

ATTACHMENT "I"

Summary of Draft LA County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance

What does the Draft Ordinance do?

LA County's Pharmaceuticals and Sharps Collection and Disposal Stewardship ordinance has been created to address the problem of unwanted medicines and sharps through an Extended Producer Responsibility program. Unwanted medicines and sharps pose a growing risk to people's health and safety when stored in homes, can pollute the environment when disposed as trash or flushed through the sewer system, and jeopardize the health of waste collection and recycling workers exposed to used sharps (needles).

The Ordinance establishes Pharmaceutical and Sharps Stewardship Plans that:

(1) Allow for the safe, convenient and sustainable collection and disposal of unwanted Drugs and Sharps by County residents, and

(2) Protect, maintain, restore and/or enhance the environment and its natural resources

The Stewardship Plans established under the ordinance will be designed, operated and funded by "Responsible Stewards", with oversight by the Director of the County's Department of Public Health.

Who is a Responsible Steward?

A Responsible Steward is defined by the Ordinance as— (a) A Person who Manufactures Covered Drugs or Sharps; or (b) If the Manufacturer is beyond the County's jurisdiction, the first Person who repackages or distributes the Covered Drug or Sharps in or into the County, including but not limited to a Wholesaler or Repackager; or (c) if the Persons described in (a) and (b) are beyond the County's jurisdiction, the first Person who sells or offers for sale the Covered Drug or Sharps in or into the County.

What is a Covered Drug?

A Covered Drug includes **prescription, nonprescription, brand name, and generic drugs sold or distributed for use in LA County.**

Covered Drugs do not include vitamins or supplements, herbal-based and homeopathic remedies, and personal care products that are regulated as both cosmetics and nonprescription drugs by the Federal government.

What are Responsible Stewards required to do?

Mandatory participation is required by all Responsible Stewards, who must notify the Director of their intent to operate or participate in a Stewardship Plan within 6 months of the effective date of the Ordinance or 6 months after the Covered Drugs or Sharps are first sold. Responsible Stewards can participate in Stewardship Plans either by: **(1) operating, individually or jointly with other Responsible Stewards; or (2) entering into an agreement with a Stewardship Organization.**

A Responsible Steward must submit a Stewardship Plan within 9 months of the effective date of the ordinance or 9 months after the Covered Drugs or Sharps are first sold. Stewardship Plans must be approved by the Director and include contact information for an official point of contact for the plan. The Stewardship Plan must be implemented within **3 months of the Directors approval**, and thereafter, any substantive changes made to the plan must be submitted to the Director at least every 3 years.

Within 6 months of the effective date of the Ordinance or 6 months after the Covered Drugs or Sharps are first sold and annually thereafter, Responsible Stewards are required to notify the following Persons, of the opportunity to participate in the Stewardship Plan by serving as Collectors:

1. All retail Pharmacies, hospitals/clinics with on-site Pharmacies, and other Potential Authorized Collectors;
2. Persons other than Potential Authorized Collectors, such as retail establishments, that could potentially host Collection Sites for Sharps; and
3. All law enforcement agencies in the County.

Additionally, any Person who is not a Responsible Steward, such as a Person providing Covered Drugs or Sharps free of charge, can also 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 must in good faith consider allowing such Person to participate in its Stewardship Plan.

What must a Stewardship Plan consist of?

A Stewardship Plan must consist of the name of each Responsible Steward participating in the plan and the Covered Drug and type of Sharp manufactured or purchased by the Responsible Steward. The plan must have the contact information for an official Point of Contact to whom the Director can direct all inquiries regarding a Responsible Steward's compliance.

A Stewardship Plan must describe the collection system designed to provide safe, convenient and continuous collection services for Covered Drugs and Sharps from County Residents. The description should include a list of - all collection methods, participating and potential collectors, and collection sites; a description of where and how periodic collection events will be held; and a description of how any Mail-Back Services will be provided to County Residents.

The plan must also describe the handling and disposal system (including the person retained to transport the collected item and the Hazardous Waste Disposal Facility to be used). The plan must take into consideration: 1) the use of existing providers of waste pharmaceutical services; 2) separation of Covered Drugs and Sharps from packaging to reduce transportation and disposal cost; and 3) recycling of Drug and Sharp packaging to the extent possible.

A Stewardship Plan must ensure that any patient information appearing on Drug and Sharp packaging will be kept secure and promptly destroyed. It must also include a strategy (including short-term and long-term plans) to educate the public and promote the plan.

How are the Covered Drugs and Sharps Collected?

The ordinance **does not require mandatory participation of any Person as a Collector**. A Person can volunteer to be a Collector and may or may not be compensated by Responsible Stewards or a Stewardship Organization.

A Collection Plan must offer ongoing, convenient and equitable access for all County residents in the Service Area regardless of the racial, cultural, or socioeconomic composition of the neighborhoods within which the Collection Sites are located. In each participating Unincorporated Community and City with at least one Potential Authorized Collector, each Stewardship Plan shall provide at least one Collection Site for each Unwanted Covered Drugs and Unwanted Sharps. For every 30,000 County residents at least one additional Collection Site should be provided for each Unwanted Covered Drugs and Unwanted Sharps.

Collection sites must be geographically distributed to ensure that every resident within the Service Area is **within 2.5 miles** of a Collection Site for each Unwanted Covered Drugs and Unwanted Sharps. Additionally, there must be **at least 10 collection sites** for each Unwanted Covered Drugs and Unwanted Sharps in each County Supervisorial District.

In areas, where a collection system with the above requirements cannot be met, Responsible

Stewards or the Stewardship Organization must provide monthly collection events and/or Mailers to be distributed to consumers. The Mailers and Mail-Back Services, should be provided free of charge, to residents in the Service Area upon request through the Stewardship Plan's 24-hour, toll-free phone number and website.

Collection systems must **maintain patient confidentiality** by destroying patient information on packaging. Responsible Stewards must also provide for distribution of FDA-compliant Sharps containers for the safe handling of Sharps to the **consumer free of charge**, preferably at the point of sale of the injectable Drug or at the time the consumer otherwise receives the Sharps for usage. Additionally, Responsible Stewards or the Stewardship Organization should provide FDA-compliant Sharps collection receptacles to any hosts of Collection Sites for Sharps.

How are the collected Covered Drugs and Sharps Disposed of?

Covered Drugs collected under a Stewardship Plan must be disposed of at a **permitted Hazardous Waste Disposal Facility**. Sharps collected under a Stewardship Plan must be disposed of in accordance with California Health and Safety Code Section 118286 or any successor legislation.

If the Director deems the use of a Hazardous Waste Disposal Facility to be infeasible for the Stewardship Plan based on cost, logistics, or other considerations, the Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor.

Alternatively, a Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection, by providing superior expectations in– (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.

Who bears the cost of the Stewardship Program?

Each Responsible Steward, group of Responsible Stewards or Stewardship Organization participating in a Stewardship Plan must pay for the preparation and implementation of their Stewardship Plan. Responsible Stewards are not required to pay for costs of staff time at Collection Sites provided by Collectors volunteering to participate in a Stewardship Plan.

Responsible Stewards or Stewardship Organizations are prohibited by the Ordinance from charging customers a point-of-sale fee or a specific point-of-sale collection fee, to recoup the cost of the Stewardship Plan.

What are the penalties of non-compliance or violating the Ordinance?

A Person found in non-compliance or violation of the Ordinance would be notified by the Director, and has 45 days after the date of mailing to come into compliance or correct the violation. Any Person who knowingly and willfully violates the requirements of the Ordinance is guilty of a misdemeanor and is punishable by a fine between fifty dollars (\$50) and one thousand dollars (\$1,000) for each day per violation, or by imprisonment for a period not to exceed six months, or by both such fine and imprisonment. Additionally, any Person in violation of the Ordinance shall be liable to the County for a civil penalty of a maximum of one thousand dollars (\$1,000) per day per violation. Each day in which the violation continues shall constitute a separate violation.

The appropriate penalty is determined by the Director depending on 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. County Counsel, the District Attorney, and any applicable City Attorney can also bring a civil action against a Person found in violations or out of compliance with the Ordinance.

How will the Public be educated about this Program?

Any Person selling Covered Drugs or Sharps to the public has to 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. These materials shall be legible and easily understandable by the average person and can be in English, Spanish, and any other language as determined by the Department of Public Health. Stewardship Plans are also required to **establish a 24-hour, toll-free phone number and single website** where information can be obtained regarding collection options and current locations of Collection Sites

Stewardship Plans are required to develop a system of promotion, outreach and public education. The system must promote the collection options provided under the plan to residents and the health care community through educational and outreach materials that include- (1) promoting safe storage practices of drugs and sharps, (2) describing where and how unwanted drugs and sharps should be returned, (3) discouraging stockpiling of drugs and sharps, and, (4) discouraging disposal of unwanted drugs and sharps through trash or a plumbing or septic system.

The education and outreach 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. Responsible Stewards or Stewardship Organizations must work with Collectors to develop clear, standardized instructions, signage and promotional materials for residents on the use of collection receptacles and a readily-recognizable, consistent design of collection receptacles.

Within six months of the effective date of the Ordinance and biennially thereafter Responsible Stewards and Stewardship Organizations are required to 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 plans. These surveys should include questions that - (1) assess the awareness of the County's Stewardship Program, the Stewardship Plans in operation, and the location of all available Collection Sites; (2) assess to what extent Collection Sites and other collection methods are safe, convenient, easy to use, and utilized by residents; and (3) assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription Drugs used in the home.