

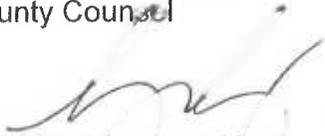
ANALYSIS

This ordinance amends Title 11 - Health and Safety of the Los Angeles County Code, by adding Chapter 11.17, relating to requirements for the safe, convenient, and sustainable collection and disposal of unwanted pharmaceutical drugs and unwanted sharps.

The ordinance requires manufacturers of certain pharmaceutical drugs and sharps that are sold, offered for sale, or otherwise distributed for use in the County to create and fund a stewardship program that provides safe, convenient, and legal means of disposal of said drugs and sharps for County residents.

Collection areas will be limited to the unincorporated County and may include any incorporated city for which the County Department of Public Health acts as the local health officer if the respective city council adopts the requirements of the ordinance into its municipal code.

MARY C. WICKHAM
County Council

By 

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GVC:sc

Requested: 1/6/16

Revised: 4/8/16

ORDINANCE NO. _____

An ordinance amending Title 11 – Health and Safety of the Los Angeles County Code, by adding Chapter 11.17, relating to requirements for the safe, convenient, and sustainable collection and disposal of unwanted pharmaceutical drugs and sharps.

The Board of Supervisors of the County of Los Angeles ordains as follows:

SECTION 1. Chapter 11.17 is hereby added to read as follows:

Chapter 11.17 Stewardship Program for Collection and Disposal of

Unwanted Covered Drugs and Unwanted Sharps.

11.17.010 Title.

11.17.012 Purpose.

11.17.015 Findings.

11.17.020 Definitions.

11.17.030 Stewardship Plans – Participation.

11.17.040 Stewardship Plans – Components.

11.17.050 Stewardship Plans – Collection of Unwanted Covered

Drugs and Unwanted Sharps.

11.17.060 Stewardship Plans – Disposal of Unwanted Covered

Drugs and Unwanted Sharps.

11.17.070 Stewardship Plans – Costs to Be Borne by Responsible

Stewards.

11.17.080 Stewardship Plans – Reporting Requirements.

11.17.090 Stewardship Plans – Identification of Responsible

Stewards of Covered Drugs and Sharps.

11.17.100 Stewardship Plans – Review.

11.17.110 Stewardship Plans – Prior Approval for Changes.

11.17.120 Stewardship Plans – Enforcement and Penalties.

11.17.130 Stewardship Plans – Regulations, Guidelines, and

Reports.

11.17.140 Stewardship Plan – County Review and Oversight Fees.

11.17.150 Information Required at Point of Sale.

11.17.160 Stewardship Plans – Promotion, Outreach, and

Education.

11.17.170 Undertaking for the General Welfare.

11.17.180 Compliance With Federal, State, and Local Laws.

11.17.190 Severability.

11.17.010 Title.

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

11.17.012 Purpose.

The purpose of this Chapter is to establish a Pharmaceutical Drugs and Sharps Stewardship Program that: (1) allows for the safe, convenient, and sustainable collection and disposal of Unwanted Covered Drugs and Unwanted Sharps, and

collection and disposal of Unwanted Covered Drugs and Unwanted Sharps, 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 Department of Public Health.

This Chapter is intended to supplement the provisions of State law by prescribing higher standards of sanitation, health and safety where not preempted by federal or State law.

11.17.015 Findings.

In adopting this Chapter, the Board of Supervisors recognizes and hereby adopts the following, non-exhaustive list of findings:

A. Pharmaceutical drugs allow people to live longer, healthier, and more productive lives.

B. A Mayo Clinic study issued in June 2013 found that nearly seventy percent (70%) of Americans take at least one (1) prescription drug, up from forty-eight percent (48%) in 2007-2008. As an example, the Centers for Disease Control and Prevention reported that in 2012, health care providers in the United States wrote two hundred and fifty-nine million (259,000,000) prescriptions for painkillers alone, enough for every American adult to have a bottle of such pills.

C. Estimates show that forty percent (40%) of pharmaceutical drugs prescribed to consumers in the United States each year are never entirely used. There are a number of reasons for this. For example, a patient's course of treatment may be

modified or discontinued, and some medications are prescribed on an "as needed" basis.

D. Many residents are unsure of safe disposal methods for their unwanted drugs and sharps, and proper disposal services are limited. These situations can negatively impact the environment and represent a significant public health problem.

E. Improper disposal of unwanted drugs provides a pathway for active pharmaceutical compounds to enter the environment, including the water supply. The United States Environmental Protection Agency ("EPA"), for example, recognizes that disposal of unwanted pharmaceutical drugs in the toilet, sink, and household trash contributes to the presence of active pharmaceutical compounds in some groundwater and drinking water. Reducing the amount of pharmaceutical drugs that are disposed in this manner will help reduce the presence of pharmaceutical drugs in the environment.

F. Failure of consumers to properly dispose of their leftover, expired, and otherwise unwanted pharmaceutical drugs can lead to pharmaceutical drug abuse, addiction, and overdoses. According to the Health Officer for Los Angeles County, pharmaceutical drug abuse has become one of the fastest growing public health concerns in the United States, and in Los Angeles County. Results from the 2013 National Survey on Drug Use and Health indicate that about 15.3 million people aged twelve (12) or older engaged in non-medical use of pharmaceutical drugs during the year prior to the study. Seventy percent (70%) of those addicted to pharmaceutical drugs say they first accessed pharmaceutical drugs by taking them from friends and family who kept them unlocked in the house.

G. In addition, deaths from drug overdose have been rising steadily over the past two (2) decades. Every day in the United States, on average, one hundred and thirteen (113) people die as a result of drug overdose, and another six thousand seven hundred and forty-eight (6,748) are treated in emergency departments for the misuse or abuse of pharmaceutical drugs. In 2011, eighty percent (80%) of the forty-one thousand three hundred and forty (41,340) drug overdose deaths in the United States were unintentional. In Los Angeles County from 2000 to 2009, there were eight thousand two hundred and sixty-five (8,265) drug-related deaths.

H. The accessibility of pharmaceutical drugs that are not properly disposed of can also lead to unintentional poisonings. Nearly nine (9) out of ten (10) poisoning deaths are caused by pharmaceutical drugs.

I. The EPA also estimates that about eight million (8,000,000) people in the United States use more than three billion (3,000,000,000) needles, syringes, and lancets each year.

J. Improper disposal of needles, syringes, and lancets, commonly known as "sharps," puts many people at risk of injury and serious infection. There are frequent reports of workers at waste facilities, recycling centers, parks, recreation centers, hotels, health clubs, and other places finding and being injured in the workplace by Sharps that have been disposed of improperly. Additionally, flushed sharps can make their way to beaches and streams, creating a risk of injury to individuals, including children.

K. Although it is illegal to dispose of unwanted sharps in the trash or down the toilet, there are limited options available for County residents to legally and conveniently dispose of their unwanted sharps.

L. There is a considerable need to provide residents in Los Angeles County with safe, convenient, and sustainable methods for disposal of unwanted pharmaceutical drugs and sharps. Since 1988, the County has funded various programs that collect and dispose of expired or unused pharmaceutical drugs and sharps waste. These programs collect more than fifty thousand (50,000) pounds of pharmaceutical drugs and sharps waste annually but they do not offer adequate disposal options for the County's ten million (10,000,000) residents.

M. On November 5, 2008, the Los Angeles County Board of Supervisors adopted a resolution supporting Extended Producer Responsibility (EPR), also called Product Stewardship. EPR is a strategy that places 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 stage of the product's lifecycle. Many other local and national governments have expressed support for variations of EPR, including CalRecycle, the National Association of Counties, and the National League of Cities.

N. A number of Canadian provinces and other countries, including France, Spain, and Portugal already have active, well-established drug product stewardship programs in place, which are paid for by drug companies and operated by Product Stewardship Associations on their behalf. To date, however, despite several legislative

attempts, there is no voluntary or mandatory Statewide product stewardship program for unwanted pharmaceutical drugs in California.

O. In 2012, Alameda County became the first local government in the United States to pass such an ordinance requiring pharmaceutical companies to design, fund, and operate a safe pharmaceutical drug collection and management program. On September 30, 2014, the Ninth Circuit Court of Appeal rejected a legal challenge to Alameda County's ordinance brought by drug manufacturers, and the United States Supreme Court declined to review that decision.

P. King County, Washington, as well as the California Counties of Marin, Santa Clara, Santa Cruz, and San Mateo, and the City and County of San Francisco subsequently enacted similar ordinances requiring manufacturers to design, fund, and operate programs to safely collect and dispose of local residents' unwanted pharmaceutical drugs.

Q. In 2010, Congress passed the "Secure and Responsible Drug Disposal Act of 2010," Public Law No. 111–273, which authorized the Attorney General to increase the methods by which controlled substances may be collected. The goal of the bill was to increase opportunities for drug collection in order to reduce the instances of substance abuse, accidental poisoning, and release of harmful substances into the environment. On September 9, 2014, the Drug Enforcement Agency (DEA) promulgated regulations that authorize authorized collectors registered with the DEA, defined below, to maintain secure collection bins for controlled substances.

R. A manufacturer-funded collection and disposal program for unwanted pharmaceutical drugs and sharps would significantly increase the options available to County residents for the safe and convenient disposal of unwanted pharmaceutical drugs and sharps.

11.17.020 Definitions.

For purposes of this Chapter, the following definitions shall apply. Whenever any technical words or phrases are not defined herein, but are defined under State law, such definitions are incorporated into this Chapter and shall be deemed to apply as though set forth herein in full.

A. "Authorized Collector" shall mean any Person registered with the DEA, defined below, to collect Controlled Substances. For purposes of this Chapter, Authorized Collector shall also include federal, State, tribal, or local law enforcement agencies.

B. "C.F.R." shall mean the Code of Federal Regulations.

C. "Collection Site" shall mean a location where a Host provides one or more receptacles pursuant to a Stewardship Plan for County residents to safely and securely deposit Unwanted Covered Drugs and/or Unwanted Sharps.

D. "Contact Information" shall mean a business telephone number, facsimile telephone number, mailing address, and electronic mail address.

E. "Controlled Substances" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 11053 through

11058 or Title 21 of the U.S.C., defined below, Sections 812 and 813, or any successor legislation.

F. "Covered Drug" shall mean a Drug, as defined in this Chapter, in any form, including injectable, that is sold to, offered for sale to, or otherwise distributed for use by, one or more consumers in the County, including prescription, nonprescription, brand name, and generic; however, notwithstanding the foregoing, Covered Drug 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 as described in Title 21 of the U.S.C., defined below, Section 355-1; and (5) drugs that are biological products as defined by Title 21 of the C.F.R. Section 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.

G. "DEA" shall mean the United States Drug Enforcement Administration.

H. "Department" shall mean the Department of Public Health.

I. "Director" shall mean the Director of the Department of Public Health or his or her designee.

J. "Drug" shall mean, per Title 21 of the U.S.C., defined below: (1) any article recognized in the official United States Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) any article, other than food, intended to affect the structure or any function of the body of humans or animals; and (4) any article 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. For purposes of this Chapter, Drug shall also include Controlled Substances.

K. "EPA" shall mean the United States Environmental Protection Agency.

L. "FDA" shall mean the United States Food and Drug Administration.

M. "Hazardous Waste Disposal Facility" shall have the meaning set forth by the EPA under Title 40 of the C.F.R., parts 264 and 265, or any successor legislation.

N. "Host" shall mean either: (1) an Authorized Collector who collects Unwanted Covered Drugs and/or Unwanted Sharps pursuant to this Chapter; or (2) a Person who is not an Authorized Collector who collects only Unwanted Sharps pursuant to this Chapter.

O. "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.

P. "Manufacturer" shall mean a Person who Manufactures or causes to be Manufactured a Covered Drug and/or Sharps.

Q. "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.

R. "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.

S. "Nonprescription Drug" shall mean a Drug that may be lawfully sold without a prescription.

T. "Participating City" shall mean an incorporated city within the County that adopts the requirements of this Chapter into its respective municipal code and within which the County Health Officer is authorized to enforce said requirements.

U. "Person" shall mean 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.

V. "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 prescription Drugs are dispensed. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the Board of Pharmacy wherein Controlled Substances, dangerous Drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from

which the Controlled Substances, dangerous Drugs, or dangerous devices are furnished, sold, or dispensed at retail. For purposes of this Chapter, Pharmacy shall include on-line pharmacies and mail-order pharmacies.

W. "Potential Authorized Collector" shall mean any Person, such as a Manufacturer, distributor, Reverse Distributor, narcotic treatment program, retail Pharmacy, or a hospital/clinic with an on-site Pharmacy, that is registered, or that may apply to register, with the DEA for the collection of Drugs. For purposes of this Chapter, Potential Authorized Collector shall also include any Federal, State, tribal, or local law enforcement agency.

X. "Repackager" shall mean a Person who owns or operates an establishment that repacks and/or relabels a Covered Drug or Sharp for further sale or distribution.

Y. "Responsible Steward" shall mean a Manufacturer of a Covered Drug or Sharp. Responsible Steward does not include: (1) a retailer whose store label appears on a Covered Drug or its packaging if the Manufacturer from whom the retailer obtains the Drug is identified under Section 11.17.090; (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Section 11.17.090; (3) a pharmacist who compounds or repackages a prescribed individual Drug product for a consumer; or (4) a Wholesaler unless said Wholesaler is also a Manufacturer.

Z. "Reverse Distributor" shall mean every Person who acts as an agent for Pharmacies, Drug Wholesalers, third-party logistics providers, Manufacturers, and other Persons by receiving, inventorying, warehousing, and managing the disposition of

outdated or nonsaleable dangerous Drugs, as defined in California Business and Professions Code Section 4040.5 or its successor legislation.

AA. "Service Area" shall mean the unincorporated County and all Participating Cities.

BB. "Sharp" shall mean a needle, safety engineered needle, lancet, or other similar instrument that is designed to puncture the skin of individuals or animals for medical purposes and that is sold to, offered for sale to, 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.

CC. "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.

DD. "Stewardship 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.

EE. "Stewardship Program" or "Program" shall mean the County program described in this Chapter.

FF. "U.S.C." shall mean the United States Code.

GG. "Unincorporated Community" shall mean an unincorporated statistical area located within the unincorporated area of the County, as identified by the County's Internal Services Department and listed on the Department's website.

HH. "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.

II. "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.

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

11.17.030 Stewardship Plans — Participation.

A. Each Responsible Steward shall participate in 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 a Stewardship Plan, on the Responsible Steward's behalf.

B. Each Stewardship Plan must be approved by the Director before any collection of Covered Drugs and/or Sharps may commence thereunder. Proposed changes to an approved Stewardship Plan shall be subject to the requirements set forth in Section 11.17.110.

C. Each Responsible Steward operating individually, jointly with other Responsible Stewards or through a Stewardship Organization shall:

1. Within six (6) months of the effective date of this Chapter or six (6) months after a Covered Drug or Sharp is first sold to, offered for sale to, or otherwise distributed for use by, one or more consumers in the County, whichever is later, notify the Director in writing of the Responsible Steward's intent to operate or participate in a Stewardship Plan.

2. Within six (6) months of the effective date of this Chapter or six (6) months after a Covered Drug or Sharp is first sold or offered for sale in 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 individual's name and contact information. Contact information shall be kept current at all times. A Responsible Steward shall notify the Director of any change in contact information within ten (10) business days.

3. Within six (6) months of the effective date of this Chapter or six (6) months after a Covered Drug or Sharp is 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 Hosts, and provide the Director with copies of all such notifications:

a. All Potential Authorized Collectors within the Service Area and those within two and one-half (2.5) miles of the outer boundaries of the Service Area;

b. Persons other than Potential Authorized Collectors, such as retail establishments, that could potentially serve as Hosts for Unwanted Sharps within the Service Area and those within two and one-half (2.5) miles of the outer boundaries of the Service Area; and

c. All law enforcement agencies within the Service Area and those within two and one-half (2.5) miles of the outer boundaries of the Service Area.

4. Within nine (9) months of the effective date of this Chapter or nine (9) months after a Covered Drug or Sharp is first sold or offered for sale in the County, whichever is later, submit to the Director for review a proposed Stewardship Plan as described in Section 11.17.040 for each Covered Drug and type of Sharp it Manufactures. A Responsible Steward may submit separate Stewardship Plans for each Covered Drug or type of Sharp it Manufactures or a combined Stewardship Plan for multiple Covered Drugs or types of Sharps.

5. Within three (3) months of the Director's approval of the Stewardship Plan, the Stewardship Plan shall be implemented in accordance with this Chapter.

6. At least every three (3) years after the Stewardship Plan commences operations, submit an updated Stewardship Plan to the Director explaining any substantive changes to the Stewardship Plan. The updated Stewardship Plan shall be accompanied by the Stewardship Plan review fee in accordance with Section 11.17.140 of this Chapter. The Director shall review updated Stewardship Plans using the process described in Section 11.17.100.

D. 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.

E. Should the Responsible Steward undergo any change in ownership or control, it must notify the Director within thirty (30) days of such change and provide the Contact Information of the Person to whom ownership or control has shifted.

F. Each Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, shall commence good faith negotiations with any other Responsible Steward expressing an interest in participating in its Stewardship Plan within thirty (30) calendar days of receiving notice of such interest. For every Responsible Steward not accepted as a participant in the Stewardship 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 the reasons for such decision.

G. 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 same within thirty (30) calendar days.

H. 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 (3) 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 11.17.040 to the Director for review. The new Stewardship Plan shall be accompanied by the Stewardship Plan review fee in accordance with Section 11.17.140 of this Chapter. The Director shall review new Stewardship Plans using the process described in Section 11.17.100.

I. Should a Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, become aware of any Covered Drug or Sharp being sold to, offered for sale to, or otherwise distributed for use by, one or more consumers in 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.

J. 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 11.17.030.

K. The Director may audit all records of a Responsible Steward, group of Responsible Stewards, or Stewardship Organization reasonably 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.

11.17.040 Stewardship Plans — Components.

Each Stewardship Plan, which must be submitted and reviewed according to Section 11.17.110, 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 Manufactures; and the Contact Information of an official point of contact 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 11.17.050. The description of the collection services shall include but not be limited to a list of all collection methods and participating Hosts; a list of addresses for the Collection Sites; a description of how any periodic collection events will be scheduled and where they will be located; and a description of how any

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 11.17.030, and a list of all who expressed an interest in serving as Hosts in the Stewardship Plan.

C. A description of the proposed handling and disposal system, including the name and Contact Information for each Host, each Person retained to transport the collected items, each Hazardous Waste Disposal Facility to be used by the Stewardship Plan in accordance with Sections 11.17.050 and 11.17.060, 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 Host, each Reverse Distributor, all participating Hazardous Waste Disposal Facilities, and any other Person retained to implement any portion of the Stewardship 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 DEA and the State of California Board of Pharmacy.

E. A certification that any patient information appearing on Unwanted Covered Drug and/or Unwanted Sharp packaging will be kept secure and promptly destroyed.

F. A description of the public education and promotion strategy required in Section 11.17.160, including but not limited to a copy of instructions, signage, and promotional materials for County residents, as well as instructions and signage, as needed, for Host, Reverse Distributors, Hazardous Waste Disposal Facilities, and all other Persons implementing any portion of the Stewardship Plan.

G. Proposed short-term and long-term plans for frequency of collection from Collection Sites, public education, and promotion of the Stewardship 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.

11.17.050 Stewardship Plans — Collection of Unwanted Covered Drugs and Unwanted Sharps.

A. This Chapter does not require any Person to serve as a Host in a Stewardship Plan. A Person may offer to serve as a Host 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:

1. Provide ongoing, reasonably convenient and equitable access for all 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 must be met:

a. 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 (1) Collection Site for Unwanted Covered Drugs, at least one (1) Collection Site for Unwanted Sharps, and for every thirty thousand (30,000) residents at least one (1) Additional Collection Site for Unwanted Covered Drugs and at least one (1) Additional Collection Site for Unwanted Sharps. A list of all unincorporated communities can be obtained from the Department; and

b. Travel Distance: Collection Sites shall be geographically distributed so as to ensure that every resident within the Service Area is within two and one-half (2.5) miles of a Collection Site for Unwanted Covered Drugs and a Collection Site for Unwanted Sharps to the greatest extent feasible.

2. In areas where the minimum requirements set forth in subsection 1 are not met, the Stewardship Plan shall set forth the reasons for such failure and provide for: (a) monthly collection events; and/or (b) mailers to be distributed to consumers in those areas upon request.

3. Responsible Stewards must ensure the safe and secure handling and disposal of the Unwanted Covered Drugs and/or Unwanted Sharps via the

Stewardship Plan, including but not limited to the prompt destruction of patient information on any and all packaging.

4. Responsible Stewards must include a mechanism for distributing to consumers FDA-compliant Sharps containers designed for the safe handling of Unwanted Sharps within the consumer's home, and at no cost to the consumer. This distribution should preferably occur at the point of sale of the injectable Drug to the consumer, or at the time the consumer otherwise receives the Sharps for usage. A Sharps Manufacturer that can demonstrate that its product is designed to be protective of public health and safety and/or the environment, such as by housing the Sharp within a built-in retractable device, may apply to the Director for exemption from this specific requirement. The Director shall make such determinations on a case-by-case basis.

5. Responsible Stewards must provide FDA-compliant Sharps collection receptacles to Hosts with Sharps Collection Sites.

6. Commence good faith negotiations with each Potential Authorized Collector and any other Person expressing an interest to serve as a Host within thirty (30) calendar days of the Person's expression of such interest. For every Person not accepted as a Host, the Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall submit a written explanation to the Director within thirty (30) calendar days of the rejection setting forth the reasons for such decision.

a. Should a Responsible Steward receive more notices of interest than are needed for the number of Collection Sites required under Section 11.17.050 B.1, then to the greatest extent feasible, the Responsible Steward

shall give priority to Pharmacies and hospitals/clinics with an on-site Pharmacy to serve as Hosts under its Stewardship Plan.

b. A Responsible Steward may not discriminate against small or independent Pharmacies, and must make best efforts to allow such Pharmacies to serve as Hosts under its Stewardship Plan.

7. 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 telephone number and website. Assistance through the toll-free telephone 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 Host 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 twenty-four (24) hour, toll-free telephone number and website for the Stewardship Plan. Said toll-free telephone 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 twenty-four (24) hours of notice of same.

E. Commercial and institutional establishments, including but not limited to hospitals, clinics, and Pharmacies, are responsible for proper disposal of their Drugs and Sharps waste and may not utilize any collection mechanism developed pursuant to this Chapter or by any public entity designed for use by, residents.

11.17.060 Stewardship Plans — Disposal of Unwanted Covered

Drugs and Unwanted Sharps.

A. Covered Drugs collected under a Stewardship Plan must be disposed of by combustion at a permitted hazardous waste incinerator or cement kiln, or an incinerator that meets the EPA's Large Municipal Waste Combustor or Small Municipal Waste Combustor standards under Title 40 of the C.F.R., Parts 60 and 62, or any successor legislation and assures all materials are "non-retrievable" as defined by the DEA.

B. Sharps collected under a Stewardship Plan must be disposed of in accordance with California Health and Safety Code Section 118286 or any successor legislation.

C. A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections A and B, 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, bio accumulative, and toxic pollution; and (4) overall impact on the environment and human health.

11.17.070 Stewardship Plans —Costs to Be Borne by Responsible

Stewards.

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 or defray the costs of its Stewardship Plan, nor may it charge a point-of-collection fee at the time that Unwanted Covered Drugs and/or Unwanted Sharps are collected.

C. Responsible Stewards are not required to pay for any costs incurred, including staff time, by Hosts that voluntarily participate in a Stewardship Plan without compensation.

11.17.080 Stewardship Plans — Reporting Requirements.

A. Within six (6) months after the end of the first 12-month period of operation, and annually thereafter, each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall submit a report to the Director on behalf of participating Responsible Stewards describing the Stewardship Plan's activities during the previous reporting period. The report must include:

1. A list of Responsible Stewards participating in the Stewardship Plan.
2. The amount, by weight, of Unwanted Covered Drugs and the amount, by weight, of Unwanted Sharps collected each month, including the amount by weight from each collection method used.
3. A list of Collection Sites.
4. The number of Mailers provided to County residents and the method and location of distribution.
5. The number of Unwanted Sharps containers provided to County residents and the method and location of distribution.
6. The dates and locations of collection events held.
7. The names and contact information of each Person retained to transport the collected items and the disposal facility or facilities used for all Unwanted Covered Drugs and/or Unwanted Sharps.
8. 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 been 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, and a summary of all comments received from users, and the responses provided to them, during the reporting period.

10. 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.

11. A summary of the Stewardship Plan's goals, the degree of success in meeting those goals in the past year, and, if any goals have not been met, what effort will be made to achieve the goals in the next year.

12. The total expenditures of the Stewardship Plan during the reporting period; and

13. An Executive Summary.

B. 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 Stewardship Plan must be provided to the Department within thirty (30) days of the change.

C. For the purposes of this Section 11.17.080, "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.

11.17.090 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 sixty (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, wholesales, otherwise 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.

11.17.100 Stewardship Plans — Review.

A. By nine (9) months 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 Stewardship Plan review fee in accordance with Section 11.17.140 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 ninety (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 to the Director within sixty (60) 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 Stewardship 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.

11.17.110 Stewardship Plans — Prior Approval for Proposed

Changes.

A. Proposed changes to an approved Stewardship Plan that substantively alter Stewardship Plan operations, including but not limited to changes to participating Responsible Stewards, Hosts, 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 thirty (30) days before the change is scheduled to take effect. Any such submittal shall be accompanied by the review fee in accordance with Section 11.17.140 of this Chapter.

C. A Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall notify the Director at least fifteen (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 11.17.050 of this Chapter, or other changes that do not substantively alter Stewardship 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 Stewardship Plan operations.

11.17.120 Stewardship Plans —Enforcement and Penalties.

A. The Director shall administer the penalty provisions of this Chapter.

B. If the Director determines that any Person has violated any provision of this Chapter or a regulation adopted pursuant to this Chapter, the Director shall issue a Notice of Violation to the Person or Persons who violated it. The Person or Persons shall have thirty (30) days after the date of mailing of the Notice of Violation 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 and/or Los Angeles County Code, Title 1, Chapter 1.25, as may be amended from time to time. Except as expressly provided herein, said provisions shall govern enforcement of this Chapter or any rule or regulation adopted pursuant to this Chapter. Each day the Person or Persons are not in compliance 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.

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) per 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. 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 waive strict compliance with the requirements of this Chapter that apply to Responsible Stewards in order to achieve the objectives of this Chapter.

11.17.130 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 evaluate performance, including but not limited to collection amounts, education, and promotion for a Stewardship Plan.

C. The Director shall report to the Board of Supervisors concerning the status of all Stewardship Plans and recommendations for changes to this Chapter two years from the effective date of this Chapter and thereafter on an as-needed basis.

11.17.140 Stewardship Plan — County Review and Oversight Fees.

A. Each Responsible Steward, group of Responsible Stewards and Stewardship Organization participating in a Stewardship Plan shall pay to the Department fees to be adopted by the Board for the performance of review and oversight functions, including but not limited to:

1. Review of a proposed Stewardship Plan;

2. Review of a revised, proposed Stewardship Plan;
 3. Review of changes to an approved Stewardship Plan;
 4. Review of an updated Stewardship Plan at least every three (3) years as required under Section 11.17.030 of this Chapter;
 5. Review of any petition for approval to use alternative final disposal technologies under Section 11.17.060 of this Chapter;
 6. Environmental review of a Stewardship Plan;
 7. Oversight of Stewardship Plan implementation and operations;
 8. Enforcement of the requirements of this Chapter; and
 9. Conducting administrative appeals.
- B. A Stewardship Organization may remit the fees authorized under this Section on behalf of its participating Responsible Stewards.

11.17.150 Information Required at Point of Sale.

A. Any Person who sells to, offers for sale to, or otherwise distributes for use by, one or more consumers in the County Covered Drugs or Sharps shall 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 said Person's place of business in a location visible to the public, if applicable, and adjacent to the area where pharmaceutical Drugs are dispensed. Mail-order

Pharmacies and on-line Pharmacies that sell to, offer for sale to, or otherwise distribute for use by, one or more consumers in the County Covered Drugs or Sharps shall provide such materials with the order.

B. The Director may, in his or her discretion, authorize a Person to use alternate means to comply with the requirements of subsection A. No Person 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.

11.17.160 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. Specifically, each Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall:

1. Promote the collection options offered under its Stewardship Plan to residents and the health care community. Promotion shall include outreach and educational materials:

a. Promoting safe storage of pharmaceutical Drugs and Sharps;

b. Describing where and how to return Unwanted Covered Drugs and Unwanted Sharps under the Stewardship Plan;

- c. Expressly discouraging stockpiling of Unwanted Covered Drugs and Unwanted Sharps; and
- d. Expressly discouraging disposal of said items in the trash or through a plumbing or septic system.

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.

- 2. Use plain language and explanatory images so as to be readily understandable by all residents, including individuals with limited English proficiency.
- 3. Work with Hosts participating in Stewardship Plans to: (a) develop clear, standardized instructions, signage, and promotional materials for residents concerning the use of collection receptacles; and (b) where practicable, use a readily-recognizable and consistent symbol, color and/or design of collection receptacles and Sharps containers.
- 4. Establish a twenty-four (24) hour, toll-free telephone number and single website where information can be obtained regarding collection options and current locations of Collection Sites.
- 5. Within six (6) months of the effective date of this Chapter and biennially thereafter conduct a 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 Stewardship Plans. The surveys shall be done

by a Person who has no personal ties to or financial interest in the Responsible Steward, group of Responsible Stewards, or Stewardship Organization. This Person must be a member of a national trade organization approved by the Director, including but not limited to the American Association for Public Opinion Research, the National Council on Public Polls, the Council of American Survey Research Organizations, or the Market Research Association, Survey questions shall include but not be limited to questions designed to:

- a. Assess the awareness of the County's Stewardship Program, the Stewardship Plans in operation, and the location of all available Collection Sites;
- b. Assess to what extent Collection Sites and other collection methods are safe, convenient, easy to use, and utilized by residents; and
- c. 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 thirty (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 11.17.060 within ninety (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 11.17.160 shall be in English, Spanish, and other 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.

11.17.170 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, any liability to any Person that alleges a claim for damages arising from or related to this Chapter.

11.17.180 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 Host, each Reverse Distributor or other 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 the County to

impose any duties or obligations in conflict with limitations on municipal authority established by State or federal law at the time such County 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.

11.17.190 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.

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