

**San Luis Obispo County
Integrated Waste Management Authority
ORDINANCE NO. 2018-1**

**AN ORDINANCE ESTABLISHING A PRODUCT STEWARDSHIP DISPOSAL
PROGRAM FOR HOME GENERATED USED SHARPS AND UNWANTED
PRESCRIPTION MEDICINE**

The Board of Directors of the San Luis Obispo County Integrated Waste Management Authority ordains as follows:

SECTION 1. GENERAL PROVISIONS

The San Luis Obispo County Integrated Waste Management Authority (IWMA) finds and declares all the following:

- (a) The purpose of this Ordinance is to have the IWMA, a joint powers agency established pursuant to California Government Code Section 6500 and empowered by its member jurisdictions to exercise the members' common powers to achieve the mandates imposed by the Integrated Waste Management Act of 1989 (AB 939) on a regional basis, enact a product stewardship disposal program for home generated used sharps and unwanted prescription medicine.
- (b) The purpose of this Ordinance is to complement existing IWMA Ordinance 2008-2 establishing a sharp (hypodermic needles) waste management program and IWMA Ordinance 2015-1 establishing a home-generated unwanted prescription medicine disposal program.
- (c) The purpose of this Ordinance is to assure that the costs associated with the handling and disposal of used sharps and unwanted prescription drugs are primarily the responsibility of the producers and not Retail Pharmacies and government agencies.
- (d) The purpose of this Ordinance is to assure that producers of sharps and drugs, while working to achieve the goals and objectives of this Ordinance, should have the flexibility to partner with those private, nonprofit business and government enterprises that provide collection and processing services to develop and promote a safe and effective home generated used sharps and unwanted prescription medicine waste management system.

SECTION 2. DEFINITIONS

For the purposes of this Ordinance, the following terms have the following meanings, unless the context clearly requires otherwise:

- (a) "Consumer" means a person who has lawfully obtained, and who possesses, a prescription drug and/or sharps for his own use or the use of a member of his household or for an animal owned by him or by a member of his household and who resides in the IWMA region.
- (b) "Controlled Substance" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 1 1053 through 1 1058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.
- (c) "Drugs" means: (i) articles 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; (ii) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) substances, other than food, intended to affect the structure or any function of the body of humans or other animals.
- (d) "IWMA Region" means the geographic area that includes the unincorporated area of San Luis Obispo County, California and the seven incorporated cities within San Luis Obispo County.
- (e) "Mail-back Program" means a system whereby Consumers of Unwanted Products obtain prepaid and preaddressed mailing envelopes in which to place Unwanted Products for shipment to an entity that will dispose of them safely and legally.
- (f) "Manufacture" means the production, preparation, propagation, compounding, or processing of Drugs or Sharps but does not include the activities of a repackager, wholesaler or medical practitioner.
- (g) "Nonprescription drugs" means any drug that may be lawfully sold without a prescription.
- (h) "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.
- (i) "Prescription drugs" means any drug that by federal or state law may be dispensed lawfully only by prescription, including Controlled Substances, scheduled II, III, IV and V.
- (j) "Producer" shall be determined, with regard to Drugs and Sharps that are sold, offered for sale, or distributed in the IWMA Region as meaning one of the following:

1. The Person who Manufactures Drugs or Sharps and who sells, offers for sale, or distributes Drugs or Sharps in the IWMA Region under that Person's own name or brand.
2. If there is no Person who sells, offers for sale, or distributes Drugs or Sharps in the IWMA Region under the Person's own name or brand, the Producer of Drugs or Sharps is the owner or licensee of a trademark or brand under which the Drugs or Sharps are sold or distributed in the IWMA Region, whether or not the trademark is registered.
3. If there is no Person who is a Producer of Drugs or Sharps for purposes of paragraphs (1) and (2), the Producer of Drugs or Sharps is the Person who brings the Drug into the IWMA Region for sale or distribution.

“Producer” does not include either a Retail Pharmacy that puts its store label on a Drug or a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for a Consumer.

- (k) “Product Stewardship Program” or “Program” means a program financed and operated by Producers to collect, transport, and dispose of Unwanted Products.
- (l) “Retail Pharmacy” means any retail store which sells prescription drugs and/or sharps to a Consumer.
- (m) “Sharps” means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.
- (n) “Stewardship Organization” means an organization designated by a group of Producers to act as an agent on behalf of each Producer to operate a Product Stewardship Program.
- (o) “Unwanted Products” means Drugs or Sharps no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

SECTION 3. PRODUCT STEWARDSHIP PROGRAM

- (a) Requirement for Sale. This section shall apply only to Producers whose Drugs or Sharps are sold and/or distributed in the IWMA Region and to Retail Pharmacies who sell Drugs or Sharps in the IWMA Region. Each Producer must:
 1. Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the IWMA; or
 2. Enter into an agreement with a Stewardship Organization to operate, on the

Producer's behalf, a Product Stewardship Program approved by the IWMA.

(b) Product Stewardship Program Costs.

1. A Producer, group of Producers, or Stewardship Organization must pay all administrative and operational fees associated with their Product Stewardship Program, including, but not limited to, the cost of collecting, transporting, and disposing of Unwanted Products collected from Consumers and the recycling or disposal, or both, of packaging collected with the Unwanted Product.
2. No Person, Producer, group of Producers or Stewardship Organization may charge a specific point-of-sale fee to Consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Consumers or delivered for disposal.
3. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the IWMA in the enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the IWMA shall only recover its actual cost of enforcement under this Ordinance and shall not charge any amounts under this Ordinance in excess of its actual enforcement cost.
4. A Producer, group of Producers, or Stewardship Organization must pay all collection, transportation and disposal costs of Unwanted Products after 180 days of the effective date of the Ordinance. If after 180 days of the effective date of the Ordinance, the IWMA incurs any costs resulting from the collecting, transporting, and disposing of Unwanted Products due to delays in implementation of an approved Stewardship Plan, the Producer, Group of Producers, or Stewardship Organization must reimburse the IWMA in full for such costs. Reimbursement shall be paid each month.

SECTION 4. PRODUCT STEWARDSHIP PLAN

(a) Plan Content. Each Product Stewardship Program shall have a Product Stewardship Plan "Plan" that contains each of the following:

1. Certification that the Product Stewardship Program will accept all Unwanted Products, regardless of who produced them, unless excused from this requirement by the IWMA as part of the approval of the Plan;
2. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program;

3. For Drugs, a description of the collection receptacle program that will be made available to every Retail Pharmacy in the IWMA Region. The collection receptacle program shall include a description of kiosks to be used, collection methods and the service provider. If a Retail Pharmacy decides not to participate in the collection receptacle program, but instead decides to provide Consumers with mail back envelopes under a Mail-back Program, the Product Stewardship Program is not required to provide the mail back envelopes. For any Drug, such as chemotherapy drugs, inhalers, liquids, etc excluded from kiosks, the Product Stewardship Program must provide and pay for an alternative method of managing these excluded Drugs.
4. For Sharps, a description of the Sharps collection program that will be made available to every Retail Pharmacy in the IWMA Region. The Sharps collection program shall include: (1) A convenient location within the Retail Pharmacy for the "take-back" from the Consumer of home-generated Sharps at no cost to that Consumer. (2) An appropriate receptacle or receptacles for the collection of home-generated Sharps within the Retail Pharmacy. In addition, the Sharps collection program shall provide, at no cost to the Retail Pharmacies, Retail Pharmacies with small (1 quart) Sharps containers with customized disposal information preprinted on the label. Retail Pharmacies shall distribute the small Sharps containers to Consumers. For any Sharps excluded from collection receptacles, the Product Stewardship Program must provide and pay for an alternative method of managing these excluded Sharps.

As an alternative to bringing Sharps containers back to Retail Pharmacies, the Sharps collection program can provide, at no cost to the Retail Pharmacies, the Retail Pharmacies with a Sharps container that is designed to be mailed back. Retail Pharmacies would distribute the Sharps container to Consumers. All Sharps mail back systems shall include a Sharps container, a prepaid and preaddressed return shipping box, components to package for transport and instructions for use.

5. A starting date when collection of Unwanted Products will begin.

(b) IWMA Review and Approval

1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with this Ordinance until it has received written approval of its Product Stewardship Plan from the IWMA. The IWMA will continue collection, transportation and dispose of Unwanted Products on an interim basis if there is any delay in establishing a Stewardship Program as required.

2. Product Stewardship Plans must be submitted to the IWMA for approval. The initial Plan must be submitted within 90 days of the effective date of the Ordinance.
 3. Within 30 days after receipt and review of a Product Stewardship Plan, the IWMA will determine whether the Plan complies with the requirements of this Ordinance and of any Ordinances previously adopted.
 - a. As part of its approval, the IWMA may set reasonable performance goals for the Program.
 - b. If the IWMA approves a Plan, it shall notify the applicant of its approval in writing.
 - c. If the IWMA rejects a Plan, it shall notify the applicant in writing of its reasons for rejecting the Plan.
- (c) An applicant whose Plan has been rejected by the IWMA must submit a revised Plan to the IWMA within thirty (30) days after receiving notice of the rejection. The IWMA may require the submission of a further revised Plan or, at its sole discretion, the IWMA may develop, approve and impose its own Product Stewardship Plan or an approved Plan submitted by other Producer(s) pursuant to this chapter.
- (d) If the IWMA rejects a revised Product Stewardship Plan or any other subsequently revised Plan, the Producer(s) at issue shall be out of compliance with this Ordinance and shall be subject to the enforcement provisions contained in this Ordinance.
1. At least every three years, a Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall update its Product Stewardship Plan and submit the updated Plan to the IWMA for review and approval.
 2. A Producer who begins to offer Drug or Sharps for sale in the IWMA Region after the adoption of Product Stewardship Plan, must submit a Product Stewardship Plan to the IWMA or provide evidence of having joined an existing approved Product Stewardship Program within sixty (60) days following the Producer's initial offer for sale of a covered Drug or Sharp.
 3. Any proposed changes to a Product Stewardship Plan must be submitted in writing to the IWMA and approved by the IWMA in writing prior to implementation of any change.

SECTION 5. DISPOSAL OF UNWANTED PRODUCTS

- (a) Compliance with Applicable Law. Each Product Stewardship Program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the collection, transport, treatment and disposal of Unwanted Products.
- (b) Treatment and Disposal. Each Product Stewardship Program must treat Sharps waste by high heat sterilization and dispose of all unwanted Drugs by incineration at a Medical Waste or Hazardous Waste facility. Each treatment or disposal facility utilized must be in possession of all required regulatory permits and licenses.
- (c) New Technologies. Producers with Product Stewardship Programs may petition the IWMA for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current Medical Waste disposal technologies for Sharps and Drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:
 - 1. Monitoring of any emissions or waste;
 - 2. Worker health and safety;
 - 3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution;
 - 4. Overall impact on the environment and human health.
- (d) Packaging Separation. Each Product Stewardship Program shall encourage Consumer to separate Unwanted Products from their original containers and packaging, when appropriate, prior to collection or disposal.

SECTION 6. PRODUCT STEWARDSHIP PROGRAM PROMOTION AND OUTREACH

- (a) A Product Stewardship Program must promote the Program to Consumers by placing signage on Drug collection receptacles and small Sharps containers. The Product Stewardship Plan shall include the proposed language which is subject to approval by the IWMA.
- (b) A Product Stewardship Program may prepare additional outreach material.

SECTION 7. REPORTING

- (a) On or before May 1, 2019 (or at a later date as approved in writing by the IWMA

and in each subsequent year, every Producer, group of Producers, or Stewardship Organization operating a Product Stewardship Program must prepare and submit to the IWMA an annual written report describing the Program activities during the previous reporting period. The report must include, at minimum, the following:

1. A list of Producers participating in the Product Stewardship Program;
 2. The amount, by type and by weight, of Unwanted Products collected from Consumers at each Retail Pharmacy;
 3. The name and location of disposal facilities at which Unwanted Products were disposed of and the weight by type of Unwanted Products collected from Consumers disposed of at each facility;
 4. Whether policies and procedures for collecting, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;
 5. Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Products 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;
 6. How the Product Stewardship Program complied with all other elements in the Product Stewardship Plan approved by the IWMA, including its degree of success in meeting any performance goals set by the IWMA as part of its approval of the Program; and
 7. Any other information that the IWMA may reasonably require.
- (b) For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

SECTION 8. ENFORCEMENT

- (a) The IWMA may enforce the provisions of this Ordinance through a civil action for civil penalties in the amounts established herein, and any other civil remedy, including prohibitory and mandatory injunctive relief, file in the Superior Court for the County of San Luis Obispo to compel and enforce the provisions herein against any Producer, group of Producers, or Stewardship Organization who violates this Ordinance. In addition to any relief available to IWMA to enforce this Ordinance, the IWMA shall also be entitled to recover its reasonable attorneys' fees and costs incurred in enforcing this Ordinance.

- (b) For any violation of this Ordinance, the IWMA may sue to recover civil penalties in the amount of \$1,000.00 per day for every day on which a violation exists. For purposes of calculating the civil penalties to be established hereunder, each day on which the Producer, group of Producers, or Stewardship Organization fails to comply with the requirements of this Ordinance, after having received a written notice of violation issued by the IWMA, shall constitute a separate offense.
- (c) In addition to the civil relief available to the IWMA set forth above, any violation of this Ordinance shall also constitute a misdemeanor punishable under the laws of the State of California. The District Attorney, the County Counsel, or any City Attorney shall be authorized to enforce the provisions of this Ordinance within their respective jurisdictions. In the event of such criminal enforcement, the following criminal penalties apply to violations of this Ordinance:
1. Violation as Misdemeanor. Violations of the provisions of this Ordinance or failure to comply with any of its requirements shall constitute a misdemeanor.
 2. The San Luis Obispo County Sheriff and/or any other police or law enforcement agencies located within the IWMA's jurisdiction may issue a Notice to Appear Citation for any misdemeanor pursuant to California Penal Code Section 853.6 for any violation of this Ordinance.
 3. Penalty for Misdemeanor. Any Producer, group of Producers, or Stewardship Organization found to be in violation of any provision of this Ordinance, or who fails to comply with any of its requirements, shall upon conviction thereof be punished by imprisonment in the county jail for not more than six months, or be fined not more than one thousand dollars (\$1,000.00), or by both. Each day such violation continues shall be considered a separate offense.
- (d) To the extent that the County of San Luis Obispo, the incorporated cities, and the districts within said County have adopted code enforcement ordinances applicable to their jurisdictions, this Ordinance shall be enforceable by said governmental entities under said ordinances as land-use or code-enforcement violations consistent with said ordinances.

SECTION 9. CONFLICT WITH STATE OR FEDERAL LAW

This Ordinance shall be construed so as not to conflict with applicable federal or state laws, rules or regulations. Nothing in this Ordinance shall authorize the IWMA to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such action is taken. The IWMA shall suspend enforcement of this Ordinance to the extent that said enforcement would conflict with any state or federal legislation.

SECTION 10. CEQA FINDINGS

The Board of Directors finds that this Ordinance falls within the activities described in Section 15061(b)(3) of the CEQA Guidelines which are deemed not to be "projects" for the purposes of CEQA, because it can be seen with certainty that the adoption of the Ordinance will not have a significant effect on the environment. The IWMA Manager is directed to prepare and file an appropriate notice of exemption.

SECTION 11. SEVERANCE CLAUSE

If any section, subsection, sentence, clause or phrase of this Ordinance is for any reason held to be unconstitutional, ineffective or in any manner in conflict with the laws of the United States, or the State of California, such decision shall not affect the validity of the remaining portions of this Ordinance. The Governing Board of the IWMA hereby declares that it would have passed this Ordinance and each section, subsection, sentence, clause and phrase thereof, irrespective of the fact that any one or more sections, subsection, sentence, clause or phrase be declared unconstitutional, ineffective, or in any manner in conflict with the laws of the United States or the State of California.

SECTION 12. EFFECT OF HEADINGS IN ORDINANCE

Title, division, part, chapter, article, and section headings contained herein do not in any manner affect the scope, meaning, or intent of the provisions of this Ordinance.

This Ordinance was introduced and the title thereof read at the regular meeting of the IWMA Board of Directors on November 9, 2017 and further reading was waived by a majority vote of those Directors present.

This Ordinance shall take effect and be in full force on and after thirty (30) days from the date of its passage, and before the expiration of fifteen (15) days from the date of its passage it shall be published once with the names of the members of the Board of Directors voting for and against the same, said publication to be made in a newspaper of general circulation published in the County of San Luis Obispo.

On a motion by Director O'Malley, seconded by Director Hamon, the foregoing Ordinance was passed and adopted by the Board of Directors of the San Luis Obispo County Integrated Waste Authority, this 10th day of January, by the following vote:

AYES: Arnold, Brown, Compton, Davis, Enns, Gibson, Gomez, Hamon, O'Malley, Lee

NOES: None

ABSENT: Blake, Hill, Peschong

Original signed by

Jeff Lee, President of the San Luis Obispo County
Integrated Waste Management Authority

ATTEST:

Original signed by

Carolyn Goodrich, IWMA Board Secretary

ORDINANCE CODE PROVISION APPROVED
AS TO FORM AND CODIFICATION:

Original signed by

RAYMOND A. BIERING
IWMA Counsel

Date: January 10, 2018