

ORDINANCE NO. _____
ORDINANCE OF THE MARIN COUNTY BOARD OF SUPERVISORS
AMENDING THE MARIN COUNTY CODE BY ADDING CHAPTER 7.90, SECTIONS 7.90.010
THROUGH 7.90.150 TO REQUIRE ANY PERSON WHO PRODUCES A DRUG OFFERED FOR
SALE IN MARIN COUNTY TO PARTICIPATE IN AN APPROVED DRUG STEWARDSHIP
PROGRAM FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS FROM
RESIDENTIAL SOURCES; TO PROVIDE FOR IMPLEMENTATION, ENFORCEMENT, FEES
AND PENALTIES; AND TO MAKE ENVIRONMENTAL FINDINGS

THE BOARD OF SUPERVISORS OF THE COUNTY OF MARIN HEREBY ORDAINS AS FOLLOWS:

SECTION I. Chapter 7.90 is hereby added to the Marin County Code to read as follows:

"Chapter 7.90 Marin County Safe Drug Disposal Ordinance."

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7.90.010 – Findings.

The Marin County Board of Supervisors finds as follows:

- A. Legal medicinal drugs allow us to live longer, healthier, and more productive lives.
- B. The lack of sufficient safe, convenient disposal locations for unwanted drugs creates significant risks to human health and to the environment.
- C. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of drugs and the illegal resale of prescription drugs.
- D. Establishing a safe, convenient collection system for unwanted drugs will reduce unintentional poisonings and drug overdose deaths by making drugs less accessible to persons who might accidentally ingest them.
- E. Our groundwater and surface drinking water are being contaminated by unwanted, leftover or expired drugs passing through our wastewater and treatment centers.

- F. Establishing a safe, convenient collection system will reduce the quantity of pharmaceutical compounds that are discharged in to receiving waters throughout the County.
- G. Extended Producer Responsibility (EPR) laws, sometimes referred to as Product Stewardship laws, place responsibility for end-of-life management of consumer products on the manufacturers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every state of the product's lifecycle.
- H. In 2012, Alameda County became the first local government in the United States to pass legislation requiring pharmaceutical companies to design, fund, and operate a program to safely collect and dispose of unwanted drugs.
- I. Subsequently, in California, the City and County of San Francisco, the County of San Mateo and the County of Santa Clara have adopted similar drug stewardship programs.
- J. There is currently no mandatory statewide drug stewardship program for unwanted household drugs in California.
- K. There is considerable demand in Marin County for a permanent drug stewardship program. Since 2005, the County has operated a County-funded program. As of July 28, 2015, this program consists of 16 secure drop box locations at County pharmacies and law enforcement stations, which collect both controlled and non-controlled substances. The County program collected and disposed of 7518 pounds of drugs in 2013. This is estimated to be only 1/3 the amount of unwanted drugs generated in the County.
- L. With a limited number of collection locations, these programs do not offer adequate disposal options for the County's residents. Lack of available funds prevents the County program from expanding and from collecting a significant portion of County resident's unwanted drugs.
- M. A manufacturer-funded collection and disposal program for unwanted drugs would significantly increase convenient disposal options for County residents' unwanted drugs, enabling collection of larger quantities of unwanted drugs and reducing the risks to public safety, health, and the environment.

7.90.020 – Definitions.

- A. "Collector" means a Person that gathers Unwanted Covered Drugs from County residents for the purpose of collection, transportation, and disposal, including, but not limited to, a retail pharmacy or law-enforcement drop-off site, or mail back service.
- B. "County" means the County of Marin.
- C. "County Residents" mean human beings residing in the County. "County residents" does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor's offices, veterinary clinics, pharmacies, or airport security and law enforcement drug seizures.
- D. "Covered Drug" means a Drug sold in any form and used by County residents, including prescription, nonprescription, brand name, and generic drugs.
Notwithstanding the previous sentence, "Covered Drug" does 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 (Title 21 U.S.C. Chapter 9); (4) Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration-managed risk evaluation and

mitigation strategy (21 U.S.C. sec. 355-1); (5) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Chapter if the Producer already provides a pharmaceutical product stewardship or take-back program; and (6) medical devices or their component parts or accessories.

- E. "Department" means the Environmental Health Services division of the Department of Marin County Community Development Agency.
- F. "Director" means the Director of the Marin County Environmental Health Services division or his or her designee.
- G. "Drug Wholesaler" means a Person who buys Drugs for resale and distribution to corporations, individuals, or entities other than consumers.
- H. "Drug" means: (1) any article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States or any supplement of the formulary or those pharmacopoeias as published by the U.S. Pharmacopoeial Convention and the Homeopathic Pharmacopoeia Convention of the United States; (2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) any substance, other than food, intended to affect the structure or any function of the body of humans or other animals; or (4) any substance intended for use as a component of any substance specified in (1), (2), or (3) of this definition.
- I. "Mail-back Services" means a collection method for the return of Unwanted Covered Drugs from County Residents utilizing prepaid and preaddressed mailing envelopes.
- J. "Manufacture" means the production, preparation, propagation, compounding, or processing of a Drug, but does not include the activities of a Repackager or Wholesaler, or practitioner who, distributes or dispenses such substance or device in the course of his or her professional practice or, prepares, compounds, packages, or labels such substance or device.
- K. "Manufacturer" means a Person engaged in the Manufacture of Drugs.
- L. "Nonprescription Drug" means a Drug that may be lawfully sold without a prescription.
- M. "Person" means a human being, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.
- N. "Pharmacy" means a place licensed by the State of California Board of Pharmacy where the practice of pharmacy is conducted.
- O. "Plan Operator" means the Person that develops, implements, and operates a Stewardship Plan, including, but not limited to, a Producer or Stewardship Organization.
- P. "Prescription Drug" means any Drug, including any controlled substance, that is required by federal or state law or regulation to be dispensed by prescription only or is restricted to use by practitioners only.
- Q. "Producer" means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County, including a brand-name or generic Drug. Notwithstanding the previous sentence, "Producer" does not include: (1) a retailer whose store label appears on a Covered Drug or the drug's packaging if the Manufacturer from whom the retailer obtains the Drug is identified in Section 7.90.040(E) of this Chapter; (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Section 7.90.040(E) of this Chapter; (3) a pharmacist who compounds or repackages a prescribed individual drug product for a consumer; or (4) a wholesaler who is not also the Manufacturer.
- R. "Repackager" means a Person who owns or operates an establishment that repacks and re-labels a product or package for further sale, or for distribution without a further transaction.

- S. "Retail Pharmacy" means a Pharmacy licensed by the State of California Board of Pharmacy for retail sale and dispensing of Drugs.
- T. "Stewardship Plan" means a plan for the collection, transportation, and disposal of County Residents' Unwanted Covered Drugs required under Section 7.90.040 of this Chapter that is: (1) financed, developed, implemented, and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; and (3) approved by the Director.
- U. "Stewardship Organization" means an organization designated by a Producer or group of Producers to act as an agent on behalf of one or more Producers to develop, implement, and operate a Stewardship Plan.
- V. "Unwanted Covered Drug" means any Covered Drug that the owner has discarded or intends to discard.

7.90.030 – Jurisdiction.

This ordinance shall apply to all of Marin County including unincorporated and incorporated areas, except for those incorporated areas where the governing body of that incorporated area has authorized its own local health officer or environmental director to administer and enforce the provisions of California Health and Safety Code section 117800 *et seq.*

7.90.040 – Stewardship Plan – Participation.

- A. Each Producer shall participate in a Stewardship Plan. Each Producer must:
 - 1. Operate, individually or jointly with other Producers, a Stewardship Plan approved by the Director; or
 - 2. Enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Stewardship Plan approved by the Director.
- B. Each Stewardship Plan must be approved by the Director before the entity administering the Stewardship Plan starts collecting Unwanted Covered Drugs. Once approved, each Stewardship Plan must have prior written approval of the Director for proposed changes as described in Section 7.90.070.
- C. Beginning 60 days after the effective date of this Chapter, each Drug Wholesaler that sells any Covered Drugs in the County must provide a list of the Producers of those Covered Drugs to the Director in a form prescribed by the Director. Wholesalers must update and resubmit the list by January 15 each year.
- D. Within six months after the effective date of this Chapter, or – if a Producer is not already participating in a Stewardship Plan - within six months after a Producer starts the sale of a Covered Drug in the County, a Producer must notify the Director in writing of the Producer's intent to participate in an existing Stewardship Plan or to form a new Stewardship Plan.
- E. Within six months after the effective date of this Chapter, or within six months after a retailer whose label appears on a Covered Drug or on the Covered Drug's packaging starts selling the Covered Drug in the County, or within six months after a Covered Drug repackaged by Repackager is first sold in the County, and, thereafter, upon request from the Director, a retailer or Repackager whose label appears on a Covered Drug or the Covered Drug's packaging must provide:
 - 1. Written notification as to whether the Manufacturer from whom the retailer or Repackager obtains the Covered Drug has provided its written notice of intent to participate in a Stewardship Plan or form a new Stewardship Plan; and

2. The contact information of the Manufacturer from whom the retailer or Repackager obtains the Covered Drug, including the telephone number, mailing address and email address of the retailer's or Repackager's point of contact at the Manufacturer.
- F. A Producer, either individually or jointly with other Producers, shall:
1. Within nine months after the effective date of this Chapter, or nine months after starting sale of a Covered Drug in the County, identify in writing to the Director a Stewardship Plan Operator, including the Plan Operator's telephone, mailing address and email contact information, that is authorized to be the official point of contact for the Stewardship Plan;
 2. Within nine months after the effective date of this Chapter, or nine months after starting sale of a Covered Drug in the County, notify all Retail Pharmacies and law enforcement agencies in the County of the opportunity to participate as a drop-off site in accordance with Section 7.90.080 of this Chapter and provide a process for forming an agreement between the Stewardship Plan and interested Collectors; and annually thereafter, make the same notification to any nonparticipating or new Retail Pharmacies in the County;
 3. Within one year after the effective date of this Chapter, or one year after starting sale of a Covered Drug in the County, submit a proposed Stewardship Plan as described in Section 7.90.050 to the Director for review;
 4. Within three months after the Director's approval of the Stewardship Plan, operate or participate in the Stewardship Plan in accordance with this Chapter;
 5. Pay all costs and fees associated with its Stewardship Plan, as described in Sections 7.90.120 and 7.90.130.
- G. A Producer, either individually or jointly with other Producers, may:
1. Enter into contracts and agreements with Stewardship Organizations, other service providers, or other entities as necessary, useful or convenient to carry out all or portions of their Stewardship Plan;
 2. Notify the Director of any Producer selling Covered Drugs Manufactured by that Producer or group of Producers in the County that is failing to participate in a Stewardship Plan; and
 3. Perform any other functions as may be necessary or proper to carry out the Stewardship Plan and to fulfill any or all of the purposes for which the plan is organized.
- H. Pursuant to his or her authority under this Chapter, the Director, at his or her discretion, may promulgate regulations allowing smaller Producers to engage in alternate means for supporting safe disposal of Covered Drugs in lieu of participating in a Stewardship Plan. Those regulations may, among other things, define which Producers qualify for this alternative. The Director shall provide a report to the Board of Supervisors if and why any such regulations are promulgated.
- I. The Director may, on a case-by-case basis, approve in writing requests for extensions of time for the submission dates and deadlines in this Section 7.90.040.
- J. The Director may audit the records of a Producer, group of Producers, or Stewardship Organization related to a Stewardship Plan or request that the Producer, group of Producers, or Stewardship Organization arrange for the Director to inspect at reasonable times a Stewardship Plan's or a Collector's facilities, vehicles, and equipment used in carrying out the Stewardship Plan.

7.90.050 – Stewardship Plans – Components.

Each Stewardship Plan, which must be submitted and reviewed according to Section 7.90.060, shall include:

- A. Contact information for all Producers participating in the Stewardship Plan, including each Drug Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Director may direct all inquiries regarding the Producer's participation in the Stewardship Plan;
- B. A description of the proposed collection system to provide convenient ongoing collection service for all Unwanted Covered Drugs from County residents in compliance with the provisions and requirements in Section 7.90.080, including a list of all collection methods and participating Collectors, a list of drop-off sites, a description of how any periodic collection events will be scheduled and located, a description of how any Mail-Back Services will be provided and an example of the prepaid, preaddressed mailers the plan will use. The description of the collection service shall include a list of Retail Pharmacies and law enforcement agencies contacted by the Plan Operator under Section 7.90.040(F)(2) of this Chapter, and a list of all Collectors who offered to participate;
- C. A description of the handling and disposal system for Unwanted Covered Drugs including identification of and contact information for Collectors, transporters and waste disposal facilities to be used by the Stewardship Plan in accordance with Section 7.90.080 and Section 7.90.090 of this Chapter;
- D. A description of the policies and procedures to be followed by Persons handling Unwanted Covered Drugs collected under the Stewardship Plan, including a description of how all Collectors, transporters, and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal, how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Drug Enforcement Administration, and how any Pharmacy collection site will operate under applicable rules and guidelines of the State of California Board of Pharmacy;
- E. A description of how any patient information on Drug packaging will be promptly destroyed;
- F. A description of the public education effort and promotion strategy required in Section 7.90.100 of this Chapter, including a copy of standardized instructions for County Residents, signage developed for Collectors, and required promotional materials the Stewardship Plan proposes to use, and an explanation of how the Stewardship Plan Operator will collaborate with all other Stewardship Plan Operators to develop a single system of promotion for all Stewardship Plans;
- G. Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education, and promotion; and
- H. A description of how the Stewardship Plan will consider:
 1. Use of existing providers of waste pharmaceutical services;
 2. Separating Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and
 3. Recycling of Drug packaging to the extent feasible.
- I. Any additional information specified in Regulations adopted pursuant to this Chapter.

7.90.060 – Stewardship Plans – Review and Approval of Proposed Plan.

- A. Within one year after the effective date of this Chapter, each Producer, group of Producers or Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review, accompanied by the plan review fee in accordance with Section 7.90.130 and any regulations adopted pursuant to this Chapter. The Director may upon request provide information, counseling, and technical assistance about the requirements of this Chapter to assist with the development of a proposed Stewardship Plan.
- B. The Director shall review the proposed Stewardship Plan and determine whether it meets the requirements of this Chapter. In reviewing a proposed Stewardship Plan, the Director shall provide an opportunity for written public comment on the proposed Stewardship Plan and consider any comments received.
- C. After the review under subsection (B) of this Section 7.90.060 and within 90 calendar days after receipt of the proposed Stewardship Plan, the Director shall either approve or reject the proposed Stewardship Plan in writing and, if rejected, provide reasons for the rejection.
- D. If the Director rejects a proposed Stewardship Plan, a Producer, group of Producers, or Stewardship Organization must submit a revised Stewardship Plan to the Director within 60 calendar 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) of this Section 7.90.060.
- E. If the Director rejects a revised Stewardship Plan, or any subsequently revised plan, the Director may deem the Producer or group of Producers out of compliance with this Chapter and subject to the enforcement provisions in this Chapter.
- F. In approving a proposed Stewardship Plan, the Director may exercise reasonable discretion to waive strict compliance with the requirements of this Chapter that apply to Producers in order to achieve the objectives of this Chapter.
- G. At least every four years after the Stewardship Plan starts operations, submit an updated Stewardship Plan to the Director explaining any substantive changes to components of the Stewardship Plan required in Section 7.90.050. The Director shall review updated Stewardship Plans using the process described in Section 7.90.060 of this Chapter; and
- H. The Director shall make all Stewardship Plans and proposed plans submitted under this Section 7.90.060 available to the public.

7.90.070 – Stewardship Plans – Prior Approval for Change.

- A. After the first full year of participation in a Stewardship Plan, a Producer or group of Producers may notify the Director in writing of intent to form a new Stewardship Plan, and identify a Plan Operator, including the Plan Operator's telephone, mailing address, and email contact information, that is authorized to be the official point of contact for the proposed new Stewardship Plan. Within three months of such notification, the Producer or group of Producers shall submit a proposed Stewardship Plan as described under Section 7.90.050 to the Director for review.
- B. Proposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to, changes to participating Producers, collection methods, achievement of the service convenience requirement described under Section 7.90.080(B)(1), policies and procedures for handling Unwanted Covered Drugs, or education and promotion methods or disposal facilities, must be approved in writing by the Director before the changes are implemented.

- C. A Producer or group of Producers participating in a Stewardship Plan shall submit to the Director any proposed change to the Stewardship Plan as described under subsection (B) of this Section 7.90.070 in writing at least 30 calendar days before the change is scheduled to occur.
- D. The Plan Operator of an approved Stewardship Plan shall notify the Director at least 15 calendar days before implementing any changes in drop-off site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, pre-addressed mailers, that do not substantially alter achievement of the service convenience requirement under Section 7.90.080(B)(1) of this Chapter, or other changes that do not substantially alter plan operations under subsection (B) of this Section 7.90.070.
- E. The Plan Operator may request an advance determination from the Director of whether a proposed change would be deemed to substantively alter plan operations. The Director shall provide a determination within 90 calendar days after receipt of the request, and shall provide reasons for the determination.

7.90.080 – Stewardship Plans - Collection of Covered Drugs.

- A. This Section does not require any Person to serve as a Collector in a Stewardship Plan. A Person may offer to serve as a Collector voluntarily, or may agree to serve as a Collector in exchange for incentives or payment offered by a Producer, group of Producers or Stewardship Organization. Collectors may include law enforcement agencies, Pharmacies, Mail-Back Services or other entities, operating in accordance with state and federal laws and regulations for the handling of Covered Drugs, including but not limited to those of the United States Drug Enforcement Administration, and in compliance with this Chapter. A Pharmacy collection site shall operate under applicable rules and guidelines of the State of California Board of Pharmacy.
- B. The collection system for each Stewardship Plan shall:
 1. Provide reasonably convenient and equitable access for all County Residents through drop-off sites. The system of drop-off sites shall be geographically distributed to provide reasonably convenient access throughout the County, and at no time shall there be less than 25 drop-off sites throughout the County. If the service convenience goal in this subsection (B)(1) cannot be achieved due to a lack of drop-off sites at pharmacies, law enforcement agencies, or other qualified Collectors, then those areas shall be served through periodic collection events and/or Mail-Back Services;
 2. Be safe and secure, including providing for the prompt destruction of patient information on Drug packaging.
 3. Give preference to having Retail Pharmacies and law enforcement agencies serve as drop-off sites.
 4. Include, as Collectors, any Retail Pharmacy or any law enforcement agency willing to serve voluntarily as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Chapter within three months of their offer to participate, unless the Collector requests a longer time frame. A Stewardship Plan may also accept other Collectors willing to serve as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of this Chapter; and
 5. Make Mail-Back Services available, free of charge, to disabled and homebound County residents upon request through the Stewardship Plan's toll-free telephone number and website, and through distribution of prepaid, preaddressed mailers to Persons providing services to such County residents.

C. Drop-off sites shall accept all Covered Drugs from County residents during all hours that the Retail Pharmacy, law enforcement agency, or other Collector is normally open for business with the public. Drop-off sites not operated by a law enforcement agency shall utilize secure collection bins in compliance with all applicable requirements, including but not limited to those of the United States Drug Enforcement Administration and the State of California Board of Pharmacy. In the event that more than one Stewardship Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.

7.90.090 – Stewardship Plans - Disposal of Unwanted Products.

- A. Each Stewardship Plan shall comply with all local, state, and federal laws and regulations applicable to disposal of pharmaceutical waste and controlled substances.
- B. Each Stewardship Plan shall dispose of collected Covered Drugs by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must possess all required regulatory permits and licenses.
- C. A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection or equivalent protection at lesser costs than those provided by the disposal technologies in subsections (B) of this Section 7.90.090. The proposed technology must at a minimum 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.

7.90.100 – Stewardship Plans - Promotion and Outreach.

- A. All Stewardship Plans shall coordinate with each other and develop a single system of promotion that shall:
 - 1. Promote the Stewardship Plans so that collection options for Covered Drugs are widely understood by County Residents, pharmacists, retailers of Covered Drugs, and health care practitioners including doctors and other prescribers, veterinarians and veterinary hospitals, and promote the safe storage of Covered Drugs by County Residents;
 - 2. Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions for County Residents on the use of collection bins and a readily-recognizable, consistent design of collection bins;
 - 3. Establish a single toll-free telephone number and single website where collection options and current locations of drop-off sites will be publicized, and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drugs to the Stewardship Plan. These materials must be provided to Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County Residents. Plain language and explanatory images should be used to make use of medicine collection services readily understandable by all County residents, including individuals with limited English proficiency;
 - 4. Conduct a biennial survey of County residents and a survey of pharmacists, veterinarians, and health professionals in the County who interact with patients on use of medicines after the first full year of operation of the plans. Survey

questions shall measure percent awareness of the Stewardship Plans, assess to what extent drop-off sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from Prescription and Nonprescription Drugs used in the home. Draft survey questions shall be submitted to the Director for review and comment at least 30 calendar 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 7.90.100 within 90 calendar days of the end of the survey period. The privacy of all survey respondents shall be maintained.

- B. All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 7.90.100 shall be in translated into or conducted in languages specified by the Director.
- C. The Director shall provide guidance on the development of a single system of promotion for all Stewardship Plans, if there is more than one Stewardship Plan.

7.90.110 – Stewardship Plans - Reporting Requirements.

- A. Within six months after the end of the first 12-month period of the Stewardship Plan Operation, and annually thereafter, the Plan Operator of a Stewardship Plan shall submit a report to the Director on behalf of participating Producers describing the Plan's activities during the previous reporting period. The report must include:
 - 1. A list of Producers participating in the Stewardship Plan;
 - 2. The amount, by weight, of Covered Drugs collected, including the amount by weight from each collection method used;
 - 3. A list of drop-off sites;
 - 4. The number of mailers provided for disabled and/or home-bound County residents;
 - 5. The locations where mailers were provided, if applicable;
 - 6. The dates and locations of collection events held, if applicable;
 - 7. The transporters used and the disposal facility or facilities used for all Covered drugs;
 - 8. Whether any safety or security problems occurred during collection, transportation or disposal of Unwanted Covered Drugs during the reporting period and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and to improve safety and security in the future;
 - 9. A description of the public education, outreach and evaluation activities implemented during the reporting period;
 - 10. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
 - 11. A summary of the Stewardship Plan's goals, the degree of success in meeting those goals in the past year, and, if any goals have not been met, what effort will be made to achieve the goals in the next year; and
 - 12. The total expenditures of the Stewardship Plan during the reporting period.
- B. The Director shall make reports submitted under this Section available to the public.
- C. For the purposes of this Section 7.90.110, "reporting period" means the period from January 1 through December 31 of the same calendar year, unless otherwise specified to the Plan Operator by the Director.

7.90.120 – Stewardship Plans - Administrative and Operational Costs and Fees.

- A. A Producer or group of Producers participating in a Stewardship Plan shall pay all administrative and operational costs related to their Stewardship Plan, except as provided under this Section 7.90.120. Administrative and operational costs related to the Stewardship Plan include but are not limited to the following:
1. Collection and transportation supplies for each drop-off site;
 2. Acquisition of all secure collection bins for drop-off sites;
 3. Ongoing maintenance or replacement of secure collection bins, as requested by Collectors;
 4. Prepaid, preaddressed mailers provided to disabled and/or home-bound County residents;
 5. Operation of periodic collection events, including costs of law enforcement staff time if necessary;
 6. Transportation of all collected Covered Drugs to final disposal, including costs of law enforcement escort if necessary;
 7. Environmentally sound disposal of all collected Covered Drugs under Section 7.90.090 of this Chapter;
 8. Program promotion under Section 7.90.100 of this Chapter; and
 9. Costs related to any review of a Stewardship Plan for purposes of obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code section 21000, et seq.).
- B. No Person or Producer may charge a point-of-sale fee to consumers to recoup the costs of a Stewardship Plan, nor may they charge a specific point-of collection fee at the time the Covered Drugs are collected.
- C. Producers are not required to pay for costs of staff time at drop-off sites provided by Collectors volunteering to participate in a Stewardship Plan.

7.90.130 – Plan Review and Annual Operation Fees.

- A. The Board of Supervisors authorizes the Director to charge Producers or a group of Producers participating in a Stewardship Plan fees to cover all costs the County incurs in administering and enforcing this Chapter.
- B. A Producer or group of Producers participating in a Stewardship Plan shall pay to the Director plan review fees to be established under subsection E of this Section 7.90.130 for:
1. Review of proposed Stewardship Plan;
 2. Resubmittal of a proposed Stewardship Plan;
 3. Review of changes to an approved Stewardship Plan;
 4. Submittal of an updated Stewardship Plan at least every four years under Section 7.90.060(G) of this Chapter; or
 5. Review of any petition for approval to use alternative final disposal technologies under Section 7.90.090(C) of this Chapter.
- C. In addition to plan review fees, a Producer or group of Producers participating in a Stewardship Plan shall pay to the Director annual operating fees to be established under subsection E of this Section 7.90.140.
- D. A Plan Operator or Stewardship Organization may remit fees on behalf of participating Producers.

- E. The Board of Supervisors authorizes the Director to set fees pursuant to this Chapter by regulation to recover but not exceed actual costs to the County at a rate duly approved by the Board of Supervisors.

7.90.140 – Stewardship Plans - Enforcement and Penalties.

- A. The Director shall administer the enforcement and penalty provisions of this Chapter.
- B. If the Director makes findings and determines that any Person has violated this Chapter or a regulation adopted pursuant to this Chapter, the Director 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 30 calendar days after receipt 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 Director may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter. Upon findings made under subsection (B), the Person or Persons shall be subject to an administrative fine set forth in the regulations adopted pursuant to this Chapter. Each day a violation continues constitutes a separate violation.
 - 1. Fine Procedures. Notice of the fine shall be served on the Person or Persons. The notice shall contain an advisement of the right to request a hearing before the Director or his or her designee contesting the imposition of the fine. Said hearing must be requested within 10 calendar days of the date appearing on the notice of the fine. The decision of the Director shall be based upon a finding that the above-listed ground for a contest has been met and shall be a final administrative order, with no administrative right of appeal.
 - 2. Failure to Pay Fine. If said fine is not paid within 30 calendar days from the date appearing on the notice of the fine or of the notice of determination of the Director after the hearing, the Director may use any lawful means for collecting the fine, including instituting an action in any court of proper jurisdiction.
- D. The County, a Producer, group of Producers, a Stewardship Organization, a group of Stewardship Organizations, any organization with tax exempt status under 26 United States Code section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof 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 the County, Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof that is the prevailing party in a civil action brought under this subsection (D). A Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof may institute a civil action under this subsection (D) only if:
 - 1. The Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof has filed a Complaint with the Director;
 - 2. 90 calendar days have passed since the filing of the Complaint;

3. After such 90 calendar day period has passed, the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof provides 30 calendar day written notice to the Director and the County of its intent to initiate civil proceedings; and
 4. The County has not provided notice to the Producer, group of Producers, Stewardship Organization, group of Stewardship Organizations, organization with tax exempt status under 26 United States Code Section 501(c)(3) or 501(c)(4) and with a primary mission of protecting the environment in the San Francisco Bay Area, or a combination thereof of the County's intent to initiate civil proceedings by the end of the 30 calendar day period.
- 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 five hundred (\$500) for each day per violation, or by imprisonment in the County Jail 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 (\$1000) per day per violation. Each day in which the violation continues shall constitute a separate violation.
 - 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. No criminal, civil or administrative action under this Section 7.90.140 may be brought more than four years after the date of the alleged violation.

7.90.150 – Stewardship Plan – Regulations, Performance Standards, and Report to Board.

- A. The Director may adopt regulations necessary to implement, administer, and enforce this Chapter.
- B. The Director may work with a Stewardship Plan Operator to define goals for collection amounts, education, and promotion for a Stewardship Plan.
- C. The Director shall report as requested to the Board of Supervisors concerning the status of all Stewardship Plans and recommendations for changes to this Chapter.

7.90.160 – General Provisions.

- A. **Undertaking for the General Welfare.** In adopting and implementing this Chapter, the County is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing, on its officers or employees an obligation by which they could be liable in money damages to any Person or entity who claims that a breach proximately caused injury.
- B. **No Conflict with State or Federal Law.** This Chapter shall be construed so as not to conflict with applicable federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any County agency or department to impose any duties or obligations in conflict with limitations on authority established by State or federal law at the time such agency or department action is taken. The County shall suspend enforcement of this Chapter to the extent that said enforcement would conflict with any preemptive State or

federal legislation subsequently taken. Nothing in this Chapter is intended or shall be construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair competition laws of the State of California or the United States.

- C. **Severability.** If any article, section, subsection, paragraph, sentence, clause, or word of this Chapter is, for any reason, held to be unconstitutional or invalid by a court of competent jurisdiction, such decision shall not affect the validity of the remaining portions of this ordinance. To this end, the provisions of this Chapter and its regulations are severable.
- D. This Chapter is categorically exempt from the provisions of the California Environmental Quality Act under California Code of Regulations, Title 14, sections 15307 and 15308.

SECTION II. Effective Date. This ordinance shall be and is hereby declared to be in full force and effect as of thirty (30) days from and after the date of its passage and shall be published once before the expiration of fifteen (15) days after its passage, with the names of the supervisors voting for and against the same in the *Marin Independent Journal*, a newspaper of general circulation published in the County of Marin.

PASSED AND ADOPTED at a regular meeting of the Board of Supervisors of the County of Marin held on this ___th day of _____ 2015 by the following vote:

AYES: SUPERVISORS
NOES:
ABSENT:

PRESIDENT, BOARD OF SUPERVISORS

ATTEST:

CLERK