV, 12-20-16)

#### 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 (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. No. 2016-24, § IV, 12-20-16)

#### 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. No. 2016-24, § IV, 12-20-16)

#### 418-16.224 - Enforcement.

- (a) The health officer will enforce the provisions of this chapter.
- (b) The health officer is authorized to determine whether a person has violated a provision of this chapter.
- (c)

If the health officer determines that any person has violated any provision of this chapter, the health officer will first serve a notice of violation on the person who violated it as specified in subsection 418-16.226(h), and provide an opportunity to the person to cure the violation before any other enforcement action is taken under Section 418-16.226 or other provisions of this Code. The notice of violation will include all of the following information:

- (1) The date of the violation.
  - (2) The name of the violator.
  - (3) The address or location where the violation occurred.
  - (4) The Code section(s) violated and a description of the violation.
  - (5) A description of how the violation can be corrected.
  - (6) A specified time period, beginning on the service date, within which the violation must be corrected.
  - (7) An advisement that the violator may be subject to an administrative fine under this article if the violation is not corrected by the effective date, and the amount of that fine.
- (d) The person shall have thirty 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. No. 2016-24, § IV, 12-20-16)

#### 418-16.226 - Administrative penalties.

- (a) Applicability and Authorization.
  - (1) This section provides for administrative fines that the health officer may impose, enforce, and collect to address any violation of this chapter.
  - (2) Remedies under this section are in addition to any other remedy allowed by this Code or applicable law.
- (b) Definitions. For purposes of this section, the following words and phrases have the following meanings:
  - (1) "Effective date" means the date by which a violation must be corrected, as specified in a notice of violation.
  - (2) "Hearing examiner" means the public health director.
  - (3) "Service date" means the date a notice or decision is served in accordance with subsection (h).
  - (4) "Responsible person" means a person who is determined by the health officer to have violated a provision of this chapter.

(c) Administrative Fines.

- (1) Imposition. The health officer may impose an administrative fine on a responsible person if the violation has not been corrected in the time period specified in the notice of violation.
- (2) Notice of Fine. An administrative fine will be assessed by means of a notice of fine. The responsible person will be served with the notice of fine as specified in subsection (h). The notice of fine will include all of the following information:
  - (A) The date of the violation.
  - (B) The code section(s) violated and a description of the violation.
  - (C) The amount of the fine.
  - (D) An advisement of the right to request a hearing before the hearing examiner, contesting the imposition of the fine.
- (3) Continuing Violations. Acts, omissions, or conditions in violation of any section of this chapter that continue, exist or occur on more than one day constitute separate violations and offenses on each day. Violations continuing, existing, or occurring on the service date, the effective date, and each day between the service date and the effective date are separate violations.
- (4) Fine Amounts. The amount of the fine is one hundred dollars for a first violation, two hundred dollars for a second violation of the same provision of this chapter, and five hundred dollars for each additional violation of the same provision within one year.

(d) Appeals.

- (1) Any person upon whom an administrative fine is imposed by the health officer may request a hearing pursuant to the procedures set forth in this subsection. The appellant must file a written appeal with the health officer within fifteen calendar days after the service date of the notice of fine. The written appeal must contain:
  - (A) A brief statement explaining who the appealing party is and what interest the appealing party has in challenging the imposition of the fine; and
  - (B) A brief statement of the material facts that the appellant claims supports his or her contention that no administrative fine should be imposed or that an administrative fine of a different amount is warranted.
- (2) Notice of the hearing will be served on the appellant as specified in subsection (h). The health officer will set the hearing no sooner than twenty days and no later than forty-five days following the service date of the notice of hearing.

- (3) An appeal of an administrative fine imposed for violations of this chapter will be heard by the hearing examiner.
  - (4) At the hearing, the appellant will be given the opportunity to testify, and present written and oral evidence.
  - (5) An appellant's failure to appear at the hearing shall constitute an abandonment of any defense the appellant may have to the administrative fine.
  - (6) After considering the testimony and evidence submitted at the hearing, or after the appellant has failed to appear at the hearing, the hearing examiner will issue a written decision to uphold, modify, or cancel the administrative fine and will list in the decision the reason or reasons for that decision. The decision will be served as specified in subsection (h).
- (e) Final Administrative Order. The imposition of the administrative fine becomes a final administrative order at one of the following times:
- (1) On the date the notice of fine is served, if the responsible person fails to file a written appeal to the health officer within the time specified.
  - (2) On the date the written decision by the hearing examiner is served, if the responsible person files a written appeal to the health officer within the time specified.
- (f) Payment of the Fine. The fine must be paid to the county within thirty days after the imposition of the administrative fine becomes a final administrative order. Payment of a fine under this article does not excuse or discharge any continuation or repeated occurrence of the violation that is the subject of the notice of fine. The payment of a fine does not bar the county from taking any other enforcement action regarding a violation that is not corrected.
- (g) Collection. If the fine is not paid within thirty days after the imposition of the fine becomes a final administrative order, the county may collect the fine, the county's collection costs, and interest. An administrative fine accrues interest at the same annual rate as any civil judgment, beginning on the twentieth day after the fine becomes a final administrative order. The county may collect by using any available legal means, including but not limited to the following:
- (1) The county may file a civil action. If a civil action is commenced, the county is entitled to recover all costs associated with the collection of the fine, including those costs set forth in Code of Civil Procedure Section 1033.5.
  - (2) The county may take such other actions as are allowed for enforcement of a civil judgment as provided for pursuant to the Enforcement of Judgments Law, California Code of Civil Procedure Section 680.010 et seq.

- (h) Service. All notices or decisions required to be served by this section or Section 418-16.224 will be served by any of the methods specified below:
- (1) First Class Mail. First class mail will be addressed to the responsible person at the address for service of process for the responsible person or to the last address provided by the responsible party to the health officer. Service is deemed complete upon the deposit of the notice or decision, postage pre-paid, in the United States mail.
  - (2) Personal Service. Personal service is deemed complete on the date the notice or decision is personally served on the violator.
- (i) Judicial Review. A final administrative order may be appealed to the superior court of the county in accordance with the provisions set forth in Government Code Section 53069.4.
- (Ord. No. 2016-24, § IV, 12-20-16)

#### 418-16.228 - 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. No. 2016-24, § IV, 12-20-16)