

## ORDINANCE NO. 2061

### AN ORDINANCE CREATING CHAPTER 9.29 FO THE TEHAMA COUNTY CODE, RELATING TO THE REQUIREMENTS FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS AND SHARPS

The Board of Supervisors of the County of Tehama ordains as follows:

Chapter 9.29 is hereby added as follows: **Stewardship Program for Collection and Disposal of Unwanted Covered Drugs and Unwanted Sharps.**

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9.29.010 TITLE.

This Chapter may be cited as the Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance.

9.29.015 PURPOSE.

The purpose of this Chapter is to establish a Pharmaceutical and Sharps Stewardship Program that: (1) allows for the safe, convenient and sustainable collection and disposal of unwanted Drugs and Sharps by County residents, and (2) protects, maintains, restores and/or enhances the environment and its natural resources. Said Stewardship Program shall be designed, operated and funded by the Pharmaceutical and Sharps industries with oversight by the County Health Services Agency.

This Chapter is intended to supplement the provisions of federal and state law by prescribing higher standards of sanitation, health and safety where not preempted by federal or state law. Whenever any technical words or phrases are not defined herein, but are defined under federal or state law, such definitions are incorporated into this Chapter and shall be deemed to apply as though set forth herein in full.

9.29.020 DEFINITIONS.

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

“Collection Site” shall mean a location where one or more receptacles are provided pursuant to the Stewardship Plan for County residents to safely and securely deposit Unwanted Covered Drugs and/or Unwanted Sharps.

“Collector” shall mean a Person who hosts one or more receptacles for the collection of Unwanted Covered Drugs and/or Unwanted Sharps pursuant to this Chapter.

“Combined Target Reach Percent” shall mean the percentage of the Target Audience who are exposed to at least one outreach message across all media used.

“Contact Information” shall mean a business phone number, facsimile phone number, mailing address, and electronic mail address.

“Controlled Substances” for purposes of this Section shall mean 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.

“County” shall mean the County of Tehama.

“Covered Drug” shall mean a Drug in any form, including a controlled substance, that is sold, offered for sale to, or otherwise distributed for use by, one or more consumers in the Service Area, including prescription, nonprescription, brand name, and generic. “Covered Drug” shall include controlled substances and, notwithstanding the previous sentence, shall not include: (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 or any successor legislation; (4) Drugs for which Responsible Stewards 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); and (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 Chapter if the Responsible Steward already provides a pharmaceutical product stewardship or take-back program.

“Department” shall mean the Tehama County Health Services Agency.

“Director” shall mean the Director of the Tehama County Health Services Agency or his or her designee.

“Drug” shall mean: (1) any article recognized in the official United States Pharmacopoeia – 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. Pharmacopeia 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 substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or (4) any substance intended for use as a component of any substance specified in (1), (2), or (3) of this definition, but not a device or a component, part or accessory of a device.

“Enforcing officer” means the health officer or the sheriff, or the authorized deputies or designees of either, or any person employed by the County of Tehama and appointed to the position of code enforcement officer, as established by Tehama County Resolution 125-1991, each of whom is independently authorized to enforce this chapter.

“FDA” shall mean the United States Food and Drug Administration.

“Frequency” shall mean the number of times a member of the Target Audience has an opportunity to be exposed to an outreach activity within a specified time period.

“3+ Frequency” shall mean the amount of reach obtained among audiences exposed to three or more advertising messages.

“Hazardous Waste Disposal Facility” shall have the meaning set forth by the United States Environmental Protection Agency under Title 40 Code of Federal Regulations, Parts 264 and 265, or any successor legislation.

“Manufacture” shall mean the production, preparation, propagation, compounding or processing of a Drug or other substance or device, but shall not include the preparation, compounding, packaging, or labeling of such a Drug, substance or device by a practitioner incidental to the administration or dispensing of a Drug; substance or device in the course of his or her professional practice.

“Mail-Back Services” shall mean a collection method for Unwanted Covered Drugs and/or Unwanted Sharps from County residents utilizing Mailers for shipment to a Person that will dispose of them in accordance with the Stewardship Plan.

“Mailer” shall mean a prepaid, preaddressed, tamper-resistant envelope or container used for mailing Unwanted Covered Drugs and/or Unwanted Sharps. Any Mailer used for Unwanted Sharps must be FDA-compliant.

“Medium (plural, Media)” shall mean a communication vehicle that may or may not contain advertising, such as the internet, radio, magazines, mail, newspapers, out of home media, television, telephone directories, etc.

“Nonprescription Drug” shall mean a Drug that may be lawfully sold without a prescription.

“Outreach Program” shall mean a series of activities undertaken to meet the requirements of Section 9.29.160, including but not limited to commercials or advertisements, grass roots marketing, and community based social marketing.

“Participating City” shall mean an incorporated city within the County that adopts the requirements of this Chapter into its respective municipal code by resolution or ordinance.

“Person” shall mean a human being, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or another entity of any kind or nature.

“Pharmaceutical” shall have the same meaning as drug.

“Pharmacy” shall mean an area, place, or premises licensed by the state of California Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are dispensed.

“Plan Operator” shall mean the entity designated by a Responsible Steward, group of Responsible Stewards, or Stewardship Organization to operate the Stewardship Plan.

“Potential Authorized Collector” shall mean any entity that is registered, or that may apply to register, with the U.S. Drug Enforcement Administration (DEA) for the collection of Drugs, such as a manufacturer, distributor, reverse distributor, narcotic treatment program, retail Pharmacy, or a hospital/clinic with an on-site Pharmacy.

“Proof of Performance” shall mean documentation verifying that outreach described within the approved Outreach Program did in fact fund. Examples of Proof of Performance include a photograph of a billboard, a copy of a published newspaper advertisement, reports of Internet usage, or other appropriate documentation.

“Rating” means the percentage of a given population group consuming a Medium at a particular moment. A Rating can apply to a specific demographic group or a specific geographic area. The accumulation of multiple ratings results in Target Rating Points, which in turn leads to calculations of Reach and Frequency.

“Reach” refers to the number or percentage of a population group exposed to the Outreach Program within a given period of time.

“Repackager” shall mean a Person who owns or operates an establishment that repacks and/or relabels a product or package for further sale or distribution.

“Responsible Steward” shall mean:

- (a) The Person who Manufactures or causes to be Manufactured a Covered Drug or Sharps; or
- (b) If the Person described in (a) is beyond the County’s jurisdiction, the first Person who repackages or distributes the Covered Drug or Sharps in or into the County, including but not limited to a Wholesaler or Repackager; or
- (c) If the Persons described in (a) and (b) are beyond the County’s jurisdiction, the first Person who sells or offers for sale the Covered Drug or Sharps in or into the County.

“Responsible Steward” shall not include (1) a retailer that puts its store label on a Drug or Sharp or (2) a pharmacist who dispenses Drugs or Sharps to, or compounds a prescribed individual product for, a consumer.

“Service Area” shall mean the unincorporated County and all Participating Cities.

“Sharp” shall mean a needle, safety engineered needle, lancet or other similar instrument that is deigned to puncture the skin of individuals or animals for medical purposes and that is sold, offered for sale, or otherwise distributed for use by one or more consumers in the County and may include anything affixed to the instrument, such as a syringe.

“Stewardship Organization” shall mean an organization designated by a Responsible Steward or group of Responsible Stewards to act as its agent to develop and implement a Stewardship Plan.

“Stewardship Plan” or “Plan” shall mean a plan approved by the Director for the collection, transportation, and disposal of Unwanted Covered Drugs and/or Unwanted Sharps pursuant to this Chapter that is financed, developed, and implemented by a Responsible Steward operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization.

“Stewardship Program” or “Program” shall mean the County program described in this Chapter.

“Target Audience” shall mean persons who live in the Service Area.

“Target Rating Points” shall mean the sum of all Ratings delivered by any given Medium or list of Media vehicles.

“Unincorporated Community” shall mean a community located within the unincorporated area of the County, as identified as a census designated place.

“Unwanted Covered Drug” shall mean any Covered Drug that the consumer wishes to discard. This shall exclude Covered Drugs disposed of by commercial and institutional sources, including, but not limited to, hospitals, clinics, and Pharmacies.

“Unwanted Sharps” shall mean any Sharp or Sharps that the consumer wishes to discard. This shall exclude Sharps disposed of by commercial and institutional sources including, but not limited to, hospitals, clinics, and Pharmacies.

“Wholesaler” shall mean a Person who purchases Covered Drugs and/or Sharps for resale and distribution to Persons other than consumers.

#### 9.29.030 STEWARDSHIP PLANS - PARTICIPATION.

- (a) Each Responsible Steward shall participate in such a Stewardship Plan approved by the Director either by:
  - (1) Operating, individually or jointly with other Responsible Stewards; or

- (2) Entering into an agreement with a Stewardship Organization to operate, on the Responsible Steward's behalf. A stewardship organization shall be formed as a California nonprofit public benefit corporation and hold an unrevoked determination letter from the Internal Revenue Service ("IRS") that it is exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "IRC") and is further classified as a public charity under the IRC Section 509(a). An organization that has not yet obtained a determination letter from the IRS may begin operations so long as it can demonstrate that it has applied to the IRS for the required tax-exempt status. If an organization's status as a 501(c)(3) public charity is revoked by the IRS for any reason or it fails to obtain the required determination from the IRS within one year of incorporation, such organization shall not meet the requirements to continue to operate as a stewardship organization, effective as of the IRS revocation date or the first anniversary date of its incorporation, as applicable.
- (b) Each Responsible Steward must notify the Director in writing of the Responsible Steward's intent to operate or participate in a Stewardship Plan for the collection, transportation, and disposal of the Covered Drug or Sharps, respectively, within 30 days of the effective date of this Chapter or 30 days after the Covered Drug or Sharps are first sold into or offered for sale in the County, whichever is later.
- (c) Each Stewardship Plan must be approved by the Director before any collection of Unwanted Covered Drugs and/or Unwanted Sharps may commence thereunder. Proposed changes to an approved Plan shall be subject to the requirements set forth in Section 9.29.110.
- (d) Each Responsible Steward operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization shall:
  - (1) Within 30 days of the effective date of this Chapter or 30 days after the Covered Drug or Sharps are first sold or offered for sale in or into the County, whichever is later, identify to the Director in writing an individual authorized to be the official point of contact for the Stewardship Plan and the individuals' Contact Information. Said Contact Information shall be kept current at all times. Director shall be notified of any change in such Contact Information within ten (10) businesses days.
  - (2) Within 45 days of the effective date of this Chapter or 45 days after the Covered Drug or Sharps are first sold or offered for sale in the County, whichever is later, and annually thereafter, notify the following Persons of the opportunity to participate in the Stewardship Plan by serving as collectors, and provide the Director with copies of all such notifications:

- i. All retail Pharmacies, hospitals/clinics with on-site Pharmacies, and other Potential Authorized Collectors;
  - ii. Persons other than Potential Authorized Collectors, such as retail establishments, that could potentially host Collection Sites for Sharps;
  - iii. All law enforcement agencies in the County; and
  - iv. All pre-existing Sharps disposal locations.
- (3) Within 90 days of the effective date of this Chapter or 90 days after the Covered Drug or Sharps are first sold or offered for sale in or into the County, whichever is later, submit a proposed Stewardship Plan as described in Section 9.29.040 to the Director for review;
- (4) Within 90 days of the Director's approval of the Stewardship Plan, the Stewardship Plan shall be implemented in accordance with this Chapter;
- (e) A Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, may enter into agreements with other Stewardship Organizations, service providers, or other Persons as needed to carry out its Stewardship Plan in whole or in part.
- (f) Should the Responsible Steward undergo any change in ownership or control, it must notify the Director within 30 days of such change, and should ownership or control be transferred to a company not conducting business in the County, the Responsible Steward shall provide the name and Contact Information of the first Person who causes the Covered Drug or Sharps to be brought in or into the County for repackaging, distribution, or sale.
- (g) Each Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, shall commence within thirty (30) calendar days good faith negotiations with any Responsible Steward expressing an interest to participate in its Stewardship Plan. For every Responsible Steward not accepted as a participant in the Plan, the Responsible Steward, group of Responsible Stewards, or Stewardship Organization rejecting the Responsible Steward expressing an interest to participate shall notify the Director in writing within thirty (30) calendar days of the rejection and set forth reasons for such decision.
- (h) Any Person who is not a Responsible Steward, such as a Person providing Covered Drugs or Sharps free of charge, may choose to participate in the Program. Such Person may operate individually, jointly with a Responsible Steward or group of Responsible Stewards, or through a Stewardship Organization. Any Responsible Steward, group of Responsible Stewards, or Stewardship Organization approached by such Person for potential collaboration must in good faith consider allowing such Person to participate in its Stewardship Plan. Should such Person participate in the Program, such Person shall be subject to the same requirements under this Chapter as any



Responsible Steward, group of Responsible Stewards, or Stewardship Organization. If such Person no longer wishes to participate in the Program, such person shall notify the Director of the same within thirty (30) calendar days and set forth the reasons for such decision.

- (i) After the first full year of implementation of a Stewardship Plan, a Responsible Steward may notify the Director in writing of its intent to submit a new Stewardship Plan. Within three months of such notification, the Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, shall submit a proposed Stewardship Plan as described under Section 9.29.040 to the Director for Review. The new Stewardship Plan shall be accompanied by the plan review fee in accordance with Section 9.29.100. Until such time that a new Stewardship Plan is approved by the Director, the most recently approved plan shall remain in effect.
- (j) Should a Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, become aware of any Covered Drug or Sharps being sold or offered for sale in or into the County whose Responsible Steward is neither operating nor participating in a Stewardship Plan, the Responsible Steward becoming aware of this shall notify the Director of same and the basis for such belief within thirty (30) calendar days.
- (k) The Director may, on a case-by-case basis, approve in writing requests for time extensions related to submission dates and deadlines in this Section 9.29.030.
- (l) The Director may audit the records of a Responsible Steward, group of Responsible Stewards, or Stewardship Organization related to a Stewardship Plan or request that the Responsible Steward, group of Responsible Stewards, or Stewardship Organization arrange for the Director to inspect at reasonable times the facilities, vehicles, and equipment used in carrying out the Stewardship Plan.

#### 9.29.040 STEWARDSHIP PLANS - COMPONENTS.

Each Stewardship Plan, which must be submitted and reviewed according to Section 9.29.110, shall include:

- (a) The name of each Responsible Steward participating in the Stewardship Plan; the name of each Covered Drug and Type of Sharp the Responsible Steward either Manufactures or purchases for repackaging, distribution, sale or offer for sale; and the name and Contact Information of an individual authorized to be the official point of contact for each Responsible Steward and to whom the Director may direct all inquiries regarding the Responsible Steward's compliance with the requirements of this Chapter;

- (b) A description of the proposed collection system designed to provide safe, convenient, and ongoing collection services for Unwanted Covered Drugs and Unwanted Sharps from County residents within the Service Area in compliance with the requirements set forth in Section 9.29.050. The description shall include but not be limited to a list of all collection methods and participating Collectors; a list of addresses for the Collection Sites; a description of how many periodic collection events will be scheduled and where they will be located; and a description of how many Mail-Back Services will be provided to County residents in the Service Area, including a physical sample of the Mailers to be used. The description of the collection services shall include a list of Potential Authorized Collectors, law enforcement agencies, and other Persons contacted by the Responsible Steward pursuant to Section 9.29.030, and a list of all who expressed an interest in serving as Collectors in the Stewardship Plan;
- (c) A description of the proposed handling and disposal system, including the name and Contact Information for each Collector, each Person retained to transport the collected items, each Hazardous Waste Disposal Facility to be used by the Stewardship Plan in accordance with Sections 9.29.050 and 9.29.060, and any other Person retained to implement any portion of the Stewardship Plan;
- (d) A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs and Unwanted Sharps collected under the Stewardship Plan, including a description of how each Collector, each Person retained to transport the collected items, Hazardous Waste Disposal Facilities, and any other Person retained to implement any portion of the Plan will ensure that the collected items are safely and securely tracked from collection through final disposal, and how the Responsible Stewards participating in the Stewardship Plan will ensure that all Persons participating in, operating, and otherwise implementing the Stewardship Plan will comply with all applicable federal, state, and local laws and regulations, including but not limited to those of the United States Drug Enforcement Administration and the State of California Board of Pharmacy;
- (e) A certification that any patient information appearing on Drug and Sharp packaging will be kept secure and promptly destroyed;
- (f) A description of the public education and promotion strategy required in Section 9.29.160, including but not limited to a copy of instructions, signage, and promotional materials for residents, as well as instructions and signage, as may be needed, for Collectors, Persons retained to transport collected items, Hazardous Waste Disposal Facilities, and all other Persons implementing any portion of the Plan;
- (g) Proposed short-term and long-term plans for frequency of collection from Collection Sites, public education, and promotion of the Plan; and
- (h) A description of how the Stewardship Plan will consider: (1) use of existing providers of waste pharmaceutical services; (2) separating Covered Drugs and Sharps from packaging to the extent possible to reduce transportation and disposal costs; and (3) recycling of Drug and Sharp packaging to the extent feasible.

9.29.050 STEWARDSHIP PLANS – COLLECTION OF COVERED DRUGS AND SHARPS.

- (a) This Chapter does not require any Person to serve as a Collector in a Stewardship Plan. A Person may offer to serve as a Collector with or without compensation by a Responsible Steward, group of Responsible Stewards, or Stewardship Organization. Responsible Stewards are encouraged to host Collection Sites where feasible.
- (b) The collection system for each Stewardship Plan shall:
  - a. Provide ongoing, reasonably convenient and equitable access for all County residents in the Service Area regardless of the racial, cultural, or socioeconomic composition of the neighborhoods within which the Collection Sites are located. At a minimum, the following requirements shall be met:
    - i. Population Density: In each Unincorporated Community and in each Participating City with at least one Potential Authorized Collector, each Stewardship Plan shall provide at least one Collection Site for Unwanted Covered Drugs, at least one Collection Site for Unwanted Sharps, and for every 30,000 County residents at least one additional Collection Site for Unwanted Covered Drugs and at least one additional Collection Site for Unwanted Sharps.
    - ii. Travel Distance: Collection Sites shall be geographically distributed so as to ensure that every resident within the Service Area is within 10 miles of a Collection Site for Unwanted Covered Drugs and a Collection Site for Unwanted Sharps to the greatest extent feasible; and
    - iii. Sites per Supervisorial District: In no event shall there be fewer than 1 Collection Sites for Unwanted Covered Drugs or fewer than 1 Collection Sites for Unwanted Sharps in each County Supervisorial District;
  - b. In areas where the minimum requirements set forth in subsection (b) a. are not met, the Stewardship Plan shall set forth the reasons for such failure and provide for temporary collection events that are at least six hours in length and held once per quarter of each calendar year in those areas;
  - c. The collection system shall provide a free mail-back service that allows for convenient and equitable access by all county residents in all the Unincorporated Communities and in each Participating City. In no event shall a Mailer be distributed more than three (3) businesses days

- following the receipt of a request for a Mailer by any county resident in the Unincorporated Community or a Participating City;
- d. The collection system shall make available free mail-back services to all Unincorporated Community residents and residents in each Participating City who are disabled or homebound, in a manner that allows for convenient and equitable access to those services by these persons;
  - e. Be safe and secure, including requiring the prompt destruction of patient information on any and all packaging;
  - f. Include a mechanism whereby Responsible Stewards of Sharps participating in the Plan provide for distribution of FDA-compliant Sharps containers designed for the safe handling of Sharps to the consumer free of charge, preferably at the point of sale of the injectable Drug or at the time the consumer otherwise receives the Sharps for usage;
  - g. Provide FDA-compliant Sharps collection receptacles to any hosts of Collection Sites for Sharps;
  - h. Commence good faith negotiations with any Person expressing an interest to serve as a Collector within 30 calendar days of the Person's expression of such interest. For every Person not accepted as a Collector, the Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall submit a written explanation to the Director within 30 calendar days of the rejection setting forth the reasons for such decision; and
  - i. Provide Mailers and Mail-Back Services, free of charge, to residents in the Service Area upon request through the Stewardship Plan's 24-hour, toll-free phone number and website. Assistance through the toll-free phone number and website shall be in English, Spanish, and other languages as determined by the Department.
- (c) Collection Sites for Unwanted Covered Drugs shall accept all Covered Drugs and Collection Sites for Unwanted Sharps shall accept all Sharps. All Collection Sites shall be accessible by County residents at least during the hours that the Collector is normally open for business to the public. Collection Sites shall be emptied and otherwise serviced as often as necessary to avoid creating hazardous conditions, including reaching capacity. Collection Sites shall utilize secure collection receptacles in compliance with all applicable federal, state, and local laws, including but not limited to requirements of the DEA and the State of California Board of Pharmacy.
- (d) Each Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, shall ensure that all Collection Sites prominently display a 24-hour, toll-free phone number and website for the Stewardship Plan. Said toll-free phone number and

website shall be a means by which any Person can provide feedback on collection activities, including but not limited to the need to empty the receptacles more frequently or reporting a hazardous condition observed at or near the Collection Sites. Each Stewardship Plan shall provide for the immediate abatement of any hazardous condition arising from or related to operations performed under the Stewardship Plan and shall notify the Director within 24 hours of notice of same.

9.29.060 STEWARDSHIP PLANS – DISPOSAL OF COVERED DRUGS AND SHARPS.

- (a) Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted Hazardous Waste Disposal Facility.
- (b) Sharps collected under a Stewardship Plan must be disposed of in accordance with California Health and Safety Code Division 104 Part 14 Chapter 7.
- (c) The Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under Title 40 Code of Federal Regulations, Parts 60 and 62, or any successor legislation if the Director deems the use of a Hazardous Waste Disposal Facility described under subsection (a) to be infeasible for the Stewardship Plan based on cost, logistics, or other considerations.
- (d) The Director may require a Stewardship Plan to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections (a) through (c), or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas: (1) monitoring of any emissions or waste; (2) worker health and safety; (3) reduction or elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and (4) overall impact on the environment and human health.

9.29.070 STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS.

- (a) Each Responsible Steward, group of Responsible Stewards, or Stewardship Organization participating in a Stewardship Plan shall prepare and implement its Stewardship Plan as required by this ordinance at its own cost and expense.
- (b) No Responsible Steward, group of Responsible Stewards, Stewardship Organization, or any other Person may charge a point-of-sale fee to

consumers to recoup the costs of any Stewardship Plan, nor may they charge a specific point-of-sale collection fee at the time that Covered Drugs and/or Sharps are collected.

- (c) Responsible Stewards are not required to pay for costs of staff time at Collection Sites provided by Collectors volunteering to participate in a Stewardship Plan.

9.29.080 STEWARDSHIP PLANS – REPORTING REQUIREMENTS.

- (a) By April 1<sup>st</sup> each year, each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall submit a report to the Director on behalf of participating Responsible Stewards describing their plan's activities during the previous calendar year. The report must include:
  - a. A list of Responsible Stewards participating in the Stewardship Plan;
  - b. The amount, by weight, of Covered Drugs and the amount, by weight, of Sharps collected, including the amount by weight from each collection method used per location, and by mailer per zip code;
  - c. A list of Collection Sites;
  - d. The number of Mailers provided to County residents, and the method and location of distribution;
  - e. The number of Sharps containers provided to County residents, and the method and location of distribution;
  - f. The dates and locations of collection events held;
  - g. The transporters used and the disposal facility or facilities used for all Covered Drugs and Sharps;
  - h. Whether any safety or security problems occurred during collection, transportation or disposal of Unwanted Covered Drugs and Unwanted Sharps 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;
  - i. A description of the public education, outreach and evaluation activities implemented during the reporting period;
  - j. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used, and the amount of packaging collected by weight and percent recycled;
  - k. 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;
  - l. The total expenditures of the Stewardship Plan during the reporting period; and
  - m. An Executive Summary.
- (b) Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall provide on a quarterly basis, a list of Responsible

Stewards participating in the Stewardship Plan. Any change in the official point of contact for the Plan must be provided to the Department within 30 days of the change.

- (c) The Director shall make reports submitted under this Chapter available to the public.
- (d) For the purposes of this Section 9.29.080, “reporting period” means the period from January 1 through December 31 of the same calendar year, unless otherwise specified by the Responsible Steward, group of Responsible Stewards, and Stewardship Organization to the Director.

#### 9.29.090 STEWARDSHIP PLANS – IDENTIFICATION OF RESPONSIBLE STEWARDS OF COVERED DRUGS AND SHARPS.

Any Person receiving a letter of inquiry from the Director regarding whether or not it is a Responsible Steward under this Chapter must respond in writing within 60 days. If such Person does not believe it is a Responsible Steward under this Chapter, it must state the basis for such belief. It must also provide a list of all Covered Drugs and Sharps it repackages, distributes, sells, or offers for sale within the County, if any, and identify the name and Contact Information of the Person(s) from whom it acquired said Covered Drugs or Sharps.

#### 9.29.100 STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS.

- (a) By 90 days after the effective date of this Chapter, each Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review, accompanied by the plan review fee in accordance with Section 9.29.140 of this Chapter. The Director may upon request provide information, suggestions, and technical assistance about the requirements of this Chapter 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 Chapter.
- (c) After the review under subsection (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 Responsible Steward, group of Responsible Stewards, or Stewardship Organization must submit a revised Stewardship Plan, accompanied by the plan review fee in accordance with Section 9.29.140 of this Chapter, to the Director within 30 days after receiving written notice of the rejection. The Director shall review and approve

- or reject a revised Stewardship Plan as provided under subsections (b) and (c).
- (e) If the Director rejects a revised Stewardship Plan, or any subsequently revised plan, the Director may deem the Responsible Steward, group of Responsible Stewards, or Stewardship Organization out of compliance with this Chapter and subject to the enforcement provisions in this Chapter.
  - (f) The Department, at the sole discretion of the Director, may establish a technical advisory committee to assist the Department in reviewing Stewardship Plans or otherwise assisting in the implementation of this ordinance.
  - (g) The Director shall make all proposed and approved Stewardship Plans submitted under this Chapter available to the public for review and comment.

#### 9.29.110 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 Responsible Stewards, Collectors, collection methods, Hazardous Waste Disposal Facilities, how to achieve the service convenience goal, policies and procedures for handling Unwanted Covered Drugs and Unwanted Sharps, or education and promotion methods, must be approved in writing by the Director before the changes are implemented.
- (b) A Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall submit to the Director any proposed change to a Stewardship Plan in writing at least 30 days before the proposed changes are scheduled to take effect. All changes must be approved in writing by the Director before the changes are implemented. Any such submittal shall be accompanied by the review fee in accordance with Section 9.29.140 of this Chapter.
- (c) A Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall notify the Director at least 15 days before implementing any changes to Collection Site locations, methods for scheduling and locating periodic collection events, or methods for distributing Mailers, that do not substantively alter achievement of the service convenience goal under Section 9.29.050 of this Chapter, or other changes that do not substantively alter plan operations under subsection (a).
- (d) A Responsible Steward, group of Responsible Stewards, or Stewardship Organization may request an advance determination from the Director whether a proposed change would be deemed to substantively alter plan operations.



9.29.120 STEWARDSHIP PLANS – ENFORCEMENT AND PENALTIES.

- (a) The Director shall refer any violations to the Enforcing Officer to administer the penalty provisions of this Chapter.
- (b) If the Enforcing Officer determines that any Person has violated any provision of this Chapter or a regulation adopted pursuant to this Chapter, the Enforcing Officer shall send a written warning, as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter, to the Person or Persons who violated it. The Person or Persons shall have 45 days after the date of mailing of the warning to come into compliance and correct all violations.
- (c) If the Person or Persons fail to come into compliance or correct all violations, the Enforcing Officer may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter, pursuant to Chapter 10.14 of the Tehama County Ordinance Code, as amended, as amended, which is hereby incorporated in its entirety and shall govern the imposition, enforcement, collection, and review of administrative citations issued to enforce this Chapter or any rule or regulation adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.
- (d) County Counsel, the District Attorney, and any applicable City Attorney may bring a civil action to enjoin violations of or compel compliance with any requirement of this Chapter or any rule or regulation adopted pursuant to this Chapter, as well as for payment of civil penalties and any other appropriate remedy. The court shall award reasonable attorney's fees and costs to County Counsel, the District Attorney, and any applicable City Attorney.
- (e) Any Person who knowingly and willfully violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and upon conviction thereof is punishable by a fine of not less than fifty 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.
- (f) Any Person in violation of this Chapter or any rule or regulation adopted pursuant to this Chapter shall be liable to the County for a civil penalty in an amount not to exceed one thousand 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 subsection (f) for the same violations for which the Director assessed an administrative penalty pursuant to subsection (c).
- (g) 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.

- (h) The Director may exercise reasonable discretion to waive strict compliance with the requirements of this Chapter that apply to Responsible Stewards in order to achieve the objectives of this Chapter.

#### 9.29.130 STEWARDSHIP PLANS – REGULATIONS, GUIDELINES, AND REPORTS.

- (a) The Director may adopt regulations and guidelines necessary to implement, administer, and enforce this Chapter.
- (b) The Director may work with each Responsible Steward, group of Responsible Stewards, and Stewardship Organization as needed, but no less than annually, to define goals and performance, including but not limited to collection amounts, education, and promotion for a Stewardship Plan.
- (c) The Director shall report biennially to the Board of Supervisors concerning the status of all Stewardship Plans and recommendations for changes to this Chapter. The biennial report may also include a summary of available data on indicators and trends of abuse, poisonings and overdoses from prescription and nonprescription drugs and a review of comprehensive prevention strategies to reduce risks of drug abuse, overdoses, and preventable poisonings. The first report shall be due two years from the effective date of this Chapter.

#### 9.29.140 PLAN REVIEW AND ANNUAL OPERATION FEES.

- (a) Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization participating in a Stewardship Plan shall pay to the Director plan review fees to be established under subsection (d) for the performance of certain functions as applicable, including but not limited to:
  - a. Review of a proposed Stewardship Plan;
  - b. Review of a revised, proposed Stewardship Plan;
  - c. Review of changes to an approved Stewardship Plan;
  - d. Review of an updated Stewardship Plan at least every three years as required under Section 9.29.030 of this Chapter;
  - e. Review of any petition for approval to use alternative final disposal technologies under Section 9.29.060; and
  - f. Environmental review of a Stewardship Plan.
- (b) In addition to plan review fees, each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall pay to the

Director annual operating fees to be established under subsection (d) of this Section 9.29.140.

- (c) A Stewardship Organization may remit the plan review fee on behalf of its participating Responsible Stewards.
- (d) As soon as practicable, the Director shall propose to the Board of Supervisors a schedule of fees charged to each Responsible Steward, group of Responsible Stewards, and Stewardship Organization to cover costs of administering and enforcing this Chapter. The Director shall set the fees to recover but not exceed actual and reasonable costs to the County. The Board of Supervisors must approve the schedule of fees after a public hearing for it to become effective.

#### 9.29.150 INFORMATION REQUIRED AT POINT OF SALE.

- (a) Each Responsible Steward, group of Stewards, or Stewardship Organization shall request that any Person selling or offering for sale Covered Drugs or Sharps to the public post display materials approved by the Director explaining how and where members of the public may safely and lawfully dispose of Unwanted Covered Drugs and Unwanted Sharps at no cost to the consumer. The materials shall be in English, Spanish, and other languages as determined by the Department and shall be legible and easily understandable by the average person. The materials shall be posted on the premises of the Person's place of business in a location visible to the public, if applicable, and adjacent to the area where prescription drugs are dispensed. Each Responsible Steward, group of Stewards, or Stewardship Organization shall request mail-order Pharmacies and on-line Pharmacies selling Covered Drugs or Sharps to County residents provide such materials with the order. If any Person selling or offering for sale Covered Drugs or Sharps to the public declines to post the display materials, or if mail-order Pharmacies and on-line Pharmacies decline to include such materials with the order, the Responsible Steward, group of Stewards, or Stewardship Organization shall report to the Director an explanation of why such request was declined by the Person and submit a subsequent request to the Person semiannually.
- (b) The Director may, in his or her discretion, authorize a Responsible Steward, group of Stewards, or Stewardship Organization to use alternate means to comply with the requirements of subsection (a). No Responsible Steward, group of Stewards, or Stewardship Organization may sell or offer for sale Covered Drugs or Sharps to the public using any alternate means of compliance with this Chapter unless specifically authorized to do so in advance in writing by the Director.

9.29.160 STEWARDSHIP PLANS – PROMOTION, OUTREACH AND EDUCATION.

- (a) Each Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall develop a system of promotion, outreach, and public education to be included in the Stewardship Plan as the Outreach Program. Specifically, each Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall:
- a. Promote the collection options offered under its Stewardship Plan to residents and the health care community. Promotion shall include outreach and educational materials designed to achieve the following goals:
    - i. Promote the safe storage of Drugs and Sharps by residents during the treatment period;
    - ii. Describing where to return Unwanted Covered Drugs and Unwanted Sharps under the Stewardship Plan;
    - iii. Convey disposal instructions only for the types of collection and disposal options offered through the approved Stewardship Plan;
    - iv. Expressly encourage disposal through the approved Stewardship Plan as an environmentally friendly method of disposal; and
    - v. Identify all locations and collection events in the Service Area which are authorized by the DEA and at which Unwanted Covered Drugs Unwanted Sharps can be disposed, whether operated by a Responsible Steward, group of Responsible Stewards, or Stewardship Organization or not.
  - b. These materials must be provided to Pharmacies, retailers of Covered Drugs and Sharps, health care practitioners, health care facilities, veterinary facilities, and other prescribers for their own education as well as for dissemination to residents, and use plain language and explanatory images so as to be readily understandable by all residents, including individuals with limited English proficiency, which may include but shall not be limited to, printing on prescription bags;
  - c. Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions, signage and promotional materials for residents on the use of collection receptacles and a readily-recognizable, consistent design of collection receptacles;
  - d. Outreach Program activities shall, when considered together, achieve a combined Target Audience Reach percent of 75% at 3+ Frequency for the duration of one month, at least three times per year over the first 12 months of Plan operation and a combined target reach percent

of 50% at a 2+ Frequency for the duration of one month, at least three times per year for the following years.

- e. For every fifth year of program operation, Outreach Program activities shall achieve a combined Target Audience Reach of 75% at 3+ Frequency for the duration of one month, at least three times per year for that year.
  - f. Establish a 24-hour, toll-free phone number and single website where information can be obtained regarding collection options and current locations of Collection Sites;
  - g. Within six months of the effective date of this Chapter and biennially thereafter, conduct a statistically meaningful survey of residents, pharmacists, veterinarians, retailers, and health professionals who interact with patients on the use of Drugs and Sharps after the first full year of operation of the plans. Survey questions shall include but not be limited to questions designed to: (1) assess the awareness of the County's Stewardship Program, the Stewardship Plans in operation, and the location of all available Collection Sites; (2) assess to what extent Collection Sites and other collection methods are safe, convenient, easy to use, and utilized by residents; and (3) assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription Drugs used in the home. Draft survey questions shall be submitted to the 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 this Section 9.29.060 within 90 days following the end of the survey period. Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall ensure the privacy of all survey respondents.
- (b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 9.29.160 shall be in English, Spanish, and other threshold languages as determined by the Department. If more than one Stewardship Plan is approved, then to the extent feasible, all Stewardship Plans shall coordinate with each other and develop a single system of promotion and education, with a single toll-free hotline and website and consistent signage and materials across the County. In the event that agreement cannot be achieved, the Director shall develop a final Outreach Program design and single system of promotion which meets the requirements. All costs of developing and implementing the single system of promotion shall be divided among all Stewardship Plan operators.
- (c) Each Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall include the following information on Outreach Program

activities in an the Annual Report, as required in 9.29.080 STEWARDSHIP PLANS – REPORTING REQUIREMENTS:

- a. A discussion of whether and how the Outreach Program activities undertaken during the reporting year achieved the Reach and Frequency requirements;
  - b. The identity of all Media used to promote the Plan in the reporting year;
  - c. Target Rating Points by Medium as a demonstration that the Outreach Program activities undertaken during the reporting period were sufficient to meet the combined Target Reach Percent and Frequency requirements;
  - d. Proof of Performance for each Medium utilized in the Outreach Plan activities undertaken during the reporting year; and
  - e. A discussion of Outreach Program effectiveness and a description of additional future Outreach Plan activities required, if any, as described below.
- (d) Outreach Program effectiveness shall be measured by Target Audience awareness of the Plan as demonstrated by way of the biennial survey. If the results of any biennial survey show that less than 50% of the Target Audience are aware of the Plan, future Outreach Program activities must be undertaken to increase Reach, Frequency, and duration until awareness of at least 50% is achieved, as demonstrated in subsequent biennial residential surveys.

#### 9.29.170 UNDERTAKING FOR THE GENERAL WELFARE.

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

#### 9.29.180 COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS.

Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization operating under this Chapter must comply with all applicable federal, state, and local laws and regulations.

Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization operating under this Chapter shall also ensure that each Collector, each Person retained to transport the collected items, and any other Person implementing any portion of the Stewardship Plan complies with all applicable federal, state and local laws and regulations.

This Chapter shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any 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 Chapter to the extent that said enforcement would conflict with any preemptive State or federal legislation subsequently adopted. Nothing in this Chapter is intended or shall be construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair competition laws of the State of California or the United States.

9.29.190 SEVERABILITY.

If any of the provisions of this Chapter 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 Chapter are severable.

The foregoing ordinance was duly passed and adopted by the Board of Supervisors of the County of Tehama, State of California, at a regular meeting of the Board of Supervisors on the \_\_\_\_\_ day of \_\_\_\_\_, 2018 by the following vote:

AYES:  
NOES:  
ABSENT OR NOT VOTING:

\_\_\_\_\_  
CHAIR, Board of Supervisors

STATE OF CALIFORNIA     )  
  ) ss  
COUNTY OF TEHAMA     )

I, JENNIFER A. VISE, County Clerk and ex-officio Clerk of the Board of Supervisors of the County of Tehama, State of California, hereby certify the above and foregoing to be a full, true and correct copy of an ordinance adopted by said Board of Supervisors on the \_\_\_\_\_ day of \_\_\_\_\_, 2018.

DATED: This \_\_\_\_\_ day of \_\_\_\_\_, 2018.

JENNIFER A. VISE, County Clerk and ex-officio Clerk of the Board of Supervisors of the County of Tehama, State of California.

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