

County of Los Angeles CHIEF EXECUTIVE OFFICE

Kenneth Hahn Hall of Administration 500 West Temple Street, Room 713, Los Angeles, California 90012 (213) 974-1101 http://ceo.lacounty.gov

"To Enrich Lives Through Effective And Caring Service"

Board of Supervisors HILDA L. SOLIS First District

MARK RIDLEY-THOMAS Second District

SHEILA KUEHL Third District

DON KNABE

Fourth District
MICHAEL D. ANTONOVICH

Fifth District

May 03, 2016

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

APPROVE THE INTRODUCTION AND SCHEDULING FOR ADOPTION OF AN ORDINANCE TO AMEND TITLE 11, HEALTH AND SAFETY, OF THE LOS ANGELES COUNTY CODE, RELATING TO REQUIREMENTS FOR THE COLLECTION AND DISPOSAL OF UNWANTED PHARMACEUTICAL DRUGS AND SHARPS (ALL DISTRICTS)

(3 VOTES)

SUBJECT

Approve the recommendations to introduce and schedule for adoption an ordinance to amend Title 11, Health and Safety, of the Los Angeles County Code, relating to requirements for the safe, convenient, and sustainable collection and disposal of unwanted pharmaceutical drugs and sharps by County residents.

IT IS RECOMMENDED THAT THE BOARD:

- 1. Find that the Ordinance is categorically exempt under the provisions of the California Environmental Quality Act (CEQA) pursuant to Sections 15307 and 15308 of the State CEQA Guidelines for reasons stated in this letter, the attached CEQA findings, and the record of the project.
- 2. Approve the introduction, and place on the Board of Supervisor's agenda for adoption on May 10, 2016, the attached Ordinance that amends Title 11, Health and Safety, of the Los Angeles County Code, relating to the requirements for the collection and disposal of unwanted pharmaceutical drugs and sharps.
- 3. Delegate authority to the Director of the Department of Public Health to adopt regulations, as may be needed, relating to implementation of the Ordinance.

4. Instruct the Director of the Department of Public Health to return to the Board with a schedule of fees to defray the County's regulatory oversight costs.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Justification of Recommended Action

Nationwide 200 million pounds of pharmaceutical drug (drug) waste is generated, and much of this waste is either being stored in household medicine cabinets or disposed of improperly through sewers or waste systems. Excess drugs in homes create significant opportunities for unintentional poisonings, illegal distribution, substance misuse and abuse and environmental contamination. Improper household disposal of unwanted drugs and sharps leads to environmental contamination and creates potential health risks to children and teens, sanitation and sewage treatment workers, and the beach-going public.

In a County with nearly 3.5 million households, disposal options are limited to Countywide Household Hazardous Waste (HHW) take-back events, drug collection bins at 21 Sheriff's stations, and 77 sharps collection locations, 33 of which are County operated. This is inadequate for providing 10 million County residents convenient and accessible disposal solutions. Furthermore, it places the burden and responsibility for resolving the drug and sharps disposal issue on local government and the taxpayers of Los Angeles County.

With the growing awareness of the problems that unused drugs and sharps pose, Congress passed the Secure and Responsible Drug Disposal Act in 2010, for the purpose of expanding available options to collect and dispose of controlled substances in a secure, convenient and responsible manner recognizing in the Act that: "Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be an appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water." Consistent with this Act, the federal Drug Enforcement Agency (DEA), developed regulations to expand take-back programs. Additionally, the federal Environmental Protection Agency and the federal Food and Drug Administration have both identified local take-back programs as the "first choice" or "best option" for safely and conveniently collecting these products.

Based on the direction of the federal government, the State Legislature attempted to pass a number of bills to establish product stewardship programs for drugs and sharps. However, there has been strong opposition from drug and sharps manufacturers and, to date, these bills have failed to pass the Legislature. Consequently, a number of counties have sought solutions at the local level, and have adopted take-back ordinances requiring manufacturers or retailers to undertake residential collection, transportation, and disposal of unwanted drugs and/or sharps.

Purpose of Recommended Action

Recognizing all of these facts, on August 11, 2015, the Board instructed the Chief Executive Officer (CEO), in collaboration with the County's Sustainability Council (Sustainability Council), and the Extended Producer Responsibility Working Group (EPR Working Group), including County Counsel, the Sheriff, the Departments of Health Services (DHS), Internal Services (ISD), Mental Health (DMH), Public Health (DPH), Public Works (DPW) and the Sanitation Districts of Los Angeles County

to "Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect, transport and dispose of unused and unwanted pharmaceuticals and sharps waste from County residents." As stated in the motion, the objective was to: provide County residents with access to safe, convenient, and sustainably financed take-back options to dispose of pharmaceutical drugs and sharps waste; and generate awareness about the collection program that would be created by the Ordinance. The Board also instructed the EPR Working Group to engage in a stakeholder process prior to preparation of the Ordinance.

This Board action is consistent with the Board's prior adoption on November 5, 2008 of a resolution supporting Extended Producer Responsibility (EPR). EPR, also called Product Stewardship, 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.

The purpose, as stated in the Ordinance, "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 by County residents, and 2) Protects, maintains, restores and/or enhances the environment and its natural resources." The Stewardship Program will be designed, operated and funded by the Pharmaceutical Drug and Sharps industries with oversight by DPH.

Adoption of the Ordinance (Attachment I), will require the "Responsible Stewards" of "Covered Drugs" or "Sharps", as defined in the Ordinance, to: 1) Finance, develop and implement a Stewardship Plan (Plan), approved by the Director of Public Health or her designee, for the collection, transportation and disposal of "Unwanted Covered Drugs" and/or "Unwanted Sharps"; 2) Provide ongoing, reasonably convenient and equitable access for all County residents in the "Service Area" to collection sites; 3) Provide mailers and mail-back services, free of charge, to residents in the "Service Area", upon request; 4) Conduct collection events, as described in the Ordinance; 5) Develop, implement and assess a promotion, outreach, and public education strategy for residents, pharmacists, veterinarians, retailers, and health professionals who interact with patients on the proper disposal of Drugs and Sharps; and 6) Pay fees, to be adopted by the Board at a later time, to cover DPH's reasonable costs for regulatory oversight as detailed in the Ordinance.

In addition, DPH may work with Responsible Stewards, no less than annually, to define goals and evaluate performance, including, but not limited to collection amounts, education and promotion for a Stewardship Plan. Furthermore, the Director shall report to the Board two years from the effective date of adoption of this Ordinance on the status of the Stewardship Plans and thereafter on an asneeded basis.

The Director may adopt regulations and guidelines necessary to implement, administer, and enforce the Ordinance. Furthermore, the Ordinance allows for "Potential Authorized Collectors", registered, or that may apply to register with the DEA, such as a manufacturer, distributor, reverse distributor, narcotic treatment program, retail Pharmacy or a hospital/clinic with an on-site Pharmacy; and law enforcement to voluntarily participate in the Stewardship Plan for collection of Unwanted Covered Drugs and Unwanted Sharps.

Attachment II is the Pharmaceutical Drugs and Sharps Take-Back Program Report (Report) prepared by the EPR Working Group. The Report includes: 1) An Executive Summary highlighting justification for the Ordinance, Ordinance requirements, and the implementation date; 2) Introduction highlighting the take-back options of the Ordinance; 3) Background on related Board actions, Board

policy, County programs, County supported legislative efforts, the County survey, stewardship programs in other jurisdictions, and supporting data and information; 4) Stakeholder engagement process including the stakeholder meetings involving the Technical Advisory Group (TAG) and the general public, and the EPR Working Group's conclusions based on stakeholder feedback; 5) Purpose of the Ordinance; 6) Key Elements of the Ordinance; 7) Implementation timeline; 8) Fiscal Impact of the Ordinance; 9) Matrix of Potential Roles and Responsibilities; and 10) Frequently Asked Questions.

The Ordinance and all supporting documents have been reviewed and approved by County Counsel, the Sheriff, and the Department heads of DPH; DPW; ISD; DMH; and DHS; the General Manager of the Sanitation Districts of Los Angeles County; and the Sustainability Council. The EPR Working Group representatives also provided briefings to the Council during the Ordinance development process.

March 22, 2016 Board Motion

On March 22, 2016, the Board directed the CEO to report back on the status related to inquiries and calls the County had received about the implementation of a product stewardship take-back program. The CEO and the Working Group reviewed the inquiries presented to the County regarding implementation of the program. It was determined that the Board Letter, Board Report, Ordinance, and CEQA Findings address the inquiries received and therefore, these documents are submitted for the Board's consideration.

Stakeholder Engagement Process

As directed by the Board in the August 11, 2015 motion, the EPR Working Group conducted four meetings with the TAG, which was comprised of representatives from: 1) Drug and sharps manufacturing industries; 2) Pharmacies and retailers, including distributors/wholesalers; 3) Hospital associations; 4) Waste management businesses; 5) Sanitation agencies including waste-water treatment facility operators; 6) Environmental advocacy organizations; and 7) Public interest organizations. A list of TAG participants is provided in the Report. Additionally, two general public meetings were held to obtain additional input from interested stakeholders. Representatives of the EPR Working Group also met with the City of Los Angeles, the San Gabriel Valley Council of Governments, Contract Cities, and the League of Cities, and attended the Las Virgenes-Malibu City Manager's Meeting. Conference calls and meetings were also conducted with the sharps manufacturing industry, the drug manufacturing industry, pharmacies and retailers, including distributors/wholesalers, and hospital associations as well as Kaiser Permanente.

The preliminary Draft Ordinance was shared with the TAG and all interested stakeholders on November 5, 2015, and made publicly available on DPH's website. The Draft Ordinance was discussed at the TAG meeting, as well as at the public meeting on November 13, 2015, to solicit input and comments. As a result of input received on the preliminary Draft Ordinance during the comment period, the Draft Ordinance was further revised and shared with the TAG and all interested stakeholders, and released to the public on DPH's website on January 5, 2016. Written comments received by the EPR Working Group from all stakeholders and responses to their comments from the meetings and their comments related to the Draft Ordinance are available on http://publichealth.lacounty.gov/pharma.htm.

Although the August 11th motion specifically directed the EPR Working Group to develop a draft stewardship ordinance, at the request of industry stakeholders, the EPR Working Group evaluated all potential alternatives, including a voluntary program and a program emphasizing outreach and

education. The EPR Working Group determined that the proposed alternatives would not in and of themselves meet the County's objectives to provide County residents with safe, convenient, and sustainably financed take-back options. Further, it was determined that an outreach and education campaign must be implemented in conjunction with providing residents options that maintain public health and safety and safeguard the environment from potential impacts, thereby discouraging the option of disposal in the trash or sewer system.

Implementation of Strategic Plan Goals

The Countywide Strategic Plan directs the provisions of Operational Effectiveness and Fiscal Sustainability (Goal 1), Community Support and Responsiveness (Goal 2), and Integrated Services Delivery (Goal 3). Adopting the accompanying Ordinance to amend the Health and Safety Code is consistent with these goals.

FISCAL IMPACT/FINANCING

The full cost to implement the Stewardship Plan(s) will be funded by the Responsible Steward(s), group of Responsible Stewards, and/or Stewardship Organization(s). Such Stewardship Plan(s) may offset a portion of the costs of existing County programs identified in the Report, Attachment II.

Additionally, the Ordinance requires Responsible Stewards to defray the DPH regulatory oversight costs through the collection of public health fees. DPH estimates that its oversight regulatory activities for this program, including reviewing plans and overseeing compliance with the Ordinance, will require at least four and one-half additional full-time equivalent positions estimated at \$644,000 in the first year of the program.

The Director will propose to the Board a schedule of fees to be charged to each Responsible Steward, group of Responsible Stewards, and Stewardship Organization to cover the costs of administering and enforcing the Ordinance. The Board must approve the schedule of fees for it to become effective.

Finally, under the provisions of the Ordinance, consumers may not be charged a point-of-sale fee to recoup the costs of any Plan, nor can they be charged a collection fee at the time the Drugs or Sharps are collected.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

On August 11, 2015, the Board approved a motion which directed the CEO, in collaboration with the Sustainability Council, and the EPR Working Group to:

- 1. Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect, transport and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the pharmaceutical industry, and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created;

3. Return to the Board within six months with the recommended ordinance for consideration.

The Board amended the motion to have the stakeholder process occur first before the ordinance was drafted.

If adopted, the Ordinance would be enforceable in the County unincorporated areas, and later in cities within the County, if adopted by their respective City Councils.

ENVIRONMENTAL DOCUMENTATION

The proposed Ordinance is within a class of projects that are exempt from further CEQA analysis, in that it meets the criteria set forth in Section 15307 and 15308 of the State CEQA Guidelines. Specifically, adoption of the Ordinance is an action taken by the County in a regulatory capacity to provide for maintenance, protection and/or enhancement of natural resources and the environment, and it contains procedures for the protection of the environment. Attachment III sets forth findings in support of these categorical exemptions for the Board's consideration and recommended adoption.

There is a growing body of evidence that when drugs enter the waste stream through the sewer system, trash, and/or septic systems, they have a deleterious impact on the environment, including the water supply system. Improperly disposed sharps also present public health and environmental hazards. Providing residents with a safe, convenient alternative to flushing, or discarding these materials into the trash will help protect the environment and natural resources by reducing the amount of these products that are placed into the environment while also keeping them out of the hands of people who may abuse or be injured by them.

Specifically, the proposed Ordinance will require Responsible Stewards to provide safe and convenient options for residents to return Unwanted Covered Drugs and Unwanted Sharps; and to transport and dispose of the Drugs and Sharps in an environmentally safe manner. In addition, there are no unusual circumstances or limiting factors that would make these exemptions inapplicable based upon the project record.

Upon the Board's adoption of the Ordinance, including the findings set forth in Attachment III, the Director of DPW will file a notice of exemption with the Los Angeles County Registrar Recorder/County Clerk.

<u>IMPACT ON CURRENT SERVICES (OR PROJECTS)</u>

The County will continue to maintain the current programs as described in the Board Report, Attachment II. Once the Plans are approved by the Director of Public Health or her designee, some of the costs associated with the existing County programs, such as the disposal of collected Drugs and Sharps, may be covered by the Responsible Stewards as part of their Plans. Implementation of the Plans is anticipated to begin in September 2017.

CONCLUSION

It is requested that the Executive Office, Board of Supervisors, return conformed copies of the adopted recommendations, and the certified Ordinance to County Counsel, the CEO, Directors of DPH, DPW, ISD, DMH, and DHS; the Sheriff, the Sanitation Districts of Los Angeles County, and the Sustainability Council.

Respectfully submitted,

Jan Jones ga

SACHI A. HAMAI

Chief Executive Officer

GAIL FARBER

Hail Farher

Director

Cynthia A. Harding, M.P.H.

Cynthia A. Hardiy

Interim Director

SAH:JJ:DH:DB DSP:MJS:acn

Enclosures

c: Executive Office, Board of Supervisors

County Counsel

Sheriff

County Sustainability Council

Health Services

Internal Services

Mental Health

Public Health

Public Works

Sanitation Districts of Los Angeles County

ATTACHMENT I

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 Counsel

GRAVE V. CHANG

Principal Deputy County Counsel

Health Services Division

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		
Stew	ards of Covered Dr	rugs 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		
Repo	rts.			
	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.		
		mark a		

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

11.17.012 Purpose.

11.17.010

Title.

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.

4

- 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.

5

- 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.

7

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

9

HOA 100498853 1

- 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;

15

- 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.
- 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.

HOA, 100498853.1

- 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.
- 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.
- 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.

<u>11.17.060</u> 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.

25

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:
- 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

27

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

HOA.100498853.1 28

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.

HOA.100498853.1

- 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

30

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 HOA.100498853.1

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

HOA.100498853.1 32

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;

HOA.100498853.1 33

- 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

34

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:
- 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;

35

HOA.100498853.1

- 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

36

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.

HOA.100498853.1 37

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 HOA.100498853.1

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.

39

[CH1117GCCC]

HOA.100498853.1

ATTACHMENT II

PHARMACEUTICAL DRUGS AND SHARPS TAKE-BACK PROGRAM REPORT TABLE OF CONTENTS

1	EVECUTIVE CLIMMADV	Page 1
l. II.	INTRODUCTION	2
. .	BACKGROUND	
	A. Board Actions	3 3 6
	B. Board Policy	6
	C. County Programs and Initiatives	6
	D. County Supported Legislative Efforts Related to Drug and Sharps Take-	8
	Back Programs	
	E. County Survey	12
	F. Drugs and Sharps Stewardship Programs in Other Jurisdictions	14
	G. Other Data and Information Supporting Drug and Sharps Stewardship	14
	Programs	
	General Supporting Data and Information	14
	Department of Public Health Data and Information	15
	Other Related Public Health and Safety Data Information	16
13.7	Environmental Data and Information	17
IV.	STAKEHOLDER ENGAGEMENT PROCESS	18 18
	Public Health Webpage Stakeholders Meetings:	18
	Technical Advisory Group Meetings	18
	General Public Meetings	19
V.	PURPOSE OF ORDINANCE	21
VI.	REGULATIONS	21
VII.	KEY ELEMENTS OF THE COUNTY'S PHARMACEUTICAL DRUGS AND	21
	SHARPS COLLECTION AND DISPOSAL STEWARDSHIP ORDINANCE	
	Stewardship Plan(s)	21
	A. Participation	21
	B. Components	22 22
	C. Collection of Unwanted Covered Drugs and Unwanted Sharps	23
	D. Disposal of Unwanted Covered Drugs and Unwanted SharpsE. Costs to be Borne by Responsible Stewards	23
	F. Reporting Requirements	23
	G. Review	23
	H. Enforcement and Penalties	24
	I. Regulations, Guidelines and Reports	24
	J. County Review and Oversight Fees	24
	K. Promotion, Outreach and Education	24
	L. Compliance with Federal, State and Local Laws	25
VIII.	TIMELINE AND REPORTING REQUIREMENTS FOR PRODUCT	25
	STEWARDSHIP PLAN(S) IMPLEMENTATION	
IX.	FISCAL IMPACT OF THE ORDINANCE	26
X.	MATRIX OF POTENTIAL ROLES AND RESPONSIBILITIES	27
XI.	FREQUENTLY ASKED QUESTIONS	27

PHARMACEUTICAL DRUGS AND SHARPS TAKE-BACK PROGRAM REPORT

I. EXECUTIVE SUMMARY

The National Community Pharmacists Association and the Modern Medicine Network report that nationwide an estimated 200 million pounds of pharmaceutical waste is generated, and much of that waste is either being stored in household medicine cabinets or disposed of through sewers or waste systems.¹ The United States Environmental Protection Agency estimates about 8 million people in the United States use more than 3 billion needles, syringes, and lancets, collectively known as "sharps", each year.² This health and environmental safety concern faces residents in Los Angeles County, California and throughout the Nation. Excess medications in our homes create significant opportunities for unintentional poisonings, illegal distribution, substance misuse and abuse.³ Improper disposal can lead to environmental contamination.

Unfortunately, in Los Angeles County, consumers do not have convenient access to safe take-back options to properly dispose of unused drugs and sharps. Although the County currently operates collection events and collection sites, these limited options cannot adequately serve the County's 10 million residents. To address this issue, on August 11, 2015 the Los Angeles County Board of Supervisors directed County staff to prepare a draft Ordinance that would provide constituents with disposal options. The draft Ordinance would require manufacturers of covered drugs and sharps to develop product stewardship take-back programs that are safe, convenient and sustainably financed.

Ordinance Requirements

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. To ensure that an effective Stewardship Plan is implemented, "Responsible Stewards," as defined in the Ordinance will be required to: 1) Finance, develop and implement a Plan, approved by the Director of Public Health, for the collection, transportation and disposal of "Unwanted Covered Drugs" and/or "Unwanted Sharps"; 2) Provide ongoing, reasonably convenient and equitable access for all County residents to "Collection Sites"; 3) Provide "Mailers" and "Mail-Back Services," free of charge, to residents, upon request; 4) Conduct collection events, as described in the Ordinance; and 5) Develop, implement and assess a promotion, outreach, and public education strategy emphasizing proper disposal of drugs and sharps for residents, pharmacists, veterinarians, retailers, and health professionals who interact with patients.

The Ordinance, if adopted, would be enforceable in the County's unincorporated communities and the program is anticipated to be implemented in September 2017. Cities within the County that are under the jurisdiction of the County's Public Health Officer may also adopt the Ordinance upon approval by their respective City Councils.

DisposeMyMeds.org (NCPA); and http://drugtopics.modernmedicine.com/drugtopics/news/modernmedicine/modern-medicine-feature-articles/safe-disposal-pharmaceuticals-growi
Community Options for Safe Needle Disposal (USEPA, October 2004)

³ Prescription Drug Abuse in Los Angeles County, Background and Recommendations for Action, LA County Department of Public Health, Substance Abuse Prevention and Control, January 2013

II. INTRODUCTION

County residents are currently not provided with an equitable and convenient range of disposal options for Unwanted Covered Drugs and Unwanted Sharps. With nearly 3.5 million households, disposal options are limited to Countywide Household Hazardous Waste (HHW) take-back events, drug collection bins at 21 Sheriff's stations, and 77 sharps collection locations, (including 9 HHW collection centers, 21 Sheriff's stations and 10 Public Health Clinics). This is inadequate for providing 10 million residents convenient and accessible disposal solutions and has resulted in a growing number of households stockpiling Unwanted Covered Drugs and Unwanted Sharps.

Furthermore, publically financed programs place the burden and responsibility for resolving the drug and sharps disposal issue on local government and the taxpayer. This is contrary to the County's long-standing Board policy, as articulated in the County's 2015-16 State Legislative Agenda that emphasizes the proper end-of-life disposal of materials as a manufacturer's responsibility, otherwise known as Extended Producer Responsibility (EPR) or Product Stewardship.

From a public health and safety and environmental perspective, although State law prohibits placement of sharps waste in trash or recycle bins, and requires sharps waste to be placed in special containers, these materials are still entering the waste stream and the environment and pose a hazard to residents and workers. Additionally, there is no State law that mandates an EPR take-back program for drug and sharps disposal. The *Background* section of this report contains a discussion of previous State legislative attempts to address the end-of-life management of unwanted pharmaceuticals and sharps.

At the federal level, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the Drug Enforcement Administration (DEA) recognize take-back programs as the preferable method for safe disposal of drugs, but they do not preclude household trash disposal or flushing of certain medicines as an option. The federal and State governments also do not provide funding for locally sponsored or operated take-back programs.

Barring decisive State or federal leadership in adopting EPR programs for Unwanted Covered Drugs and Unwanted Sharps waste, counties State-wide and nationally have been forced to develop comprehensive solutions at the local level. On August 11, 2015, the Board addressed this challenge by requesting County departments, the Sustainability Council and the Sanitation Districts of Los Angeles County to "draft an ordinance" that would "provide for safe, convenient and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste."

The proposed Ordinance will require manufacturers of "Unwanted Covered Drugs" and "Unwanted Sharps" to develop Stewardship Plans (Plans) to address public health and safety concerns thereby reducing opportunities of unintentional poisonings, illegal distribution, and substance misuse or abuse; ensuring greater safety for sanitation and sewage treatment workers; and reducing potential environmental contamination.

The Stewardship Plans must minimally provide for three take-back options:

Collection Site Option: "Potential Authorized Collectors", registered, or that may apply to register with the DEA, will be able to host collection bins for residents to drop off

"Unwanted Covered Drugs". Separate collection bins will be available for "Unwanted Sharps" and may be located at alternative sites from the Drug collection sites.

- Mail-Back Option: This option provides for the return of "Unwanted Covered Drugs" or "Unwanted Sharps" from residents, upon request, utilizing prepaid, preaddressed, tamper-resistant envelopes or containers used for mailing "Unwanted Covered Drugs" and/or "Unwanted Sharps". The Mailer used for "Unwanted Sharps" must be FDA-compliant.
- ➤ Collection Event Option: This option will involve periodic events that will allow residents to bring "Unwanted Covered Drugs" or "Unwanted Sharps" to specifically designated locations on a specified day and during a scheduled time period.

III. BACKGROUND

A. Board Actions

See Exhibit 1 for copies of all Board motions addressed in this section.

- November 5, 2008: Recognizing the need for manufacturers of products to take responsibility for the impacts their products have on public health and the environment at the end of life; and the need to reduce the burden on local governments while meeting environmental mandates to prevent hazardous wastes being improperly disposed of in landfills, rivers, streams and waterways, the Board passed a motion taking the following actions:
 - 1. Adopt a resolution supporting Extended Producer Responsibility;
 - 2. Direct the County's Legislative Advocates in Sacramento to actively pursue legislation and Statewide policies that shift end-of-life management product costs from local government to the manufacturers and incentivize the redesign of products that have impacts on public health and the environment;
 - 3. Authorize the Acting Director of Public Works and the Director of Internal Services to jointly participate as a member of the California Product Stewardship Council; and
 - 4. Direct the Energy and Environmental Policy Team to evaluate and develop recommendations for producer responsibility policies that County Departments can implement, such as leasing products rather than purchasing them, requiring producers to offer less toxic alternatives, and to take responsibility for collecting and recycling their products at the end of their useful life.
- October 13, 2009: In response to State law, (SB 1305, Figueroa, 2006), prohibiting the placement of home-generated sharps waste in trash and recycling containers; and in support of the County's Home-Generated Sharps Waste Management Program administered by Public Works (DPW) and Public Health (DPH), the Board adopted a motion instructing the Director of Public Works, in collaboration with the Directors of Health Services, Community and Senior Services, Public Health and the Fire Chief to:

- 1. Identify and evaluate the potential for utilizing additional County facilities, such as fire stations, pharmacies, hospitals and other locations, as sharps collection sites;
- Implement collection sites at the most feasible locations on a 12-month trial basis based on the Public Health model with costs shared equitably amongst participating departments;
- 3. Assess the feasibility of providing approved mail-back containers to assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites; and
- 4. Submit a report summarizing the results of this effort and include but not be limited to:
 - a. Success of the trial collection sites in enhancing the Program
 - b. Barriers/challenges faced
 - c. Public outreach and education implemented
 - d. Cost analysis
 - e. Recommendations on making collection sites permanent, further expanding collection and other adjustments to the Program.

On April 14, 2011, the Department of Public Works reported back to the Board in response to the motion. (See Exhibit 2 for a copy of the report.)

- October 21, 2014: The Board adopted the Roadmap to Achieve a Sustainable Waste Management Future which identified "Priority Issues," one of which was Product Stewardship/Extended Producer Responsibility as "a policy approach in which manufacturers assume a shared responsibility for the impacts and management costs of their products at the end of life." The Board adopted report included an Initiative to Advocate for Extended Producer and Manufacturer Responsibility: Explore the feasibility of establishing a County EPR ordinance for materials such as pharmaceuticals; needles...while ensuring collected items are properly managed in accordance with Federal, State and local laws using environmentally sound practices."
- ▶ June 2, 2015: Recognizing the need to conveniently and safely manage the disposal of unused and expired medication as a public health and environmental issue; and further recognizing that the volume of pharmaceuticals is too great for local programs to fully address, the Board adopted a motion directing DPW to coordinate with the Interim Chief Executive Officer (CEO), County Counsel, Sheriff and the Directors of Public Health, Mental Health, Health Services, Internal Services, and the Sanitation Districts to:
 - 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;

⁴ https://dpw.lacounty.gov/epd/Roadmap/PDF/Roadmap_Appendices.pdf

- Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medications and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue EPR legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the counties of Alameda, San Mateo, San Francisco and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

In response to that motion, on July 2, 2015, the Extended Producer Responsibility Working Group (EPR Working Group), including those entities identified above, submitted a report to the Board, *Managing Unused and Expired Medications and Sharps Waste in the County of Los Angeles*, responding to Items 4 and 5 and recommending that "the Board adopt a pharmaceutical and sharps waste EPR ordinance in which pharmaceutical manufacturers and producers would develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served." ⁵

- ▶ <u>August 11, 2015</u>: In response to the EPR Working Group's July 2nd report recommending an EPR ordinance and recognizing that other counties had adopted pharmaceutical take-back ordinances, the Board adopted a motion directing the Interim CEO, in collaboration with the County's Sustainability Council, and the EPR Working Group to:
 - 1. Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
 - Initiate stakeholder engagement with the pharmaceutical industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created;
 - 3. Return to the Board within six months with the recommended ordinance for consideration.

The Board amended the motion to have the stakeholder process occur first before the ordinance was drafted.

⁵ file.lacounty.gov/bc/q3_2015/cms1_230598.pdf

On October 1, 2015 the Working Group responded to Items 1-3 of the June 2, 2015 Board motion and provided a status update on the activities undertaken by the EPR Working Group as it related to development of the Ordinance. (See Exhibit 3 for a copy of the report.)

B. Board Policy

On December 8, 2015, the Board adopted the County's 2015-16 State Legislative Agenda, Second Year, stating that the County should:

- "Support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability; and
- ➤ "Support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management." 6

C. County Programs and Initiatives

County Programs

- Home-Generated Sharps Waste Management Program: DPW provides State-approved, puncture-proof containers for residents to safely collect their sharps waste. The containers can be obtained free of charge at 117 distribution sites and there are 77 collection sites Countywide including 9 permanent household hazardous waste collection centers, 21 Sheriff's stations, and 10 Public Health Centers. This multi-departmental effort was in response to Senate Bill 1305, (Figueroa, 2006), prohibiting the placement of home-generated sharps waste in trash and recycling containers and requiring the use of State-approved containers for the collection and transportation of sharps waste. Exhibit 4 is a list of sharps take-back sites in Los Angeles County.
- Safe Drug Drop-Off Program: On September 29, 2009, the Sheriff's department launched the Safe Drug Drop-Off Program as a 30 day trial at the Lomita Sheriff's Station with the support of the Metropolitan Water District, Sanitation Districts and Beaches and Harbors. The success of the pilot resulted in the expansion of the Program to an additional 20 Sheriff's stations. These designated Sheriff locations have self-serve drop boxes for the collection of home-generated sharps waste and

⁶ http://ceo.lacounty.gov/igr/PDF/State%20Leq%20Aqen_transmittal%20memo_121515.pdf; Section 2.7 Recycling and Waste Reduction; page 14, #12 and #13.

pharmaceutical waste. The Program was established to provide an opportunity for residents to safely and anonymously drop-off expired or unused drugs, sharps waste, and other controlled substances. DPW assumed administration of the contract to manage the home-generated sharps waste collected at the designated Sheriff's stations. Sheriff's stations also assist with public outreach and education efforts.

Program provides residents with a convenient free outlet to dispose of their pharmaceutical drugs (drugs) and sharps waste at a permanent center or collection event in various communities throughout the County. This program, however, is not authorized to accept any of the prescription drugs that are considered controlled substances.

The County's programs collect more than 50,000 pounds of drugs and sharps waste annually. While these efforts represent a much needed and important service for the proper and safe disposal of Unwanted Covered Drugs and Unwanted Sharps, the increasing volume of drugs and sharps waste is too great for these local County programs to fully address the problem. It also creates a financial burden and growing responsibility on the County for handling drugs and sharps wastes, rather than placing the responsibility for the disposal and management of these unwanted products on the manufacturers (Responsible Stewards).

County Initiatives

Safe Drug Disposal: DPH's, Prescription Drug Abuse Coalition, also known as Safe Med LA, has developed a five-year strategic plan to address prescription drug abuse, focusing on six priorities, one of which is Safe Drug Disposal. The objective of this priority is to support convenient, safe and free prescription drug disposal programs in Los Angeles County to help decrease the supply of unused drugs. Safe Med LA has reported that nearly 70% of people who have used prescription drugs for nonmedical purposes reported obtaining them from family relatives or friends.

Safe Med LA concluded that available options for safe disposal of prescriptions drugs are insufficient to meet community needs and indicated in its five-year strategic plan that it will:

- a) Support the efforts of the County's EPR Working Group in the development and implementation of an EPR ordinance in which pharmaceutical manufacturers and producers would be required to implement take-back programs for the unwanted and unused products that are convenient and adequately meet the needs of the population being served.
- b) Engage pharmacies and pharmaceutical manufacturers in discussions around implementing safe, convenient, and environmentally responsible drug disposal programs.
- c) Explore opportunities to promote and expand the number of drug drop-off locations in Los Angeles communities.

D. County Supported Legislative Efforts Related to Drug and Sharps Take-Back Programs

On April 23, 2013, the CEO sent a memo to the Board indicating support for AB 403 (Stone) and SB 727 (Jackson) finding these bills "consistent with the County's existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers..."

- AB 403 (Stone): The measure, introduced in the 2013-14 legislative session, would have required businesses that sell medical sharps to establish a product stewardship plan for the end-of-life management of home-generated medical sharps. This measure was introduced based on the following findings:
 - a) Per the State legislative analyst, an estimated 1 million people in California were using disposable needles (sharps) at home to deliver medications to treat a variety of diseases and conditions, including diabetes, cancer, multiple sclerosis, migraines, and allergies. California households were using more than 389 million disposable needles and syringes each year.
 - b) Since 2008, it has been illegal in California for individuals to throw away home-generated sharps. While the state banned needles from trash disposal in 2008, there was still no consistent, statewide program that was sustainably funded or had high levels of effectiveness at collecting the majority of sharps disposed of each year in California. As a result, thousands of pounds of illegally disposed of sharps were entering the municipal waste stream each year, putting many people at risk of injury or infection.
 - c) Sharps in the trash pose serious health risks to sanitation workers, water treatment facility operators, and the general public. In addition to the immediate risk of a needle stick injury, sharps put individuals at risk of acquiring blood borne infectious diseases, such as hepatitis or HIV. Individuals who suffer a needle stick injury must receive immediate treatment and follow-up care, including multiple lab tests and medications.
 - d) When sanitation workers encounter sharps, productivity suffers and costs increase. When workers sustain a needle stick injury, the costs of care are borne by the waste management company, the workers' compensation insurer, and ultimately, taxpayers and ratepayers.
 - e) It was the intent of the Legislature, in enacting the safe home-generated sharps recovery program, to ensure affordable and convenient sharps collection opportunities, which, in turn, would help prevent the improper management of those sharps.

The drug manufacturing industry and sharps manufacturing industry opposed the bill citing:

- a) The development and distribution of sharps involves many stakeholders and placing the responsibility for end-of life disposal solely on manufacturers was an unfair burden.
- b) The number of needle-stick injuries and associated medical costs are low compared to the growing number of self-injected medications being prescribed.
- c) The program creates a cost pressure in healthcare by establishing a statewide bureaucracy that is rigid and punitive requiring: educational outreach material distribution, establishing collections sites, hiring auditors, incurring transportation and disposal costs, and administrative penalties.
- d) The program would create a financial impact on Medi-Cal and its patients.
- e) The program would allow medical devices to be banned preventing patients from obtaining medical devices with sharps.
- f) The mandated collection rates were not practical since the manufacturer does not have control over the patient's actions and cannot compel them to return sharps.

This bill died in the Assembly Appropriation Committee on January 31, 2014.

- SB 727 (Jackson): The measure, introduced in the 2013-14 legislative session, would have required producers of pharmaceutical products sold in the State to develop and implement a program to collect, transport and process home-generated pharmaceutical drug waste. This measure was based on the following findings:
 - a) The stockpiling of unused and unwanted pharmaceuticals had increased rapidly in recent years, creating access to potentially dangerous drugs to children and adults alike. Accidental poisoning from ingestion of drugs among children often occurred in homes where medicine was easily accessible. The Partnership for a Drug-Free America released a report in February 2010 indicating that over 60 percent of teenagers were able to obtain prescription painkillers free of charge from family and friends.
 - b) Poisoning was the fastest rising cause of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications. Unintentional poisoning of adults over 60 years of age resulting in hospitalization increased by 43 percent in the County of Alameda from 1998 to 2006.
 - c) Pharmaceutical residues were accumulating in groundwater and drinking water. Drugs were entering the environment through multiple sources, including flushing toilets or through leaks in landfills. Even the most advanced wastewater treatment plants were not currently able to account for these chemicals.

The cost of developing the waste treatment for wastewater would be extremely high. Thus, many drugs would continue to pass through wastewater treatment systems and contaminate receiving waters unless the source of the problem could be addressed.

- d) Safe and convenient medical waste recovery programs were considered critical in reducing the negative social and environmental health impacts of improper or illegal disposal.
- e) Product stewardship programs in Canada and Europe for hazardous wastes, medical wastes, and hard-to-handle wastes, including electronic waste, packaging, beverage containers, batteries, mercury-containing lamps, and other mercury-containing products had demonstrated that shared producer responsibility resulted in significant improvements in safe end-of-life management and reductions in taxpayer and ratepayer costs.

The drug manufacturing industry and sharps manufacturing industry opposed the bill for the following reasons:

- a) 100% of the costly program would be borne by the manufacturers.
- b) The bill introduces harsh penalties.
- c) Manufacturers would be responsible for implementation costs including: establishing collection sites, meeting CEQA requirements, absorbing liability, transportation, and processing and disposal costs for the products. All of these requirements would impact the cost of affordable medicine.
- d) End of life for most drugs is ingestion by the patient and therefore the medicine is not returnable to a collection site. The manufacturer will not be able to collect the amount of unused medicine required by the Program as there should be none left.
- e) It is not practical to penalize a manufacturer based on whether or not a patient chooses to utilize a collection site. Establishing performance goals would penalize manufacturers for actions that are out of their control. Furthermore, penalizing manufacturers for the actions, or non-actions of patients would be a violation of due process.

This measure was returned to the Secretary of the Senate on February 3, 2014 and is an inactive (dead) bill.

On March 24, 2014, the CEO sent a memo to the Board indicating support for SB 1014 (Jackson) finding this bill "consistent with the County's existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers..."

> <u>SB 1014 (Jackson)</u>: This measure, introduced on February 13, 2014, would have required a producer of certain pharmaceuticals to submit a product stewardship plan

for the safe take-back and proper disposal of home-generated pharmaceutical waste at no cost to consumers. This measure was based on the following findings:

- a) There had been an increasingly serious problem with prescription drug abuse, accidental poisonings and the detection of pharmaceutical products in State waters.
- b) Local governments had struggled to establish safe and convenient medication take-back programs for the unused and expired prescription drugs, over the counter drugs and veterinary drugs in their homes.
- c) Unused medications were often flushed or thrown in the trash because there were few, if any, safe and convenient options.
- d) Due to the drug abuse epidemic, diversion was critical to protect public health.

The drug manufacturing industry opposed the bill for the following reasons:

- a) Voluntary programs are available through law enforcement, the DEA National Take-Back Day and education encouraging in-home disposal such as the American Medicine Chest Challenge.
- b) There are already active facilities accepting medications, pharmacies partnering with law enforcement offering take-back events, and mail-back programs.
- c) Drug take-back programs do not address the issue of pharmaceuticals in the environment which are primarily from human waste not from improper disposal and that the trace amounts found in water are not harmful to human health.
- d) Research demonstrates that household trash disposal is effective for disposing of unused medicines once patients mix them with an undesirable substance to avoid diversion. Programs such as SMARxT Disposal, a partnership between the federal Fish and Wildlife Service, the American Pharmacists Association and PhARMA accomplish the same goal of removing unused medicines from the home while discouraging patients from flushing medicines down the toilet or disposing of them down the drain. Note: U.S. Fish and Wildlife Service have not participated in this program for several years.
- e) Increases cost of pharmaceuticals which is inconsistent with the goal of keeping medicine affordable. Patients should take medications as prescribed which would cut down on the number of unused medications. This can be monitored through tools such as the Prescription Drug Monitoring Program allowing healthcare providers to review medication history.
- f) Creates a rigid program with tight bureaucratic controls with mandates, plan approval requirements and penalties.
- g) Requires an annual report detailing sales data compared to collection data penalizing companies if patients are compliant with drug treatment regimens.

The bill died in the Assembly Appropriations Committee in November 2014.

On April 27, 2015, the CEO sent a memo to the Board indicating support for AB 1159 (Gordon) finding this bill "consistent with the County's existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers..."

- AB 1159 (Gordon): This measure, as amended on April 21, 2015, would require producers and product stewardship organizations of covered products, either home-generated sharps waste or household batteries, to develop and implement a product stewardship plan by July 1, 2017. The plan would have to include strategies to achieve performance standards and a funding mechanism to carry out the plan. This measure was based on the following findings:
 - a) Sharps are widely used and lack convenient disposal and recycling opportunities for consumers.
 - b) Sharps have significant and indisputable end-of-life impacts.

The bill died in the Assembly Appropriation Committee on January 31, 2016.

Exhibit 5(a) includes CEO memos to the Board regarding AB 403 (Stone), SB 727 (Jackson), SB 1014 (Jackson) and AB 1159 (Gordon). Exhibit 5(b) includes the pharmaceutical industry opposition letters to AB 403 (Stone), SB 727 (Jackson), and SB 1014 (Jackson).

E. County Survey

- Purpose: The Medicines and Sharps Disposal Survey was conducted by the Health Care Consumer Protection Program, DPH on behalf of the EPR Working Group to find out:
 - a) How members of the public in Los Angeles County currently dispose of unused or unwanted drugs and sharps;
 - b) The public's beliefs on the possible environmental impact of drug and sharps disposal; and
 - c) The public's thoughts on potential future options for drug and sharps disposal.
- Method: Residents of Los Angeles County, who were 18 or older, were invited to complete the survey in three settings:
 - a) Los Angeles County's Department of Health Services (DHS) pharmacies (H. Claude Hudson and Hubert H. Humphrey Comprehensive Health Centers)
 - b) Ralphs pharmacies in Los Angeles County (16 pharmacies)
 - c) Online, via SurveyMonkey®

The survey was available in English and Spanish and was anonymous and confidential. Paper surveys were self-administered in the DHS pharmacies, and the online survey was posted on the DPH website and promoted via social media by e-mail and flyers. It was also sent to DPH partners, EPR public stakeholders, parent groups, and all DPH staff, people attending household hazardous waste drop-off events, and DHS patients receiving medicines through the mail. All persons who received the survey link were encouraged to share it broadly with adult residents of the County.

The study was approved by DPH and DHS's Institutional Review Board.

Results: Below are the key findings of the survey:

The survey was completed by a total of 1,062 people (342 Ralphs, 126 DHS and 594 online).

a) Medication Disposal

- More than half of respondents, (59%), said that they have medicines in their homes that are out of date or are no longer needed; and 45% of these people said that they did not know what to do with the medicines.
- In the survey there were 753 people who indicated at least one way that they usually disposed of medicines. Of these, 570 people (76%) reported disposing of medicine in the trash and/or drain but 48 of these people also selected other methods of disposal that keep medicines out of landfill and water supplies. Overall, of the 753 people who reported disposing of their medicines, 69% use the trash or drain as their only method of medication disposal.

b) Sharps Disposal

- Overall, 24% of respondents reported that they, or someone in their household, used medical sharps and of these 56% said they always place their used sharps in an approved sharps container and 16% said that they sometimes do.
- Overall, of the 196 people who reported disposing of sharps, 38% use the trash or drain as their only method of disposal.

c) Future Disposal Preferences of Medication and Sharps

All participants were asked to select one option that they would prefer to use in the future to dispose of sharps and medicines free of charge; (69%) chose a drop-off bin in a pharmacy; 15% chose mail back envelopes; 8% chose drop-off boxes at clinics; and 7% chose drop off boxes at Sheriff or police stations.

All participants were asked what best described their response to the following statement: "One of the ways that has been suggested for people to dispose of unwanted medicines and sharps is to place them in drop off bins in pharmacies." The vast majority of participants (87%) selected "this is a good approach," while 7% selected either "undecided" and 7% selected "I have some concerns." More people

were undecided (24%) or had concerns (11%) about this scenario if the pharmacies are located in stores that sell fresh food.

In the general comments section, the majority of commenters expressed support for safe, accessible, and convenient options for disposal of medicines and sharps. The survey questions are attached in Exhibit 6.

d) Environmental Concerns of Disposing of Medicines

Nearly three-quarters of respondents (74%) reported believing that putting medicine down the toilet or sink is harmful for the environment and over one-half (54%) believed that putting medicines in the trash was harmful.

F. Drugs and Sharps Stewardship Programs in Other Jurisdictions

Exhibit 7(a) provides information on EPR drug take-back programs: 1) State-wide in Alameda, Marin, Santa Clara, Santa Cruz, and San Mateo counties and the City and County of San Francisco; 2) Nationally in King County, Washington; and 3) Internationally in Belgium, Brazil, Canada, Colombia, France, Hungary, Mexico, Portugal, and Spain. One or more members of the EPR Working Group also met or conducted conference calls with Alameda County, San Francisco, and King County, Washington. To learn more about the EPR program in Mexico, the CEO contacted SINGREM, a civil non-profit association created by the pharmaceutical industry and supported by health and environmental authorities for the management and disposal of obsolete and leftover medicine stored in homes.

While Stewardship Programs have been implemented internationally, implementation in the United States was hindered, in part, by the drug manufacturing industry's court challenge to the Alameda County Drug Disposal Ordinance. However, on May 26, 2015, the United States Supreme Court declined to review the challenge to Alameda's Ordinance. The Court's decision, upheld the 9th Circuit Court of Appeals' opinion of September 30, 2014, which found that the ordinance, requiring pharmaceutical manufacturers to fund drug take-back programs in Alameda County, did not unduly interfere with interstate commerce or discriminate against out-of-state manufacturers.

Exhibit 7(a) documents the status of ordinance efforts to date. Exhibit 7(b) is a Pharmaceutical Take-Back Ordinance Comparison Chart.

G. Other Data and Information Supporting Drug and Sharps Stewardship Programs

> General Supporting Data and Information

a) CalRecycle found that local governments currently fund more than 80 percent of collection programs. CalRecycle is not aware of funding support from pharmaceutical manufacturing industries for collection programs in California; this contrasts significantly with the level of private sector funding in Canada and several European countries.⁷

⁷ CalRecycle Report to the Legislature, Recommendations for Home-Generated Pharmaceutical Collection Programs in California, December 2010, page 7

- b) The Pharmaceuticals from Households: A Return Mechanism pilot program in the State of Washington found that: 1) Medicine return programs are cost-effective to operate; 2) A statewide program could collect a substantial amount of unwanted medicines; 3) Community demand for safe disposal of medicines is high; and 4) Sustainable funding is needed for a statewide medicine return program. 8
- c) Estimates show that over 40 percent of prescription drugs dispensed each year to consumers in the United States are never actually used. Instead, over \$1.0 billion of prescription drugs are either stored in medicine cabinets or thrown away.⁹

> Department of Public Health Data and Information

- a) According to the Health Officer for Los Angeles County, prescription drug abuse has become one of the fastest growing public health concerns in the United States, and in Los Angeles County.
- b) In 2013, DPH published "Prescription Drug Abuse in Los Angeles County, Background and Recommendations for Action". The report indicated that a 2011 Los Angeles County Health Survey showed that 5.2% of adults (18 and over) or an estimated 379,000 adults reported misusing prescription drugs. Prescription drug use by youth in the County in 2010 demonstrated that 11% of students in grade 9, 14% of students in grade 11, and 37% of students in continuation, community day or alternative high schools misused prescription painkillers at least once in their lifetime. The report noted that "prescription drug abusers often obtain pills from the medicine cabinets of friends and family members." Therefore.... "unused medications should be disposed of immediately and properly."
- c) Related to prescription (Rx) Opioid misuse and abuse, DPH reported in March 2015:
 - Among individuals who misused/abused Rx opioids in the past year, most (67.6%) had obtained Rx opioids from their friends or relatives.
 - Up to 2012, approximately 42 tons of unwanted or expired prescription drugs were turned in to the DEA's drug take-back sites or Sheriff's Department Safe Drug Drop Off boxes in Los Angeles County.
 - According to the Office of Statewide Health Planning and Development Data, adjusted for inflation to 2015 US dollars, the sum of hospital charges for all hospitalizations with any Rx opioid-related diagnosis or external cause of injury at hospital discharge significantly increased by 68% from 2006 (\$399 million) to 2013 (\$673 million).

⁸ CalRecycle Report to the Legislature, Recommendations for Home-Generated Pharmaceutical Collection Programs in California, December 2010, page 21

⁹ Prepared for: Coastal Coalition for Substance Abuse Prevention: Drug Take-Back Programs: Safe Disposal of Unused, Expired, or Unwanted Medications in North Carolina, October 10, 2010, page 5

- According to the County Medical Examiner-Coroner data, nearly 400 deaths, (ranging from 360 to 469,) test positive for Rx opioids at death each year in the County. Rx opioids are involved in about 60% of all drug-related deaths from 2006-12 in the County.
- The number of hospitalizations with any Rx opioid-related diagnosis or external cause of injury increased by 30% from 2006 (11,230) to 2013 (14,594).
- The number of emergency department visits with any Rx opioid-related diagnosis or external cause of injury increased by 171% from 2006 (3,354) to 2013 (9,075).
- According to the Los Angeles County Participant Reporting System data, the number of individuals admitted to a **publicly funded** treatment program for Rx opioids as their primary drug of choice in the County increased by 86% from 1,490 in 2006 to 2,766 in 2013.

> Other Related Public Health and Safety Data and Information

- a) According to the National Institute on Drug Abuse, in 2011, 52 million people in the United States over the age of 12 used prescription drugs non-medically in their lifetime.¹⁰
- b) Prescription drug abuse is a significant public health and public safety issue, and a large source of the problem is a direct result of what is in Americans' medicine cabinets.¹¹
- c) The National Community Pharmacists Association and the Modern Medicine Network estimates that nationwide 200 million pounds of pharmaceutical waste is generated and that much of that waste ends up in medicine cabinets in homes or disposed of through sewers or waste systems.
- d) In 2009, 1.2 million emergency department visits, an increase of 98.4 percent since 2004, were related to misuse or abuse of pharmaceuticals. 12
- e) In terms of sharps, the EPA estimates that about 8 million people in the United States use more than 3 billion needles, syringes, and lancets each year.
- f) According to the EPA "people at the greatest risk of being stuck by used sharps include sanitation and sewage treatment workers, janitors and housekeepers and children." ¹³

¹⁰ NSDUH: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm

¹¹ Executive Office of the President: Epidemic: Responding to America's Prescription Drug Abuse Crisis, 2011, page 7

¹² Substance Abuse and Mental Health Services Administration. Highlights of the 2009 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. The DAWN Report. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2010. Available at http://oas.samhsa.gov/2k10/dawn034/edhighlights.htm. Accessed October 3, 2011

Environmental Data and Information

- a) Improper disposal of drugs down the toilet or drain or in the trash provides a pathway for the active pharmaceutical compounds to enter the environment including the water supply.¹⁴
- b) According to the EPA "studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing [down the drain/toilet]. Further, some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Incineration of unwanted household pharmaceuticals will reduce the amount of household pharmaceuticals that are disposed by both flushing and landfilling."¹⁵
- c) Collection programs provide a safe, legal and environmentally preferable alternative to managing unwanted drugs in the possession of consumers. This is a driving force for establishing home-generated pharmaceutical collection programs.¹⁶
- d) In 2012, the World Health Organization (WHO) reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources, and some drinking-waters.¹⁷
- e) There is broad consensus, including among the FDA¹⁸, EPA¹⁹ and the WHO²⁰ that drug take-back programs are the preferred choice for proper disposal of expired or unwanted prescription and over-the-counter drugs. Even the pharmaceutical manufacturing industry recognizes that safe disposal programs help prevent diversion in an environmentally friendly manner.²¹
- f) The EPA recommends incineration as the preferred method of disposal to address both environmental concerns and concerns regarding improper use of pharmaceuticals.²²

¹³ Community Options for Safe Needle Disposal (USEPA, October 2004)

¹⁴ Pharmaceuticals in Drinking Water (World Health Organization 2012)

¹⁵ Recommendation on Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (EPA Memorandum, September 2012)

¹⁶ CalRecycle, Report to the Legislature, Recommendations for Home-Generated Pharmaceutical Collection Programs in California, December 2010, page 12

¹⁷ Information sheet: Pharmaceuticals in drinking-water (WHO, 2012)

¹⁸ Disposing Unused Medicines: What you Should Know (FDA website)

Collecting and Disposing of Unwanted Medicines (EPA website, at http://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines)

Pharmaceuticals in Drinking Water (World Health Organization 2012); found a http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085 eng.pdf?ua=1

²¹ Safe Disposal of Prescription Medication and Environmental Protection (Pharmaceutical Research and Manufacturers of America website)

Recommendation on Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (EPA Memorandum, September 2012)

More detailed environmental findings are set forth in the CEQA Findings in Attachment III.

IV. STAKEHOLDER ENGAGEMENT PROCESS

The August 11, 2015 motion directed the EPR Working Group to conduct a stakeholder process prior to drafting the Ordinance. The following identifies the stakeholder engagement process undertaken by the EPR Working Group:

Public Health Webpage http://publichealth.lacounty.gov/pharma.htm.: The webpage includes Board motions and reports related to the Pharmaceutical Drug and Sharps Take-Back Ordinance; the goals and objectives of the Ordinance and take-back program; the draft Ordinance and key elements of the Ordinance; informational resources on sharps waste, prescription drug abuse in the County, and County programs and disposal options; stakeholder information including meeting dates and the EPR e-mail address provided for stakeholder comments; the medicines and sharps disposal survey; copies of written correspondence submitted to the EPR Working Group; and a summary chart of comments received by the EPR Working Group from all stakeholders and responses to those comments related to the Draft Ordinance.

> Stakeholder Meetings:

- a) Technical Advisory Group (TAG) Meetings: In addition to the EPR Working Group, a broad range of representatives that could potentially be most affected by the Ordinance were participants on the TAG including the pharmaceutical manufacturing industry, sharps manufacturing industry, pharmacies and retailers, including distributors/wholesalers, hospital associations, environmental advocacy organizations, pubic interest organizations, waste management businesses, and sanitation agencies including waste-water treatment facility operators. Exhibit 8 provides a list of TAG participants. The TAG held 4 meetings, noticed via e-mail invitation and the DPH website, on: September 28, October 14, October 27 and November 13, 2015. Exhibit 9 outlines the Ordinance objective, program goals and TAG purpose. TAG representatives were encouraged to provide comments throughout the meeting process, as summarized below:
 - Pharmaceutical Manufacturing Industry: The pharmaceutical manufacturing industry opposes an EPR Ordinance requiring a product stewardship plan financed by their industry. The industry believes that these plans, to date: 1) Have not been effective, largely because pharmacies and retailers are not mandated to participate; 2) Creates costs borne solely by the manufacturers for collection bins, program administration, mail-back processing, and transportation and disposal of medication; and 3) Creates a rigid and punitive bureaucratic process. Additionally, the pharmaceutical manufacturing industry does not believe that the science substantiates that their products create significant environmental or public health and safety issues for humans or animal life when disposed of properly in the home. The pharmaceutical manufacturing industry advocates for patients to be educated on the: 1) Proper use of medication; 2) Proper storage of medicines in the home; and 3) Effective methods of household trash disposal of unwanted and

unused medication. The pharmaceutical manufacturing industry proposes outreach and education efforts, such as MyOldMeds, SMARTxT Disposal and the Pharmaceutical & Sharps Safe Disposal Education Initiative to address drug abuse, drug diversion, poisoning and ingestion. These programs encourage residents to: 1) Practice in-home disposal, disposing drugs in their trash after completing a 4-step process or flushing FDA authorized drugs down the toilet; 2) Participate in community disposal programs, such as disposing of drugs and sharps at the Sheriff's stations collection bins and take-back events like the HHW Events; and/or 3) Participate in the DEA sponsored National Prescription Drug Take-Back Day.

- Sharps Manufacturing Industry: The sharps manufacturing industry also opposes an ordinance requiring a product stewardship plan financed by their industry. They believe that since State law prohibits the placement of home-generated sharps waste in trash and recycling containers that consumers have been provided with clear instruction on how to manage their sharps; and that there have been ample collection sites established in Los Angeles County. There are also distribution sites that offer sharps disposal containers. The sharps manufacturing industry encourages broadening outreach and education and addressing any other solutions through the legislative process rather than by implementing a local government ordinance.
- Pharmacies and Retailers, including Distributors/Wholesalers, and Hospital Associations: Pharmacies, retailers, distributors/wholesalers and hospitals believe that, if an ordinance is passed, their participation in a take-back program should be voluntary and offer a range of options including outreach and education programs.
- Waste Management Businesses, Sanitation Agencies including Waste-Water Treatment Facility Operators, Environmental Advocates, and Special Interest Groups (e.g. senior organizations): These groups are all advocates supporting the County Ordinance and believe this framework will address public health and safety concerns as well as potential environmental consequences that result from the lack of proper disposal options for Unwanted Covered Drugs and Unwanted Sharps. They also support a sustainably financed program by the drug and sharps manufacturing industries as Responsible Stewards. These organizations are proponents of an outreach an education program in alignment with the County's ordinance. They do not support educating the public to place drugs in the trash or dispose of them down the drain.
- b) General Public Meetings: There were 2 meetings held on September 28 and November 13, 2015 for the general public and a webinar option was offered to encourage greater participation and facilitate live, on-line access to the meetings. The EPR Working Group and many TAG representatives were also in attendance at these meetings. Public notification of the meetings was handled through e-mail blasts, flyers, information on DPH's website, and radio and cable public service announcements. The general public was largely supportive of the Ordinance and shared a number of personal stories. In particular, there was

strong representation from senior citizens, the Surf-Rider Foundation and other environmental organizations.

Exhibit 10 is a list of stakeholders that support and those that oppose the Ordinance.

- ➤ <u>Dedicated E-Mail Address</u> (<u>EPR@lacounty.gov</u>) to Obtain Feedback/Input: An e-mail address was set up so that members of the public, stakeholders, and other organizations had easy access to provide comments to the EPR Working Group.
- ➤ <u>Creation of a Stakeholder Database</u>: The EPR Working Group developed a comprehensive database of stakeholders potentially interested in the Ordinance, and requested from the TAG members any suggestions of additional stakeholders to be added to the database.
- Stakeholder Comments and Working Group Responses to Comments: A summary of written comments received by the EPR Working Group from all stakeholders and responses to their comments from the meetings and correspondences received related to the Draft Ordinance has been posted on the DPH website at http://publichealth.lacounty.gov/pharma.htm.
- Meeting Handouts Provided to Stakeholders: In order to facilitate the stakeholder meetings, the EPR Working Group prepared various documents for the meetings including: 1) Ordinance Objective, Program Goals and TAG Purpose (Exhibit 9); 2) Key Ordinance Elements Based on EPR Ordinances in California; 3) Ordinance Outline; 4) Pharmaceutical Take-Back Brochure; and 5) Matrix of Potential Roles and Responsibilities. (See Exhibit 11 for documents 2-5.)
- ▶ <u>Draft Ordinance</u>: On November 5, 2015, the EPR Working Group provided all stakeholders with the Draft Ordinance for review and comment. The revised Draft Ordinance was provided to stakeholders on January 5, 2016, requesting any additional comments by January 15, 2016.
- Other Stakeholder Meetings: One or more members of the EPR Working Group also met with the League of Cities, Contract Cities, City of Los Angeles, the San Gabriel Valley Council of Governments, and the Las Virgenes-Malibu City Manager's Meeting. Conference calls and meetings were also conducted with the sharps manufacturing industry, the pharmaceutical manufacturing industry, pharmacies and retailers, including distributors/wholesalers, and hospital associations.

EPR Working Group's Conclusions Based on Stakeholder Feedback

Although the Board's motion instructed the EPR Working Group to prepare an ordinance requiring manufacturers of drugs and sharps to develop product stewardship take-back programs, the EPR Working Group did consider proposals brought forth, specifically by opponents to the Ordinance, such as the pharmaceutical manufacturing industry, which emphasized a voluntary program and an outreach and education program. While we agree that outreach and education should include community disposal programs and take-back days, which are currently implemented and financed by the County, we do not concur that consumers should be encouraged to dispose of unused pharmaceutical products in the trash or disposed of down the drain due to public safety and environmental consequences as

detailed in this Report and the CEQA Findings, Attachment III. An outreach and education campaign must be implemented in conjunction with providing residents options that maintain public health and safety and safeguard the environment from potential impacts.

- Outside of the pharmaceutical and sharps manufacturing industries, there was strong support for the County to move forward with implementing an ordinance involving a product stewardship take-back program.
- Based on meeting discussions and written comments received, a Stewardship Program is the only way to meet the goals and direction of the Board's August 11, 2015 motion which directed that the EPR Working Group identify a safe, convenient and sustainably financed collection and disposal program, including a public education and outreach component.

V. PURPOSE OF THE ORDINANCE

The purpose of the Ordinance "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 by County residents, and 2) Protects, maintains, restores and/or enhances the environment and its natural resources." The Stewardship Program will be designed, operated and funded by the Pharmaceutical and Sharps industries with regulatory oversight by the County Department of Public Health.

VI. REGULATIONS

The Ordinance has been drafted consistent with DEA, EPA, and FDA Regulations. Exhibit 12 provides a chart highlighting the: 1) DEA Rules for Disposal of Controlled Substances; 2) FDA Recommendations on How to Dispose of Unused Medications; and 3) EPA Recommendations for Collecting and Disposing of Unwanted Medicines.

VII. KEY ELEMENTS OF THE COUNTY'S PHARMACEUTICAL DRUGS AND SHARPS COLLECTION AND DISPOSAL STEWARDSHIP ORDINANCE

Stewardship Plan(s)

A. Participation (Section 11.17.030)

- The "Responsible Steward(s)" of covered drugs or sharps will operate or participate in a Stewardship Plan (Plan) for the collection, transportation and disposal of Covered Drugs or Sharps. A Responsible Steward, as defined in the Draft Ordinance, shall mean a Manufacturer engaged in the Manufacture of a Covered Drug or Sharp.
- A Responsible Steward may submit separate Plans for each Covered Drug or type of Sharp it Manufacturers or a combined Stewardship Plan for multiple Covered Drugs or types of Sharps.
- The Responsible Steward(s) will notify all Potential Authorized Collectors, persons other than Potential Authorized Collectors, such as retail establishments, and all law enforcement agencies within the Service Area and those within two and one-half

- miles of the outer boundaries of the Service Area of the opportunity to participate in the Plan(s) by serving as Hosts.
- 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.
- The Director of Public Health (Director) will approve and have oversight of all aspects of the Plan(s).

B. Components (Section 11.17.040)

- > The Plan(s) will describe the collection services including but not limited to the 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.
- > The Plan(s) will describe the public education and promotion strategy.
- The Plan(s) will describe the proposed disposal system for the Covered Drugs and Sharps and policies and procedures for handling the collected Covered Drugs and Sharps.

C. Collection of Unwanted Covered Drugs and Unwanted Sharps (Section 11.17.050)

- No Person is required to serve as a Host in a Stewardship Plan.
- Reasonably convenient and equitable access for residents in the Service Area will minimally require:
 - a) One Collection Site for Unwanted Covered Drugs and one for Unwanted Sharps in each Participating City and Unincorporated Community with at least one Potential Authorized Collector, with one additional site for every 30,000 County residents; and
 - b) An Unwanted Covered Drug and Unwanted Sharps Collection Site within a 2.5 mile radius of the Service Area.
- If the minimum requirements cannot be met in "a" and "b" above, the Plan will provide for monthly collection events and/or mail-back services upon request.
- Responsible Stewards will provide for distribution of FDA-compliant Sharps containers, at no cost to the consumer, preferably at the point of sale of the injectable Drug. Sharps manufacturers that can demonstrate that its product is designed to be protective of public health and safety and/or environmental health may apply to the Director for an exemption of this requirement.
- Mailers and Mail-Back services will be free of charge to residents in the Service Area upon request through a 24-hour, toll-free phone number and website, minimally offered in English and Spanish.

- Collection Sites will be accessible by County residents at least during the hours that the Host is normally open for business to the public and secure collection receptacles will be in compliance with federal, State and local laws.
- Responsible Stewards must provide FDA-compliant Sharps collection receptacles to Hosts with Sharps Collection Sites.
- Commercial and institutional establishments may not utilize any collection mechanism developed pursuant to the County's Ordinance for use by residents.

D. Disposal of Unwanted Covered Drugs and Unwanted Sharps (Section 11.17.060)

- ➤ 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 standards.
- > Sharps collected under a Stewardship Plan must be disposed of in accordance with the California Health and Safety Code.

E. Costs to be Borne by Responsible Stewards (Section 11.17.070)

- The cost and expense of Plan(s) preparation and implementation will be borne by the Responsible Steward(s) or Stewardship Organization.
- Consumers may not be charged a point-of-sale fee to recoup or defray costs of a Plan, nor may they be charged a specific point-of-sale collection fee at the time of collection of Unwanted Covered Drugs or Unwanted Sharps.

F. Reporting Requirements (Section 11.17.080)

Annual reports will include:

- The amount by weight collected of Unwanted Covered Drugs and separately of Unwanted Sharps each month for each collection method used.
- ➤ List of collection sites, number of Mailers provided, number of Unwanted Sharps containers provided, details on collection events, identification of transporters and disposal facilities used, and details on the recycling process
- A summary of the Plan's goals, the degree of success in meeting the goals, and if any goals have not been met, the effort that will be made to achieve goals in the next year.
- > A description of the public education, outreach and an evaluation of activities based on survey results.

G. Review (Section 11.17.100)

> By 9 months after the effective date of the Ordinance, Responsible Steward(s) or a Stewardship Organization will submit a Plan to the Director. The Director may, upon

- request, provide information, suggestions, and technical assistance about the requirements of the Ordinance.
- The Director shall have the authority to review a proposed Plan and determine whether it meets the requirements of the Ordinance within 90 days.
- A rejected Plan(s) may be resubmitted within 60 days and the Director will review the revised Plan(s) within 90 days. If the revised Plan(s) is rejected, the Director may deem the Responsible Steward(s) or Stewardship Organization out of compliance with the Ordinance and subject to the enforcement provisions.

H. Enforcement and Penalties (Section 11.17.120)

- ➤ The Director may issue a Notice of Violation (NOV) if a provision of the Ordinance or a regulation is violated. The Person(s) will have 30 days after the date of mailing the NOV to come into compliance. Failure to come into compliance may result in administrative fines.
- County Counsel, the District Attorney or any applicable City Attorney may bring civil action to enjoin violations or compel compliance with the requirements of the Ordinance and, for payment of civil penalties and any other appropriate remedy.
- A willful violation of the Ordinance or rules or regulations is a misdemeanor punishable by a fine and/or imprisonment.

I. Regulations, Guidelines and Reports (Section 11.17.130)

- > The Director may adopt regulations and guidelines necessary to implement, administer and enforce the Ordinance.
- > Annually, the Director will work with the Responsible Steward(s) or Stewardship Organization to define goals and evaluate performance.
- > The Director will report to the Board of Supervisors concerning the status of all Stewardship Plans and make recommendations to the Ordinance two years from the effective date of the Ordinance, and thereafter on an as-needed basis.

J. County Review and Oversight Fees (Section 11.17.140)

➤ DPH will charge Board approved fees to the Responsible Steward(s) or Stewardship Organization for the performance of regulatory oversight functions as enumerated in the Ordinance.

K. Promotion, Outreach and Education (Section 11.17.160)

The Responsible Steward(s) or Stewardship Organization shall develop a system of promotion, outreach and public education to be part of their Plan, promoting collection options offered under the Plan, promoting safe storage, discouraging stockpiling, and discouraging disposal in the trash or through a plumbing or septic system.

- ➤ The Responsible Steward(s) or Stewardship Organization will provide materials 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. A 24-hour, toll-free number and website will also be established.
- ➤ The Responsible Steward(s) or Stewardship Organization will conduct a Director approved biennial survey of residents, pharmacists, veterinarians, retailers and health professionals who interact with patients.

L. Compliance with Federal, State and Local Laws (Section 11.17.180)

- The Responsible Steward(s) or Stewardship Organization are required to operate in compliance with all applicable federal, State and local laws and regulations and will ensure that each collector is also in compliance.
- > The Ordinance does not conflict with applicable federal or State laws, rules or regulations.

VIII. TIMELINE AND REPORTING REQUIREMENTS FOR PRODUCT STEWARDSHIP PLAN(S) IMPLEMENTATION

	Steps Required for Implementation of Stewardship Plan(s)	Ordinance Section (if applicable)	Responsible Entity	Reporting Criteria	Estimated Time/Date
1.	Board Letter Introducing the Ordinance		Board of Supervisors		5/3/16
2.	Second Reading of the Ordinance		Board of Supervisors		5/10/16
3.	Ordinance Effective Date		Board of Supervisors		6/10/16
4.	Responsible Steward Notification to the Director of Intent to Operate or Participate in a Stewardship Plan	11.17.030 (C) (1)	Responsible Steward	Within six months of the effective date of Ordinance	12/1/16
5.	Identification to the Director of Point of Contact for the Stewardship Plan	11.17.030 (C)(2)	Responsible Steward	Within six months of the effective date of Ordinance	12/1/16
6.	Notification to all Potential Authorized Collectors, Persons other than Potential Authorized Collectors, such as retail establishments, and all Law Enforcement Agencies	11.17.030 (C)(3)	Responsible Steward	Six months after Ordinance effective date	12/1/16
7.	Submittal of Stewardship Plan to the Director	11.17.100 (A)	Responsible Steward	9 months after the effective date of Ordinance	3/1/17
8.	Review of Stewardship Plan	11.17.100 (C)	Director	90 days after receipt of the Plan	6/1/17

	Steps Required for Implementation of Stewardship Plan(s)	Ordinance Section (if applicable)	Responsible Entity	Reporting Criteria	Estimated Time/Date
9.	Submittal of Revised Stewardship Plan (if rejected by the Director)	11.17.100 (D)	Responsible Steward	60 days after receiving written notice of the rejection	8/1/17
	Approval of the Final Stewardship Plan	11.17.100 (C) (D)	Director	90 day review period for Director of revised Plan(s)	6/1/17; or if revised 11/1/17
11.	Plan Implementation	11.17.030 (C) (5)	Responsible Steward	Within 3 months after the Director's approval of the Stewardship Plan	9/1/17; or if revised 2/1/18
12.	Report to the Board on Status of Stewardship Plans	11.17.130 (C)	Director	Two years from the effective date of the Ordinance; thereafter, on an as-needed basis	6/1/18; thereafter, on an as- needed basis.
13.	Responsible Stewards Reports	11.17.080 (A)	Responsible Steward	Within 6 months after the first 12- month period of Plan operation	3/1/19; or if revised 8/1/19
14.	Biennial Survey: of Residents, Pharmacist, Veterinarians, Retailers, and Health Professionals Who Interact with Patients on the Use of Drugs and Sharps	11.17.160 (A)(5)	Responsible Steward	Within 6 months of the effective date of the Ordinance, then biennially thereafter	12/1/16; (6 months survey); 12/1/18 (biennial survey)
15.	Updated Stewardship Plan Submittal	11.17.030 (C) (6)	Responsible Steward	Every 3 years after the plan commences operation	9/1/20; or if revised 2/1/21

IX. FISCAL IMPACT OF THE ORDINANCE

County Costs: The County's annual costs are shown below, and could potentially be included in the Responsible Steward(s) or Stewardship Organization Plan(s).

a) Home-Generated Sharps Waste Management Program	\$200,000*
b) Safe Drug Drop-Off Program (labor)	34,000
c) Household Hazardous Waste (HHW) Program expenditures	
Collection of drugs	50,000
Collection of sharps	50,000
COUNTY TOTAL EXPENDITURES	\$334,000

^{*} Sheriff's cost for sharps is included in this amount.

Estimated Plan Costs: Below is the estimated annual cost to the Responsible Steward(s) or Stewardship Organization for implementing the Plan. If adopted, the Ordinance will apply to the County's unincorporated communities. Cities for whom the County serves as their Public Health Officer will determine whether or not they want to adopt the Ordinance into their municipal code. The estimate provided would be if all

cities, under the jurisdiction of the Director, adopted the Ordinance and excludes the cities of Pasadena, Long Beach and Vernon.

a) Unincorporated Communities

\$ 3,210,500**

b) County-wide

\$16,033,000**

The estimated annual cost to the Responsible Steward(s) or Stewardship Organizations for DPH's regulatory oversight fees is \$644,000 and is included in the estimate. This estimate is expected to incur small annual increases.

X. MATRIX OF POTENTIAL ROLES AND RESPONSIBILITIES

As noted earlier, Exhibit 11 includes the Matrix of Potential Roles and Responsibilities for the "Responsible Stewards", pharmacies, retailers, hospitals, clinics, long-term care facilities, drug and sharps waste disposal service providers, non-profits, the Sheriff, DPH, DPW, and other County agencies.

XI. FREQUENTLY ASKED QUESTIONS

Exhibit 13 provides "Frequently Asked Questions" prepared by the EPR Working Group to assist stakeholders and the general public in understanding the fundamental concepts of the Ordinance.

^{**}Excludes the current County annual cost of \$334,000.

EXHIBITS TO THE PHARMACEUTICAL DRUGS AND SHARPS TAKE-BACK PROGRAM REPORT

Exhibit 1	-	Motions
Exhibit 2	-	Report on Sharps Waste Collection at County Facilities Board Motion of October 23, 2009, Agenda Item 10 (April 14, 2011)
Exhibit 3 (a)	-	Board Motion of June 2, 2015, Item 78-A - Managing Unused and Expired Medications and Sharps Waste in the County of Los Angeles (July 2, 2015)
Exhibit 3 (b)	-	Board Motion of June 2, 2015, Item 78-A - Managing Unused and Expired Medications and Sharps Waste in the County of Los Angeles (October 1, 2015)
Exhibit 4	-	Cal Recycle - Sharps Collection Locations in Los Angeles County
Exhibit 5(a)	-	County Support:
		Sacramento Update (April 23, 2013) – AB 403 (Stone); SB 727 (Jackson)
		Sacramento Update (March 24, 2014) – SB 1014 (Jackson)
		Sacramento Update (April 27, 2015) – AB 1159 (Gordon)
Exhibit 5(b)	-	Opposition Letters:
		SB1014 (Jackson) Position: Oppose (March 13, 2014)
		AB 403 (Stone): Solid waste: home-generated sharps. Oppose - As amended April 8, 2013, Set For Hearing – April 16, 2013 (April 10, 2013)
		SB 727 (Jackson); Position: Oppose (April 17, 2013)
Exhibit 6	-	Medicines and Sharps Disposal - Consumer Survey
Exhibit 7(a)	-	Pharmaceutical Drugs and Sharps Take-Back Programs in Other Jurisdictions
Exhibit 7(b)	-	Pharmaceutical Take-Back Ordinance Comparison Chart
Exhibit 8	-	EPR Pharmaceuticals and Sharps Technical Advisory Group Roster
Exhibit 9	-	Los Angeles County EPR Pharmaceuticals and Sharps Ordinance Objective, Program Goals, and TAG Purpose
Exhibit 10	-	List of Support and Opposition to the County's Draft Pharmaceutical Drugs and Sharps Ordinance (March 8, 2016)
Exhibit 11	-	Key Elements of Existing Producer Responsibility (EPR) Pharmaceutical Take-Back Ordinances in California, Outline of Proposed LA County EPR Pharmaceutical Take-Back Ordinance; Matrix of Potential Roles and Responsibilities; and Pharmaceutical Take-Back Brochure
Exhibit 12	-	Federal and State Regulatory/Recommendation Comparison Chart

EXHIBIT 1

AGN.	NO
------	----

MOTION BY SUPERVISOR YVONNE B. BURKE

NOVEMBER 5, 2008

Local governments throughout California are working hard to meet environmental mandates to reduce landfill disposal of solid waste, prevent hazardous wastes from being improperly disposed, and keep our rivers, streams and waterways free of trash. These unfunded mandates come at a time local governments are struggling with significant budgetary constraints.

At the same time, the manufacturers of products currently have no financial incentive or legal requirement to take responsibility for the impacts their products have on public health and the environment after consumption. Although many manufacturers have voluntarily taken additional responsibility for their products, for example by reducing packaging or increasing recycled content in their products, most have not been able to do the same due to the need for investment and/or the risk of being less competitive as a result.

The concept of Product Stewardship, also referred to as Extended Producer Responsibility (EPR), seeks to create shared responsibility mechanisms for manufacturers to mitigate or even eliminate the negative impacts of their products at the end of life. These mechanisms include legal requirements to phase out toxic materials or to take back products at the end of life, or financial incentives to redesign

M-O-R-E

	MOTI	<u>ON</u>
MOLINA		
YAROSLAVSKY		
KNABE		
ANTONOVICH		
BURKE		

MOTION BY SUPERVISOR YVONNE B. BURKE NOVEMBER 5, 2008 PAGE 2

products or reduce excess packaging, among other approaches. By leveling the playing field, and adapting mechanisms specific to each product. EPR allows the marketplace to develop the most cost effective methods for reducing impacts of that particular product. The County's legislative policies include support for EPR as an effective method of reducing the burden on local governments while meeting environmental mandates.

The California Product Stewardship Council is a nonprofit organization formed by local governments to advance the implementation of EPR policies in California, and has invited local governments and other interested stakeholders in California to join. The County's participation in the California Product Stewardship Council will ensure the County's support for EPR policies will be coordinated with local governments throughout the State, and that efforts to enact EPR policies will be more effective.

I, THEREFORE MOVE THAT THE BOARD OF SUPERVISORS:

1. Adopt the enclosed Resolution supporting Extended Producer Responsibility.

S./mbe/tran/chuck/motions/2008/LAC Support for Product Stewardship 110508

RESOLUTION OF THE BOARD OF SUPERVISORS OF THE COUNTY OF LOS ANGELES

SUPPORTING EXTENDED PRODUCER RESPONSIBILITY

WHEREAS, residents and businesses Countywide generate approximately 24 million tons of waste materials and products on an annual basis; and

WHEREAS, State law (AB 939, 1989 statutes) requires each jurisdiction in Los Angeles County to divert fifty percent of all waste generated from disposal, and to ensure the proper management of all waste materials whether they are diverted or disposed; and

WHEREAS, in February 2006, California expanded the list of products that are deemed hazardous and therefore banned from landfill disposal, including household batteries, fluorescent bulbs and tubes, thermostats and other items that contain mercury, as well as electronic devices such as computers, video cassette recorders, microwave ovens, cellular phones, cordless phones, printers, and radios; and

WHEREAS, due to the significant environmental and human health impacts associated with their improper management, the list of products determined to be hazardous and therefore banned from landfills is expected to grow, as demonstrated by the ban of treated wood in January 2007 and medical syringes in September 2008; and

WHEREAS, state policies currently make local governments responsible for achieving waste diversion goals, implementing programs to comply with product disposal bans, and addressing a host of products that have a disproportionate impact on the environment and quality of life of our residents, creating significant unfunded mandates; and

WHEREAS, Los Angeles County alone spends nearly \$10 million each year implementing the Countywide Household Hazardous and Electronic Waste Management Program to provide one avenue for residents to properly manage products and materials that are banned from landfill disposal; and

WHEREAS, Extended Producer Responsibility (EPR) is a policy approach in which manufacturers assume a shared responsibility for management of their products, including redesigning products to be more durable, easier to repair and recycle, and less toxic; and

WHEREAS, the County of Los Angeles has pursued and supported legislation and other statewide efforts to implement EPR policies, and has consistently supported the advancement of sustainability via policies such as the Energy and Environmental Policy adopted by the Board in 2007; and,

WHEREAS, the California Product Stewardship Council is a nonprofit organization of local governments and interested stakeholders working together to advance EPR policies in California, including legislation to establish a framework for prioritizing the most disproportionately challenging products and implementing the most effective EPR mechanisms to address those products; and

NOW, THEREFORE, BE IT RESOLVED THAT THE Board of Supervisors of the County of Los Angeles reaffirms its commitment to promoting EPR policies and directs our Sacramento legislative advocates to actively pursue legislation and Statewide policies that shift end-of-life management costs from local government to the manufacturers and incentivize the redesign of products to reduce their health and environmental impacts; and

BE IT FURTHER RESOLVED, that the Directors of Public Works and Internal Services or their designees are authorized and encouraged to jointly participate as a member of the California Product Stewardship Council; and

BE IT FURTHER RESOLVED, that the Energy and Environmental Policy Team is directed to evaluate and develop recommendations for producer responsibility policies that County departments can implement, such as leasing products rather than purchasing them, requiring producers to offer less toxic alternatives and to take responsibility for collecting and recycling their products at the end of their useful life.



SACHI A. HAMAI, Executive Officer-Clerk of the Board of Supervisors of the County of Los Angeles

By: State a Homes

APPROVED AS TO FORM: RAYMOND G. FORTNER, JR. COUNTY COUNSEL

Principal Deputy County Counsel



MINUTES OF THE BOARD OF SUPERVISORS COUNTY OF LOS ANGELES, STATE OF CALIFORNIA

Sachi A. Hamai, Executive Officer-Clerk of the Board of Supervisors 383 Kenneth Hahn Hall of Administration Los Angeles, California 90012

At its meeting held Wednesday, November 5, 2008, the Board took the following action:

The following statement was entered into the record for Supervisor Burke:

"Local governments throughout California are working hard to meet environmental mandates to reduce landfill disposal of solid waste, prevent hazardous wastes from being improperly disposed, and keep our rivers, streams and waterways free of trash. These unfunded mandates come at a time local governments are struggling with significant budgetary constraints.

"At the same time, the manufacturers of products currently have no financial incentive or legal requirement to take responsibility for the impacts their products have on public health and the environment after consumption. Although many manufacturers have voluntarily taken additional responsibility for their products, for example by reducing packaging or increasing recycled content in their products, most have not been able to do the same due to the need for investment and/or the risk of being less competitive as a result.

"The concept of Product Stewardship, also referred to as Extended Producer Responsibility (EPR), seeks to create shared responsibility mechanisms for manufacturers to mitigate or even eliminate the negative impacts of their products at the end of life. These mechanisms include legal requirements to phase out toxic materials or to take back products at the end of life, or financial incentives to redesign products or reduce excess packaging, among other approaches. By leveling the playing field, and adapting mechanisms specific to each product, EPR allows the marketplace to develop the most cost effective methods for reducing impacts of that particular product. The County's legislative policies include support for EPR as an effective method of reducing the burden on local governments while meeting environmental mandates.

(Continued on Page 2)

5 (Continued)

"The California Product Stewardship Council is a nonprofit organization formed by local governments to advance the implementation of EPR policies in California, and has invited local governments and other interested stakeholders in California to join. The County's participation in the California Product Stewardship Council will ensure the County's support for EPR policies will be coordinated with local governments throughout the State, and that efforts to enact EPR policies will be more effective."

Arnold Sachs addressed the Board.

After discussion, at the suggestion of Supervisor Burke, and on motion of Supervisor Molina, seconded by Supervisor Knabe, unanimously carried (Supervisor Yaroslavsky being absent), the Board took the following actions:

- Adopted the attached resolution supporting Extended Producer Responsibility;
- Directed the County's Legislative Advocates in Sacramento to actively
 pursue legislation and Statewide policies that shift end-of-life
 management product costs from local government to the manufacturers
 and incentivize the redesign of products that have impacts on public
 health and the environment;
- 3. Authorized the Acting Director of Public Works and the Director of Internal Services to jointly participate as a member of the California Product Stewardship Council; and
- 4. Directed the Energy and Environmental Policy Team to evaluate and develop recommendations for producer responsibility policies that County Departments can implement, such as leasing products rather than purchasing them, requiring producers to offer less toxic alternatives, and to take responsibility for collecting and recycling their products at the end of their useful life.

07110508_5

Attachment

Copies distributed:
Each Supervisor
Chief Executive Officer
County Counsel
Acting Director of Public Works
Director of Internal Services

RESOLUTION OF THE BOARD OF SUPERVISORS OF THE COUNTY OF LOS ANGELES

SUPPORTING EXTENDED PRODUCER RESPONSIBILITY

WHEREAS, residents and businesses Countywide generate approximately 24 million tons of waste materials and products on an annual basis; and

WHEREAS, State law (AB 939, 1989 statutes) requires each jurisdiction in Los Angeles County to divert fifty percent of all waste generated from disposal, and to ensure the proper management of all waste materials whether they are diverted or disposed; and

WHEREAS, in February 2006, California expanded the list-of products that are deemed hazardous and therefore banned from landfill disposal, including household batteries, fluorescent bulbs and tubes, thermostats and other items that contain mercury, as well as electronic devices such as computers, video cassette recorders, microwave ovens, cellular phones, cordiess phones, printers, and radios; and

WHEREAS, due to the significant environmental and human health impacts associated with their improper management, the list of products determined to be hazardous and therefore banned from landfills is expected to grow, as demonstrated by the ban of treated wood in January 2007 and medical syringes in September 2008; and

WHEREAS, state policies currently make local governments responsible for achieving waste diversion goals, implementing programs to comply with product disposal bans, and addressing a host of products that have a disproportionate impact on the environment and quality of life of our residents, creating significant unfunded mandates; and

WHEREAS, Los Angeles County alone spends nearly \$10 million each year implementing the Countywide Household Hazardous and Electronic Waste Management Program to provide one avenue for residents to properly manage products and materials that are banned from landfill disposal; and

WHEREAS, Extended Producer Responsibility (EPR) is a policy approach in which manufacturers assume a shared responsibility for management of their products, including redesigning products to be more durable, easier to repair and recycle, and less toxic; and

WHEREAS, the County of Los Angeles has pursued and supported legislation and other statewide efforts to implement EPR policies, and has consistently supported the advancement of sustainability via policies such as the Energy and Environmental Policy adopted by the Board in 2007; and,

WHEREAS, the California Product Stewardship Council is a nonprofit organization of local governments and interested stakeholders working together to advance EPR policies in California, including legislation to establish a framework for prioritizing the most disproportionately challenging products and implementing the most effective EPR mechanisms to address those products; and

NOW, THEREFORE, BE IT RESOLVED THAT THE Board of Supervisors of the County of Los Angeles reaffirms its commitment to promoting EPR policies and directs our Sacramento legislative advocates to actively pursue legislation and Statewide policies that shift end-of-life management costs from local government to the manufacturers and incentivize the redesign of products to reduce their health and environmental impacts; and

BE IT FURTHER RESOLVED, that the Directors of Public Works and Internal Services or their designees are authorized and encouraged to jointly participate as a member of the California Product Stewardship Council; and

BE IT FURTHER RESOLVED, that the Energy and Environmental Policy Team is directed to evaluate and develop recommendations for producer responsibility policies that County departments can implement, such as leasing products rather than purchasing them, requiring producers to offer less toxic alternatives and to take responsibility for collecting and recycling their products at the end of their useful life.

The forgoing resolution was on the ______ day of Notember 2008, adopted by the Board of Supervisors of the County of Los Angeles and ex-officio the governing body of all other special assessment and taxing districts, agencies and authorities for which said Board so acts.



SACHI A. HAMAI, Executive Officer-Clerk of the Board of Supervisors of the County of Los Angeles

By: Sai a Home Deputy

APPROVED AS TO FORM: RAYMOND G. FORTNER, JR. COUNTY COUNSEL

Principal Deputy County Counsel

3. Recommendation as submitted by Supervisor Molina: Extend the \$25,000 reward offered for any information leading to the arrest and/or conviction of the person or persons responsible for the heinous murder of 71-year-old Luis Sandoval, who was shot while riding his bike near the intersection of Olympic Blvd. and Hicks Ave. on Sunday, February 25, 2007 at approximately 5:00 a.m. (08-1857)

On motion of Supervisor Molina, Seconded by Supervisor Knabe, this item was approved.

Ayes: 3 - Supervisor Knabe, Supervisor Molina and Supervisor Burke

Absent: 2 - Supervisor Yaroslavsky and Supervisor Antonovich

4. Recommendation as submitted by Supervisor Burke: Reappoint Supervisor Don Knabe as the County's member to the Board of Directors of the California State Association of Counties and Supervisor Gloria Molina as the alternate member for 2009. (08-3145)

Attachments: See Final Action

On motion of Supervisor Burke, seconded by Supervisor Molina, this item was approved.

Ayes: 3 - Supervisor Knabe, Supervisor Molina and Supervisor Burke

Absent: 2 - Supervisor Yaroslavsky and Supervisor Antonovich

Extended Producer Responsibility and directing the County's Legislative Advocates in Sacramento to actively pursue legislation and Statewide policies that shift end-of-life management product costs from local government to the manufacturers and incentivize the redesign of products that have impacts on public health and the environment; authorize the Acting Director of Public Works and the Director of Internal Services to jointly participate as a member of the California Product Stewardship Council; and direct the Energy and Environmental Policy Team to evaluate and develop recommendations for producer responsibility policies that County departments can implement, such as leasing products rather than purchasing them, requiring producers to offer less toxic alternatives, and to take responsibility for collecting and recycling their products at the end of their useful life. (08-3168)

<u>Attachments:</u> See Supporting Document

See Final Action

Video Audio

On motion of Supervisor Molina, seconded by Supervisor Knabe, this item was approved.

Ayes:

4 - Supervisor Molina, Supervisor Antonovich, Supervisor

Burke and Supervisor Knabe

Abstentions:

Supervisor Yaroslavsky

_			
1 2	っへし	losure	- 3
F-1	11.	BSUIE	. 1

MOTION BY SUPERVISOR DON KNABE

October 13, 2009

Everyday in the County of Los Angeles millions of home-generated sharps waste such as medical needles, lancets, and syringes are produced by individuals who self administer medications at home. If disposed of improperly, sharps waste poses a significant health risk to everyone, especially sanitation and landfill workers. In addition, surface waters, groundwater, and the ocean may be polluted as a result of leakage from leftover liquid in sharps devices.

Since last September, State law (SB 1305) prohibits the placement of home-generated sharps waste in trash and recycling containers, and requires the use of State-approved containers for the collection and transportation of sharps waste. State law also encourages local governments to implement and promote sharps collection programs to provide convenient and safe means for residents to dispose of their sharps waste.

To assist residents in complying with this new State law, in June 2008 Public Works in concert with Public Health and participating cities launched a new Sharps (MORE)

	MOTION
MOLINA	
RIDLEY-THOMAS	
YAROSLAVSKY	
ANTONOVICH	
KNABE	

Waste Management Program The aim of the Program is to make it as convenient as possible for residents to properly dispose of their sharps waste. Through this Program, Public Works provides State-approved, puncture-proof containers for residents to safely collect their sharps waste. These containers can be obtained free of charge at over 100 distribution sites.

Once filled, the sharps containers can be taken to designated collection sites for safe disposal. Designated collection sites currently include 8 permanent household hazardous waste collection centers and the County's weekly household hazardous waste collection events. In addition, the Department of Public Health took a proactive approach in joining Public Work's efforts to make available 14 public health clinics as collection sites for County residents to dispose of sharps waste. The disposal cost for the sharps waste is incurred by Public Health as part of their existing internal sharps waste program. In collaboration, Public Works assists with providing sharps containers for distribution, as well as outreach materials for public education. This collaborative partnership is a great example of departments working together to provide beneficial public service to the communities. Considering the size and population of Los Angeles. County however, there is a need to expand the number of sites where residents can take their filled sharps containers. To the extent feasible, we should utilize County facilities for this purpose.

Certain County departments, such as the Fire Department, also have a need for proper disposal outlets for the sharps waste they collect when they treat patients through their emergency services. Thus, opportunities exist for additional collaborative (M O R E)

partnerships between Public Works and other County departments for properly managing sharps waste and increasing public awareness.

- I, THEREFORE, MOVE that the Board of Supervisors instruct the Director of Public Works, working in collaboration with the Directors of Health Services, Community and Senior Services, Public Health and the Fire Chief of the Fire Department to pursue the following actions
 - 1 Identify and evaluate the potential for utilizing additional County facilities, such as fire stations, pharmacies, hospitals, and other locations, as sharps collection sites.
 - Implement collection sites at the most feasible locations on a 12-month trial basis, based on the Public Health model highlighted above. Costs should be equitably shared amongst participating departments.
 - 3 Assess the feasibility of providing approved mail-back containers to assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites.
 - 4 Submit a report to the Board within 18 months summarizing the results of this effort. The report should include but not be limited to the following
 - a. Success of the trial collection sites in enhancing the Program
 - b Barriers/challenges faced
 - c Public outreach and education implemented
 - d Cost analysis
 - e Recommendations on making collection sites permanent, further expanding collection and other adjustments to the Program.

DS azr

AGN.	NO	

MOTION BY MAYOR MICHAEL D. ANTONOVICH

JUNE 2, 2015

Managing unused/expired medications is a growing concern facing the County of Los Angeles. According to the National Community Pharmacists Association, an estimated 200 million pounds of unused or expired prescription drugs are stored in American medicine cabinets. They often end up in the wrong hands where inappropriate use can lead to addiction, abuse, serious injury, and even death. According to a report released by the Department of Public Health, in 2013 there were more than 500 deaths, 3,000 hospitalizations and 5,000 emergency visits associated with prescription and over the counter drug overdose in Los Angeles County.

New studies are also demonstrating that pharmaceuticals have an impact on our environment. The World Health Organization recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources and some drinking-waters." Municipal wastewater treatment plants are not designed to remove the complex compounds in drugs that end up in the sewer system.

Pharmaceuticals delivered via needles pose an additional set of concerns, posing a risk to health professionals as well as public and private employees in law enforcement and waste management that interact with disposed needles and related sharps waste.

These are serious problems impacting the well-being of our communities. In response, the Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely, and anonymously, drop off their expired medications and sharps. The County's Household Hazardous Waste program, managed by Public Works, also collects non-controlled pharmaceuticals and sharps from residents. Unfortunately, the volume of pharmaceuticals is too great for local programs such as this to fully address the problem. We need to do more to increase public awareness of the potential impacts of improper storage and disposal of unused medication and to make it safe and convenient for residents to dispose of unused/expired medications and increase participation.

-MORE-

	MOTION
SOLIS	
RIDLEY-THOMAS	
KUEHL	
KNABE	
ANTONOVICH	

I, THEREFORE, MOVE that the Board of Supervisors:

Direct the Director of Public Works, in coordination with the Chief Executive Office; County Counsel; the Sheriff's Department; the Departments of Health Services, Internal Services, Mental Health and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an Ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa Clara:
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs; and
- 6. Report back within 4 months with findings and recommendations.

#

MDA:evo pharmaceuticalsdisposal060215



STATEMENT OF PROCEEDINGS FOR THE REGULAR MEETING OF THE BOARD OF SUPERVISORS OF THE COUNTY OF LOS ANGELES HELD IN ROOM 381B OF THE KENNETH HAHN HALL OF ADMINISTRATION 500 WEST TEMPLE STREET, LOS ANGELES, CALIFORNIA 90012

Tuesday, August 11, 2015

9:30 AM

Present:

Supervisor Solis, Supervisor Ridley-Thomas, Supervisor Kuehl,

Supervisor Knabe and Supervisor Antonovich

Video Link for the Entire Meeting (03-1075)

Attachments:

Video Transcript

Invocation led by Supervisor Mark Ridley-Thomas, 2nd Supervisorial District, County of Los Angeles.

Pledge of Allegiance led by Peter Roman, Veteran Service Officer II, Department of Military and Veteran's Affairs (4).

I. PRESENTATIONS/SET MATTERS

Presentation of plaque to the Honorable Marin Dimitrov, commemorating his departure from the post of Consul General of Bulgaria in Los Angeles, as arranged by the Mayor.

Presentation of scroll to Philip Browning, Director of the Department of Children and Family Services, for being the recipient of the Chauncey Alexander Lifetime Achievement Award, as arranged by Supervisors Knabe and Kuehl.

Presentation of scroll to Dr. Marvin Southard and the Los Angeles County Department of Mental Health, in recognition of being selected as the 2015 winner of The National Association of Counties Achievement award for their program titled Veterans and Loved Ones Recovery (VALOR), as arranged by Supervisor Knabe.

Presentation of scroll to the Los Angeles County Department of Children and Family Services, in recognition of "Adopt a Child with Medical Needs Month," as arranged by Supervisor Antonovich.

- 4. Recommendation as submitted by Supervisors Antonovich and Solis: Direct the Interim Chief Executive Officer, in collaboration with the County's Sustainability Council and the Pharmaceutical Working Group, to: (Continued from the meeting of 7-28-15)
 - Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
 - Initiate stakeholder engagement with the pharmaceutical industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste and generate awareness about the collection program that will be created; and
 - 3. Return to the Board within six months with the recommended ordinance for consideration. (15-3552)

Dr. Genevieve Clavreul, Heidi Sanborn, Kreigh Hampel, Carlos Gutierrez, Brandon Stephenson, Scott Shepard, Hal Dash and Sharon Green addressed the Board.

Supervisor Knabe made a friendly amendment to Supervisors Antonovich and Solis' joint motion to ensure that the stakeholder process occurs before the ordinance is drafted.

On motion of Supervisor Antonovich, seconded by Supervisor Solis, this item was approved as amended and duly carried by the following vote:

Ayes: 4 - Supervisor Solis, Supervisor Kuehl, Supervisor

Knabe and Supervisor Antonovich

Abstentions: 1 - Supervisor Ridley-Thomas

Attachments: Motion by Supervisors Antonovich and Solis

Motion by Supervisor Knabe

<u>Video</u> Audio

	AGN NO.		
JULY	28.	2015	

MOTION BY MAYOR MICHAEL D. ANTONOVICH AND SUPERVISOR HILDA SOLIS

On June 2, 2015, the Board of Supervisors directed the Director of Public Works, in coordination with a Working Group that included the Chief Executive Office; County Counsel; the Sheriff's Department; the Departments of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to investigate the feasibility of adopting an ordinance similar to the pharmaceutical takeback ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara as well as utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs, and to report back in 30 days with recommendations.

Public Works, in collaboration with the Working Group, developed and submitted its report, entitled *Managing Unused and Expired Medications and Sharps Waste in The County of Los Angeles*, to the Board on July 2, 2015. The Working Group found that adopting a similar ordinance is feasible for the County and recommended that the Board adopt a pharmaceutical and sharps waste extended producer responsibility ordinance in which pharmaceutical manufacturers and producers would develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served. The report did not recommend utilizing the County's purchasing power to negotiate take-back programs as this would not be as effective.

The Working Group also recommended drafting the ordinance to allow incorporated Cities within the County to adopt the ordinance by reference, in order to establish a Countywide collection system.

-MORE-

	MOTION	
SOLIS		
RIDLEY-THOMAS	NAME AND ADDRESS OF THE PARTY O	
KUEHL		
KNABE		
ANTONOVICH		

WE, THEREFORE, MOVE THAT THE BOARD OF SUPERVISORS direct the Interim Chief Executive Officer, in collaboration with the County's Sustainability Council and the Pharmaceutical Working Group, to:

- Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the pharmaceutical industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within six months with the recommended Ordinance for consideration.

#

MDA:evo pharmaceuticaltakebackprogram072815

Amendment by Supervisors Knabe

Item 4

I would like to make a friendly amendment.

The ordinance needs to be based on best practices that include full stakeholder engagement and expertise. The stakeholder process carries a great deal of value that is why it should be conducted first.

Therefore, we move that the Board approve the motion but have the stakeholder process occur first before the ordinance is drafted.

M	\cap	T	A.	F

SOLIS	
RIDLEY-THOMAS	
KUEHL	
KNABE	
ANTONOVICH	

EXHIBIT 2



GAIL FARBER, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

"To Enrich Lives Through Effective and Caring Service"

900 SOUTH FREMONT AVENUE ALHAMBRA, CALIFORNIA 91803-1331 Telephone (626) 458-5100 http://dpw.lacounty.gov

ADDRESS ALL CORRESPONDENCE TO: P.O. BOX 1460 ALHAMBRA, CALIFORNIA 91802-1460

IN REPLY PLEASE

REFER TO FILE:

EP-3 A3191

April 14, 2011

TO.

Each Supervisor

FROM:

Director of Public Works

REPORT ON SHARPS WASTE COLLECTION AT COUNTY FACILITIES BOARD MOTION OF OCTOBER 13, 2009, AGENDA ITEM 10

On October 13, 2009, your Board directed the Department of Public Works to work in collaboration with the Directors of Health Services, Community and Senior Services, Public Health, and the Fire Chief of the Fire Department to pursue the following actions.

- Identify and evaluate the potential for utilizing additional County facilities, such as fire stations, pharmacies, hospitals, and other locations, at sharps collection sites;
- 2 Implement collection sites at the most feasible locations on a 12-month trial basis with costs equitably shared amongst participating departments,
- Assess the feasibility of providing approved mail-back containers to assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites, and
- 4 Submit a report to the Board within 18 months summarizing the results of this effort.

This memorandum provides a summary of the actions taken by Public Works in collaboration with Health Services, Public Health, Community and Senior Services, Sheriff, and Fire Departments (Working Group), in response to the Board's direction. This includes the evaluation and identification of potential locations for sharps collection sites, preliminary results, and recommendations. A more detailed discussion is provided in the attached Report.

Evaluation, Identification, and Siting of Sharps Collection Centers

Public Works, in conjunction with the Working Group, identified and evaluated potential locations for suitability as sharps collection sites. The Working Group concluded that designated Public Health clinics, Health Services' health centers, and Sheriff's stations are most suitable for the establishment of sharps collection sites. Community and

Each Supervisor April 14, 2011 Page 2

Senior Services' facilities as well as Fire Stations were deemed to be less suitable due primarily to safety and traffic concerns.

Pilot Sharps Collection Locations and Preliminary Results

Pursuant to the Board's direction, Health Services identified and implemented a pilot sharps collection site at its Wilmington Health Center Concurrently, the Sheriff's Department launched the Safe Drug Drop-off Program, which included a sharps collection component. This was done initially at the Lomita Sheriff's station and was subsequently expanded to include a total of 20 Sheriff stations.

These additions doubled the number of sharps collection sites available to residents Countywide to a total of 42 sites. These sites, in addition to the weekly household hazardous waste collection events conducted by Public Works, in concert with the County Sanitation Districts, provide significantly enhanced convenience for residents to properly manage their home-generated sharps waste

These expansion efforts have been very successful In 2010, approximately 30,000 pounds of home-generated sharps waste were collected through Public Works' collection events and the Sheriff's drop-off sites (a 50 percent increase over 2009).

Mail-Back Containers

Due to the high cost of mail-back containers, limited funding, and legal limitations on the screening of participants for eligibility (pursuant to the Americans with Disabilities Act), the Working Group concluded that a permanent, Countywide mail-back program is not feasible at this time. However, as discussed in the Report, the mail-back programs for elderly and disabled residents in the unincorporated areas are gradually being provided through residential solid waste collection franchise agreements.

Recommendations

The following actions are recommended by the Working Group in light of the findings and initial results of the efforts undertaken pursuant to the Board's direction:

- Continue to operate sharps collection sites at the designated Sheriff's stations and County health clinics. As discussed in the Report, funding would continue to be provided by the individual departments for the programs and/or contracts that they currently administer. Public Works would continue to administer and fund the contract for collection and disposal of sharps waste at the Sheriff stations.
- Public Works to continue to incorporate sharps collection programs, including a mail-back component into residential solid waste collection franchise agreements as franchises in the unincorporated County areas are established or renewed

- Public Works, in concert with Public Health, Health Services, and other
 partners, to continue to conduct and enhance educational efforts to inform
 County residents about the proper management of sharps waste and the
 resources available to assist them in this effort.
- Continue to support and promote legislation that would encourage manufacturers to take more responsibility for the end-use management of sharps they produce.
- Public Works to continue to look for innovative partnerships and grant opportunities to further enhance home-generated sharps waste management programs.

These collective actions will significantly assist in protecting public health and the environment, thereby, improving the quality of life of County residents.

Finally, it is our pleasure to inform you that CalRecyle recently honored Los Angeles County's Home-Generated Sharps Waste Management Program with the Best New Program Award at its 2011 Used Oil/HHW Training and Conference. We are encouraged by this recognition and are committed to continued enhancement of the Program for the benefit of our communities.

If you have any questions, please contact me or your staff may call Pat Proano, Assistant Deputy Director, at (626) 458-3500

CM:AK:td/my P:\sec\A3191

Attach

cc: Chief Executive Office (Rita Robinson)
Community and Senior Services (Geraldo Rodriguez)
Department of Health Services (Elizabeth Agusta, Phillip Moore)
Department of Public Health (David Caley)
Fire Department (Terry Millsaps)
Sheriff Department (Alissa Dedmon)

On October 13, 2009, the County of Los Angeles Board of Supervisors directed the Department of Public Works to work in collaboration with the Directors of Health Services, Community and Senior Services, Public Health, and the Fire Chief of the Fire Department to pursue the following actions.

- 1 Identify and evaluate the potential for utilizing additional County facilities, such as fire stations, pharmacies, hospitals, and other locations, at sharps collection sites;
- 2 Implement collection sites at the most feasible locations on a 12-month trial basis with costs equitably shared amongst participating departments,
- 3. Assess the feasibility of providing approved mail-back containers to assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites; and
- 4 Submit a report to the Board within 18 months summarizing the results of this effort. The report should include, but not be limited to, the following
 - a. Success of the trial collection sites in enhancing the Program
 - b. Barriers/challenges faced
 - c. Public Outreach and education implemented
 - d. Cost analysis
 - e Recommendations on making collection sites permanent, further expanding collection and other adjustments to the program.

This report discusses the actions taken by Public Works, in collaboration with Health Services, Public Health, Community and Senior Services, Sheriff, and Fire Departments (Working Group), in response to the Board's direction. This includes the evaluation and identification of potential locations for sharps collection sites, preliminary results, and recommendations.

BACKGROUND

Effective September 2008, State law (Senate Bill 1305) made it illegal to place home-generated sharps waste in the trash or recycling bin. The law also requires that sharps waste be transported in State-approved sharps containers. The enactment of this law created a pressing need to provide convenient outlets for residents to properly manage their sharps waste. Home-generated sharps waste includes hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household.

In an effort to assist residents to comply with the law, in July 2008, Public Works launched the Home-Generated Sharps Waste Management Program (Sharps Program) utilizing State grant funds supplemented with landfill tipping fee revenues. Through the Sharps Program, Public Works in collaboration with the City of West Covina, established several locations throughout the County for residents to obtain free sharps containers (distribution sites), as well as locations for residents to properly drop off their filled sharps containers (collection sites) free of charge.

Prior to the Board's October 13, 2009, motion, Public Works had started working with several partners, such as the County Department of Public Health and some cities, to establish convenient sites for the collection of home-generated sharps waste at their facilities and distribution of sharps containers. Public Health assisted Public Works in this effort by designating 14 of its public health clinics to serve as distribution sites to provide free sharps containers to residents, as well as collection sites for the filled sharps containers. Costs associated with the Program were integrated into Public Health's existing disposal system used for the internally generated infectious waste at their health clinics. Public Health reaches over 250,000 individual patients each year through its health clinics.

Other collection sites established prior to the motion included six permanent Household Hazardous Waste (HHW) collection centers operated by the City of Los Angeles and available to residents Countywide through an agreement with the County, a permanent HHW collection center operated by the City of Santa Monica, the County's permanent HHW collection center in the Antelope Valley, and the County's numerous mobile collection events held throughout the County

Due to the large size of the County, and to fill in service gaps that create further convenience to residents, Public Works continued looking for new partnership opportunities for safe and convenient collection of home-generated sharps waste. Recognizing the need for further expansion of this service, the Board adopted the October 13, 2009, motion (See Enclosure I)

WORKING GROUP ACTIVITIES

Evaluation, Identification, and Challenges in Siting of Sharps Collection Centers at County Facilities

Public Works convened the Working Group (see Enclosure II) for the participating departments to meet regularly and discuss the goals and objectives outlined in the motion.

The Working Group assessed potential locations at the departments' facilities to determine their feasibility for use as collection sites.

- Public Works did not have any new sites to consider but continued to offer its
 weekly mobile collection events (over 60 annually) and the Antelope Valley
 Environmental Collection Center as sharps container distribution as well as
 collection sites. Public Works also partnered up with the Sheriff's Department to
 administer and fund the disposal of home-generated sharps waste at 20 Sheriff
 Stations throughout the County
- On a paralell track, in September 2009, the Sheriff's Department (Sheriff's) launched the Safe Drug Drop-Off Program providing designated Sheriff's stations

with self-serve drop boxes for the collection of home-generated sharps waste and home-generated pharmacuetical waste. The Sheriff's Program was established to provide an opportunity for residents to safely and anonymously drop-off expired or unused drugs, sharps waste, and other controlled substances. This program was initially established at the Sheriff's Lomita Station and was subsequently expanded to include a total of 20 locations

Recognizing the significant contribution of the Sheriff's Program to achieving the objective of the Motion, Public Works and the Sheriff's teamed up in an effort to integrate the Sheriff's sharps program into Public Works' Countywide Home-Generated Sharps Waste Management Program. As a result, Public Works assumed administration of the contract to manage the home-generated sharps waste collected at the designated Sheriff's stations. The annual cost of this contract is approximately \$40,000. The Sheriff's will continue offering the designated Sheriff's stations as sharps waste collection sites and assisting with public outreach and education efforts.

• The Department of Health Services (Health Services) identified and implemented a pilot collection location at the Wilmington Health Center starting April 2010. The center was feasible for a pilot program because of its small size which allowed for a controlled service area. The center was set up to offer residents a convenient outlet to properly dispose of their sharps waste, as well as the opportunity to conveniently receive a free sharps container. Health Services was able to easily integrate costs associated with sharps colletion under this program into their existing disposal system used for internally-generated infectious waste at its health clinics.

Furthermore, Health Services did not find its pharmacies feasible as sharps collection sites, due to safety and liability concerns, and the need to maintain a clean pharmacy environment. Health Services was equally concerned with experiencing an increased numbers of visitors at their hospitals, pharmacies, and high traffic clinics. Health Services estimates that 700,000 patients are seen annually at their facilities and with shortage of staff, and parking space, Health Services did not find it feasible to have a pilot sharps collection site at these high-traffic service areas.

- The Department of Public Health did not have additional clinics to offer but further committed to being a permanent partner through the already established 14 clinics as distribution and collection sites
- The Department of Community and Senior Services (CSS) was unable to identify
 a facility as a potential pilot location. Due to the usage demographics of the
 centers, CSS felt that the collection of sharps waste at their facilities would pose
 a safety hazard to the participants. Community and Senior Services expressed
 concerns about potential liability issues directly related to the health and safety of
 participants coming within a close proximity of sharps waste collected at their

centers. Community and Senior Services reported that patrons are mainly children and elderly residents and felt that community and senior centers were not conducive for the collection of sharps waste.

• The Fire Department initially identified five of their stations as potential collection sites. However, upon further study and due to funding limitations as well as safety concerns, a pilot location was not established to serve the purposes of the motion. However, for their own internal needs, the Fire Department was able to secure a contract to utilize 22 of their Battalion Headquarters sites as sharps waste disposal sites for their Paramedic Squads only These locations are not available for public use.

PILOT SHARPS COLLECTION LOCATIONS AND PRELIMINARY RESULTS

The implementation of the Sharps Board Motion has been highly successful and well received by the residents of the County Together with Health Services and the Sheriff's, a total of 21 new sharps waste collection sites at County facilities were added to the Sharps Program.

Wilmington Health Center

The new location at the Wilmington Health Center in Wilmington, California offered by the Health Department has proved to be feasible as a collection site for the home-generated sharps waste. The Program was easily integrated into the Department's existing disposal system already in place for the internally generated infectious waste at the health center. Due to shortage of staff, the Department has not been able to properly track usage of this service by the public. However, Health Services has not reported any issues associated with this service at the center

Sheriff Stations

The 20 Sheriff Stations throughout the County have proved to be extremely advantageous to the public. The centers are located widespread throughout the County in the following cities and communities:

Sheriff's Site/City Name	Supervisorial District
East Los Angeles Station, Los Angeles	1
Industry Station, Industry	1
Pico Rivera Station, Pico Rivera	1
Walnut Station, Walnut	1
Carson Station, Carson	2
Century Station, Lynwood	2
Compton Station, Compton	2
South Los Angeles Station, Los Angeles	2
Malibu/Lost Hills Station, Calabasas	3

West Hollywood Station, West Hollywood	3
Lakewood Station, Lakewood	4
Lomita Station, Lomita	4
Marina Del Rey Station, Marina Del Rey	4
Norwalk Station, Norwalk	4
Palmdale Station, Palmdale	5
San Dimas Station, San Dimas	5
Santa Clarita Station, Valencia	5
Lancaster Station, Lancaster	5
Temple Station, Temple City	5
Crescenta Valley Station, La Crescenta	5

On average, 850 pounds of sharps waste are collected from these stations each month. The self-serve drop boxes at these stations have proved to be feasible and convenient.

These locations were established for the purposes of home-generated sharps waste disposal and to be used by residents only. A challenge the Sheriff's Department encountered is the apparent use by some private clinics of these boxes as a means of disposing of their sharps waste. Public Works and the Sheriff's Departments will continue to work together to educate the public on this matter, to deter businesses from improperly using these venues for their disposal needs. This is important in order to continue offering these free services to the public without burdening public funds.

PUBLIC OUTREACH AND EDUCATION EFFORTS

Through effective outreach campaign efforts, millions of County residents were reached and educated on the proper disposal of home-generated sharps waste. Public Works distributed program specific brochures and posters to all the participating departments to make available at their designated facilities. Information was posted on various department websites.

Community and Senior Services has been very instrumental with outreach efforts at their 14 community and senior centers. Brochures were posted, public presentations were conducted by Public Works' staff, flyers were distributed to the participants, and CSS's own mobile Information Van staff handed out program material at multiple events. Community and Senior Services estimated reaching over 300,000 residents through their outreach efforts. In addition, CSS and Public Works hosted a booth at the 2010 Diabetes Expo and reached approximately 8,500 attendees.

Coordinated public outreach and education for the program will be continuous with the Working Group and will include newsletter articles in various County circulations. Community and Senior Services will continue distributing outreach materials at their 14 centers and through their Information Van, and offer more opportunities to conduct presentations at individual centers and at special events. Public Works will also continue distributing brochures at its weekly mobile HHW collection events reaching approximately 60,000 households annually

REPORT ON HOME-GENERATED SHARPS WASTE COLLECTION AT COUNTY FACILITIES

MAIL-BACK CONTAINER FEASIBILITY

Due to several barriers, including limited funding and participant screening issues, the Working Group concluded that it was not feasible to provide a mail-back program. This program would primarily assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites.

Initially, as a pilot program, Public Works received grant funding to purchase a limited number of mail-back containers. In administering this service for nearly three years, Public Works, along with the Working Group, assessed that the Program would be costly to sustain. The mail-back containers cost about \$20 each, as they are postage pre-paid. To date, over 2,200 containers have been distributed at a cost of about \$44,000. Only 500 of the containers have been mailed back for proper disposal

Currently, through the County Franchise services, the residents in the unincorporated communities of Rowland Heights, Hacienda Heights, and Citrus are offered a mail-back sharps waste disposal program. The programs in these communities are supplemented through the franchise fees

RECOMMENDATIONS

As a result of this coordinated effort, the County expanded the number of sharps collection sites available to residents Countywide to a total of 42 sites (see Enclosure III). These locations, together with the weekly household hazardous waste collection events conducted by Public Works in concert with the County Sanitation Districts, provide significantly enhanced convenience for residents to properly manage their home-generated sharps waste.

The Working Group recommends the following actions:

- The County should permanently secure the 21 newly established locations through the Sheriff's and the Health Departments. So far these locations have been well utilized; are cost effective and convenient to residents. These locations are uniformly spread throughout the County and are able to fill service gaps to the originally established program.
- The County should continue offering a collaborative and comprehensive public education utilizing County newsletters, websites, community events, and other suitable means as feasible. This will ensure a uniform regional message on the proper disposal of home-generated sharps waste in the County
- To fill in service gaps and enhance services in the unincorporated communities, the County shall continue to integrate home-generated sharps waste management programs into future franchise agreements. Currently, the residents in the unincorporated communities of Rowland Heights, Hacienda Heights, Citrus, and

REPORT ON HOME-GENERATED SHARPS WASTE COLLECTION AT COUNTY FACILITIES

Santa Clarita have sharps disposal services available to them through the franchise services.

- Continue to examine alternative funding sources and grant opportunities to offset costs for the program.
- Continue to support producer responsibility bills to establish responsibility and take back programs by the vendors and manufacturers that sell pharmaceutical products.
- Additionally, Health Services and Public Health should utilize their buying power in an effort to support producer responsibility by working with the vendors and manufacturers that sell pharmaceutical products to the County to negotiate the take back of home-generated sharps waste as well as unused/expired pharmaceuticals and medication

OVERALL PROGRAM

The newly expanded Program has been recognized by the State of California as the Best New Program for its innovative collaborative partnerships and creative approach to protecting public health and safety (see Attachment IV). The Program started as a partnership with the City of West Covina and it has since expanded to include 15 more cities, the Sheriff's Department, the County Public Health Department, Health Services, Community and Senior Services, and other public/private organizations. Currently, the Program offers residents over 100 free and convenient outlets to properly dispose of sharps waste, as well as free containers to properly collect and transport sharps waste. Over 150 distribution sites have been designated through the Program and over 20,000 sharps waste containers have been distributed.

In conclusion, the efforts behind this collaborative effort resulted in significant cost savings by reducing needle-stick injuries (which costs millions of dollars to treat) and the cost to clean up illegally dumped sharps waste.

CM.AK:td

 $\verb|P:\eppub\ENGPLAN\Natalia\HHW\Sharps\Sharps\MotionFinalReport (v3). docx \\$

_							
_	m	\sim 1	-	0	1 1	rc	اڊ
_	111		t.		ш	(*	7 1

AGN	NO	

MOTION BY SUPERVISOR DON KNABE

October 13, 2009

Everyday in the County of Los Angeles millions of home-generated sharps waste such as medical needles, lancets, and syringes are produced by individuals who self administer medications at home. If disposed of improperly, sharps waste poses a significant health risk to everyone, especially sanitation and landfill workers. In addition, surface waters, groundwater, and the ocean may be polluted as a result of leakage from leftover liquid in sharps devices

Since last September, State law (SB 1305) prohibits the placement of home-generated sharps waste in trash and recycling containers, and requires the use of State-approved containers for the collection and transportation of sharps waste. State law also encourages local governments to implement and promote sharps collection programs to provide convenient and safe means for residents to dispose of their sharps waste.

To assist residents in complying with this new State law, in June 2008 Public Works in concert with Public Health and participating cities launched a new Sharps (MORE)

	MOTION
MOLINA	
RIDLEY THOMAS	
YAROSLAVSKY	
ANTONOVICH	
KNABE	

Waste Management Program The aim of the Program is to make it as convenient as possible for residents to properly dispose of their sharps waste. Through this Program, Public Works provides State-approved, puncture-proof containers for residents to safely collect their sharps waste. These containers can be obtained free of charge at over 100 distribution sites.

Once filled, the sharps containers can be taken to designated collection sites for safe disposal. Designated collection sites currently include 8 permanent household hazardous waste collection centers and the County's weekly household hazardous waste collection events. In addition, the Department of Public Health took a proactive approach in joining Public Work's efforts to make available 14 public health clinics as collection sites for County residents to dispose of sharps waste. The disposal cost for the sharps waste is incurred by Public Health as part of their existing internal sharps waste program. In collaboration, Public Works assists with providing sharps containers for distribution, as well as outreach materials for public education. This collaborative partnership is a great example of departments working together to provide beneficial public service to the communities. Considering the size and population of Los Angeles. County however, there is a need to expand the number of sites where residents can take their filled sharps containers. To the extent feasible, we should utilize County facilities for this purpose.

Certain County departments, such as the Fire Department, also have a need for proper disposal outlets for the sharps waste they collect when they treat patients through their emergency services. Thus, opportunities exist for additional collaborative (M O R E)

partnerships between Public Works and other County departments for properly managing sharps waste and increasing public awareness.

- I, THEREFORE, MOVE that the Board of Supervisors instruct the Director of Public Works, working in collaboration with the Directors of Health Services, Community and Senior Services, Public Health and the Fire Chief of the Fire Department to pursue the following actions
 - 1 Identify and evaluate the potential for utilizing additional County facilities, such as fire stations, pharmacies, hospitals, and other locations, as sharps collection sites.
 - Implement collection sites at the most feasible locations on a 12-month trial basis, based on the Public Health model highlighted above. Costs should be equitably shared amongst participating departments.
 - 3 Assess the feasibility of providing approved mail-back containers to assist the elderly, disabled, and others who are unable to utilize the County's expanded network of sharps collection sites
 - 4 Submit a report to the Board within 18 months summarizing the results of this effort. The report should include but not be limited to the following
 - a Success of the trial collection sites in enhancing the Program
 - b Barriers/challenges faced
 - c Public outreach and education implemented
 - d Cost analysis
 - e Recommendations on making collection sites permanent, further expanding collection and other adjustments to the Program.

DS azr

Home-Generated Sharps Waste Management Program County of Los Angeles

Sharps Waste Management Working Group Contact Sheet

Sharps Waste Motion Contact List

(626) 458-3530, (626) 458-3593 Fax njimenez drw.lacounty...ov Department of Public Works 900 South Fremont Avenue Management Specialist County of Los Angeles Annex 3rd Floor, EPD Alhambra, CA 91803 www.CleanLA.com Natalia Jimenez Public Works

(626) 458-3548, (626) 458-3593 fax akesablyan@dpw.lacounty.gov Armine Kesablyan

(626) 458-2521 (626) 458-3593 Fax cmar uez@di w.lacount...ov Cynthia Marquez

Battalion Chief of Emergency Medical Suite100Commerce, CA 90040-4001 (323) 839-2212, (323) 869-0311 Fax os Angeles County Fire Department 5801 South Eastern Avenue, egandara@fire.lacounty.gov Fire Department Services Section Ed Gandara

millsaps@fire lacounty.gov Paramedic Coordinator Captain Terry Millsaps (323) 838-2219

Quality Improvement & Patient Safety (213) 240-8283, (213) 482-3895 fax Elizabeth Augusta RN, MSN, LNCC, Patient Safety & Quality Consultant Health Services Administration augusta@dhs.lacounty.gov Los Angeles, CA 90012 313 N Figueroa #703 Health Department Los Angeles County Program

Office of the Chief Network Officer Director, Administrative Services Department of Health Services 313 N Figueroa, Suite 904-C hmoore adhs.lacounty, ov Phillip L Moore III, M.P.A os Angeles, CA 90012 County of Los Angeles (213) 250-8620

Department of Health Services deflores@dhs.lacounty.gov County of Los Angeles (310) 222-5321 Dawn Flores

(213) 240-8019, (213) 250-8755 fax 241N. Figueroa St. Suite 306 Deputy and Planning Support Community Health Services Public Health David Caley, RN, BSN, PHN Department of Public Health dcalev可 h.lacountv. lov Los Angeles, CA 90012 os Angeles County

cchen@ph.lacounty.gov Los Angeles County Cindy Chen

Monterey Park, CA 91754 (323) 267-4813, (323) 267-6694 Fax Department of Public Health Deputy Bill Brauberger Sheriff's Department whbraube@lasd.org 4700 Ramona Blvd

Sergeant Alissa Dedmon akdedmon@lasd.org Narcotics Bureau (562) 946-7105

(323) 810-1973, (323) 267-6694 Fax Nicole Nishida

Community and Senior Services Community and Senior Services nnishida@lasd.org Ken Regalado

3175 W. 6th Street, L. A. 90020 Ph. (213) 738-2920 * Fax. (213) 637-

kre alad css lacount ov

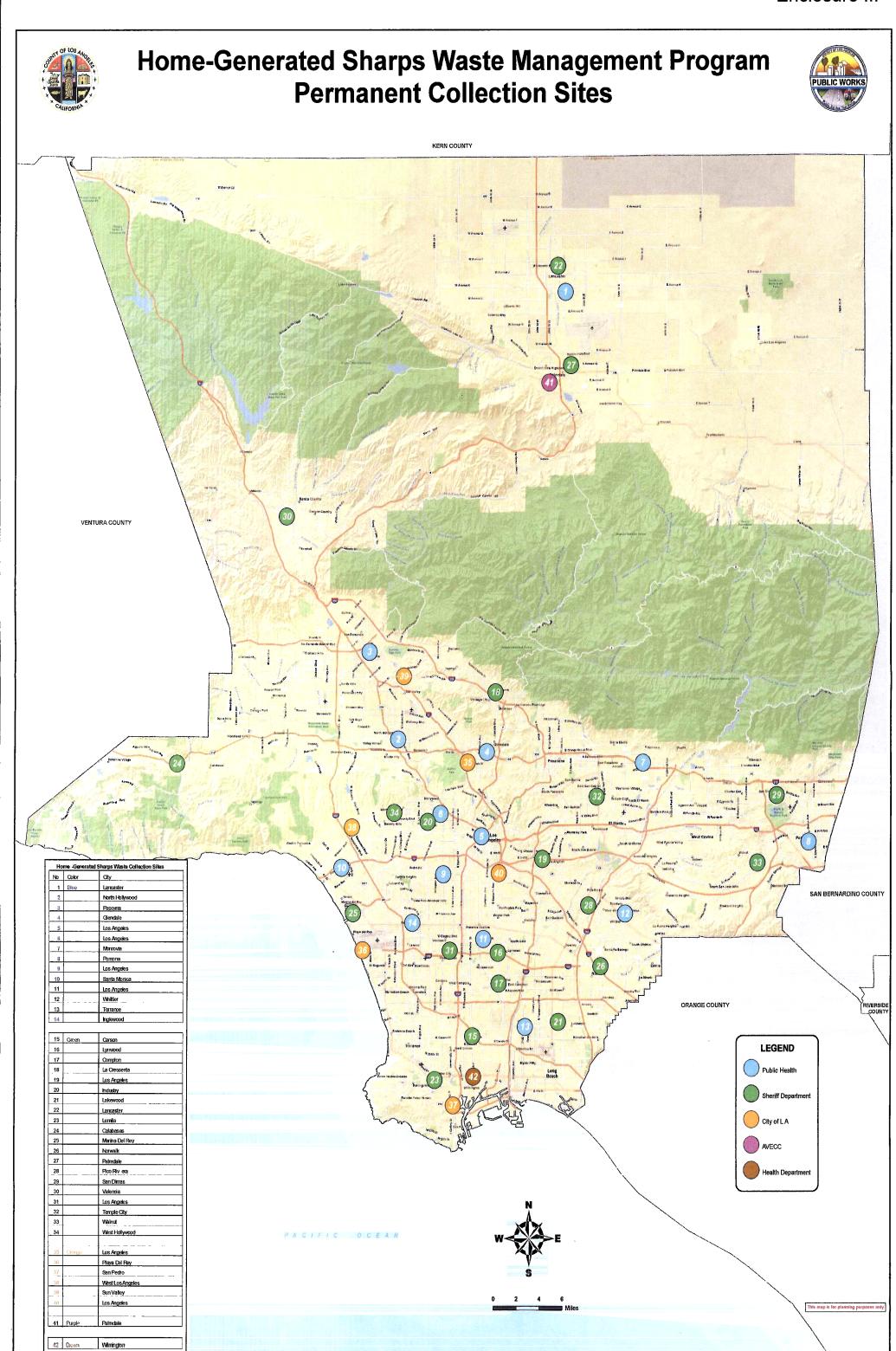
Manager Internal Support Services (213) 738-2681, (213) 637-4874 Fax ewolfe@css.lacounty.gov Ellie Wolfe

(213) 738-2273, (213) 637-4874 Fax Margaret Quinn, Assistant Director Administrative Services Branch MQuinn@css lacounty gov

(213)738-2065, (213) 385-3893 Fax senette css.lacounty, ov Public Information Officer Patricia Senette-Holt

Department of Community and Senior 3175 W Sixth Street, Room #306 (626) 398-6174, (626) 296-1198 Fax Geraldo J. Rodriguez, MSW, ACSW Community and Senior Centers rodriouez css.lacounty. ov Los Angeles, CA 90020 County of Los Angeles Program Manager Services Division

Department of Community and Senior (310) 603-7401, (310) 763-1372 Fax Community Center Specialist sgonzalez@css.lacounty.gov County of Los Angeles Sandra Gonzalez Services



County of Los Angeles Home-Generated Sharps Waste Management Program

INNOVATIVE PARTNERSHIPS



As a partner, the Department of Public Health opened up its 14 public health clinics for County residents to conveniently and safely dispose of sharps waste and have easy access to obtaining new sharps containers.



The collaborative partnership with the County Sheriff's Department encourages residents to anonymously dispose of home-generated sharps waste at 20 Sheriff's Stations throughout the County.

EXHIBIT 3(a)



GAH, FARRER, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

"To Enrich Lives Through Effective and Caring Service

900 SOUTH FREMONT AVENUE ALHAMBRA, CALIFORNIA 91803-1231 Telephone: (626) 458-5100 http://dpw.lacounty.gov

ADDRESS ALL CORRESPONDENCE TO P.O. BOX 1460 ALHAMBRA, CALIFORNIA 91802-1460

IN REPLY PLEASE

REFER TO FILE

EP-4 A4272

TO

Each Supervisor

July 2, 2015

Gail Farber Laufarlur
Director of Public Works

BOARD MOTION OF JUNE 2, 2015, ITEM 78-A MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

On June 2, 2015, the Board approved a motion introduced by Mayor Michael D. Antonovich, as amended, directing the Director of Public Works, in coordination with the Interim Chief Executive Officer: County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County,
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future:
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo. San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5.

Each Supervisor July 2, 2015 Page 2

The attached report is in response to items 4 and 5 of the motion. Below is a summary of the findings and conclusion of the report.

Item 4: Pharmaceutical Take-Back Ordinance

The County Departments and Agency listed in the motion formed a Working Group to evaluate the feasibility of adopting an ordinance similar to the pharmaceutical waste take-back ordinances adopted by the Counties of Alameda (July 10, 2012). San Francisco (March 17, 2015), San Mateo (May 19, 2015), and Santa Clara (May 28, 2015).

Utilizing the principle of EPR, an environmental policy introduced in Sweden in 1990, these Counties adopted ordinances that mandate drug manufacturers design and implement a safe take-back and disposal program. Based on this premise and for the additional reasons cited below, the Working Group has determined that a similar ordinance is feasible for the County:

- The United States Drug Enforcement Agency promulgated regulations at, *inter alia*, 21 CFR Parts 1317, *et seq.* in 2014 allowing the collection of controlled substances at collection receptacles, take-back events, and mail-back programs.
- To date, there is no voluntary or mandatory Statewide product stewardship program for unwanted or expired pharmaceuticals or sharps waste in California.
- Publicly financed take-back programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County.
- The California Medical Waste Management Act allows local jurisdictions to promulgate more stringent requirements to dispose of medical waste pursuant to Health and Safety Code section 117800.
- In May of this year, the United States Supreme Court declined to review a challenge to Alameda County's Drug Disposal Ordinance. The Court's decision upholds the 9th Circuit Court of Appeals' opinion of September 30, 2014, which found that the ordinance, requiring pharmaceutical manufacturers to fund drug take-back programs in the County, did not interfere with interstate commerce or discriminate against out-of-state manufacturers.

<u>Item 5: Utilization of the County's Purchasing Power to Negotiate a Take-Back Program</u>

The Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3 percent of the overall pharmaceutical sales in Los Angeles County.

Each Supervisor July 2, 2015 Page 3

Recommendation

The Working Group recommends the Board adopt an EPR ordinance similar to those adopted by the Counties of Alameda, San Francisco, San Mateo, and Santa Clara requiring manufacturers/producers to develop and finance a product stewardship plan that addresses a take-back program, identifying at a minimum:

- Collection systems and services, including drop-off sites, collection events, and mail-back services;
- Handling and disposal procedures that are safe and in compliance with applicable Federal and State laws;
- Public education and outreach promotion strategies; and
- Tracking reports of disposal amounts, short-term and long-term goals for collection amounts, and education and promotion programs.

Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County, but contain other components, such as over-the-counter pharmaceutical waste. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the Working Group has considered these risks and believes that they are outweighed by the benefits of achieving the policy goals.

Next Steps

Upon the Board's direction, the Working Group will prepare a draft EPR ordinance with participation of stakeholders that ensures the safe and convenient take-back and disposal of sharps and pharmaceutical waste by producers and manufacturers. Additionally, the Working Group will report back to the Board by October 2, 2015, regarding items 1-3 of the June 2, 2015. Board order.

If you have any questions regarding this matter, please contact me or your staff may contact Shari Afshari at (626) 458-4008.

CS:ao h/adhome/ag/EPD/Pharma EPR Cover Memo

Attach.

cc: Chief Executive Office (Sachi A. Hamai, Rochelle Goff), County Counsel, Executive Office, Department of Health Services, Internal Services Department, Department of Mental Health, Department of Public Health, Sheriff's Department, Sanitation Districts of Los Angeles County

MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

A report on the feasibility of adopting a pharmaceutical take-back ordinance and utilizing the County's purchasing power to negotiate take-back programs

July 2, 2015

PREPARED BY:

Chief Executive Office
County Counsel
Department of Health Services
Internal Services Department
Department of Mental Health
Department of Public Health
Department of Public Works
Sheriff's Department
Sanitation Districts of Los Angeles County

Contents

INTRODUCTION	1
MOTION	1
BACKGROUND	1
Health and Safety Issues	2
Environmental Issues	3
Financial Issues	3
OPTIONS FOR MANAGING PHARMACEUTICAL AND SHARPS WASTE	4
DISPOSAL	4
TAKE-BACK AND MAIL-BACK	5
Utilizing the County's Purchasing Power for Take-Back	5
Publicly Financed Take-Back Program	5
Establishing a Privately Financed Take-Back Program	6
A SUSTAINABLE SOLUTION	
RECOMMENDATION	8
PHARMACEUTICAL AND SHARPS WASTE EPR ORDINANCE	8
NEXT STEPS	9
DRAFT ORDINANCE	9
CONDUCT OUTREACH	9

INTRODUCTION

MOTION

On June 2, 2015, the Board of Supervisors approved a motion introduced by Mayor Michael D. Antonovich directing the Director of Public Works, in coordination with the Interim Chief Executive Officer; County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- 3. Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5. The County Departments and Agency listed in the motion formed an Extended Producer Responsibility Working Group (EPR Working Group) to prepare this report, which is in response to items 4 and 5 of the motion.

BACKGROUND

Pharmaceuticals play a critical role in treating diseases and saving lives. However, there are times consumers of pharmaceuticals no longer need the supply that is in their possession – for example, their physician has changed their medication therapy, the medication is expired, or a patient in a long-term care facility has died. Current options for managing this excess pharmaceutical supply, or pharmaceutical waste, are limited. Pharmaceutical waste includes unused and/or expired over-the-counter or prescription tablets, oral liquids and injectable products, but also may contain biomedical or biohazardous waste. For this reason, pharmaceutical waste disposal options must provide for the management of biomedical and biohazardous waste as well as disposal of devices commonly used to

puncture the skin (e.g., syringes/needles) that are also used by consumers to inject pharmaceuticals. The U.S. Environmental Protection Agency (USEPA) states that "reducing, minimizing, or eliminating leftover drugs represents a very significant opportunity to improve both ecological and human health while also reducing expenses associated with medical care and waste treatment." In addition, improper management of discarded sharps waste such as needles, syringes, and lancets can pose a health risk to residents, including certain classes of workers and children.²

The safe disposal of pharmaceutical and sharps waste is a public safety and environmental need that calls for safe, convenient, and sustainable disposal options for residents in Los Angeles County.

Health and Safety Issues

According to the National Community Pharmacists Association (NCPA), an estimated 200 million pounds of unused or expired prescription drugs are stored in medicine cabinets across America.³ Given the limited waste disposal options available and the fact that many County residents are unsure of how to safely and properly dispose of pharmaceutical and sharps waste, there is an opportunity for Los Angeles County to take action to provide additional waste disposal options.

Improperly disposed sharps waste poses an additional set of concerns and risks to health professionals, pharmacists, law enforcement professionals, and the waste management industry as these individuals may unexpectedly encounter disposed needles and other related waste. The USEPA estimates that about 8 million people in the United States use more than 3 billion needles, syringes, and lancets, collectively known as "sharps," each year.4 Once used, these sharps are termed "home generated" medical waste, and by State law,5 are prohibited from disposal in regular trash cans or recycle bins. The volume of home generated sharps waste has been growing in recent years, and many people are unaware of what to do with their used sharps and end up throwing them in the trash despite the law. According to the USEPA "people at the greatest risk of being stuck by used sharps include sanitation and sewage treatment workers, janitors and housekeepers, and children." Much of the home-generated waste is sorted and processed before landfilling, which exposes sanitation workers and others to potentially dangerous conditions. According to the USEPA, all needle-stick injuries are treated as if the needle were infected with a disease. Victims of sharps-related injuries face the cost of post-injury testing, disease prevention measures, and counseling, even if no infection or disease was spread.

¹ Drug Disposal & Stewardship: Ramifications for the Environment and Human Health (USEPA, Sept. 2014)

² Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

³ DisposeMyMeds.org (NCPA, downloaded June 17, 2015)

⁴ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

⁵ California Health and Safety Code §118286

⁶ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

Some diseases can take a long time to appear on test results, leading to months of testing and apprehension.⁷

Environmental Issues

The World Health Organization (WHO) recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources, and some drinking-waters." Pharmaceuticals can enter the environment through multiple pathways, including being poured down the drain, being flushed down toilets, or via trash disposal, which can result in landfill leachate that may enter groundwater. All landfills generate leachate – the product of moisture in the deposited trash and rainfall on the surface of the landfill that collects over time. In landfills operated by the Sanitation Districts of Los Angeles County and most large landfills, the leachate is collected and treated at local wastewater treatment plants. However, municipal wastewater treatment plants in Los Angeles County are not designed to manage or remove all of the complex compounds in pharmaceutical waste, and cannot be cost-effectively retrofitted to do so. The long-term environmental impacts of the presence of pharmaceuticals in groundwater and surface water bodies are unknown; therefore, it is prudent to encourage other methods of disposal.

Financial Issues

The Los Angeles County Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely and anonymously drop off their expired and unused pharmaceutical and sharps waste. In 2013, the Sheriff's program collected about 20,000 pounds of pharmaceutical waste and 26,000 pounds of sharps waste, at a cost of over \$34,000 and \$48,000, respectively, funded through the Sherriff's Department existing budget and personnel. However, this program by itself is simply not adequate to process the volume of pharmaceutical and sharps waste produced in the County.

In addition, the County's Household Hazardous Waste (HHW) Program, managed by Public Works, also collects non-controlled pharmaceutical and sharps waste from residents at weekly HHW collection events and designated collection centers. The \$10 million HHW Program is primarily funded by a Countywide fee collected based on the total amount of solid waste disposed. This funding source is anticipated to substantially decrease as the State proceeds to achieve its policy goal to recycle at least 75% of the waste by 2020, and the County achieves its ambitious waste diversion goals identified in the County's Roadmap to Sustainable Waste Management Future. It is difficult to calculate the exact costs for the collection and management of pharmaceutical and sharps waste from the total HHW Program costs, but they are estimated to be in the range of \$500,000 per year or more. As the County's population continues to increase, demands on these programs will grow, while funding is anticipated to decrease as described above. At the same time, providing for proper management of pharmaceutical and sharps waste for all County residents solely

⁷ Ibid.

^{*} Information sheet: Pharmaceuticals in drinking-water (WHO, 2012)

through the HHW Program would require significant additional resources, which is not financially sustainable in the long term.

OPTIONS FOR MANAGING PHARMACEUTICAL AND SHARPS WASTE

Existing options for managing pharmaceutical and sharps waste are described below:

DISPOSAL

Disposal practices that involve placing medications in household trash, pouring them down the drain, or flushing them down the toilet potentially pose a threat to the environment. The U.S. Food and Drug Administration (FDA) recommends that, *if take-back options are not available*, certain pharmaceutical waste "that may be especially harmful and, in some cases, fatal with just one dose" should be "flushed down the sink or toilet as soon as they are no longer needed." However, the California Department of Resources Recycling and Recovery (CalRecycle) notes "wastewater treatment plants are not designed to remove pharmaceuticals and studies show that exposure to even low levels of drugs has negative effects on fish and other aquatic species, and also may negatively affect human health. Thus, we recommend households do not dispose of waste medication down the drain or down the toilet." 10

In addition, California Law prohibits the placement of sharps waste in trash or recycling bins, and requires that sharps waste be placed in special container to minimize the risk of injury and prevent leakage or expulsion of waste contents during storage and transport.¹¹ Therefore, home disposal of sharps waste is not an option.

There is broad consensus, including among the FDA,¹² USEPA¹³ and the pharmaceutical industry,¹⁴ that take-back programs that promote incineration disposal methods are the preferred choice for proper disposal of expired or unwanted prescription and over-the-counter medication. The USEPA recommends incineration as the preferred method of disposal to address both environmental concerns and concerns regarding improper use of pharmaceuticals.¹⁵ The USEPA notes "studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing [down the drain/toilet]. Further, some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Incineration of unwanted household pharmaceuticals

⁹ Disposing of Unused Medicines: What You Should Know (FDA, downloaded June 17, 2015)

¹⁰ Household Medication Waste Disposal (CalRecycle website, downloaded June 17, 2015)

¹¹ California Health and Safety Code §§118275-118320

¹² Disposing of Unused Medicines: What You Should Know (FDA website, downloaded June 17, 2015)

¹³ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

¹⁴ Safe Disposal of Prescription Medication and Environmental Protection (Pharmaceutical Research and Manufacturers of America website, downloaded June 17, 2015)

¹⁵ Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (USEPA Memorandum, Sept. 2012)

will reduce the amount of household pharmaceuticals that are disposed by both flushing and land filling." ¹⁶

TAKE-BACK AND MAIL-BACK

Take-back programs are a simple, safe and efficient option to provide for the environmentally safe collection and disposal of pharmaceutical and sharps waste. Through such programs, pharmaceutical and sharps waste are properly contained, incinerated and/or safely disposed. Take-back programs should include a mail-back option, which helps to ensure that the take-back program is accessible to all County residents free of charge, including those who are home bound, live in remote or rural areas, or have a large quantity of pharmaceutical and/or sharps waste that requires disposal. A take-back program with a mail-back option provides for the disposal of pharmaceutical and sharps waste that can be financially, socially, and environmentally sustainable. Three options for implementing a take-back program are discussed below:

Utilizing the County's Purchasing Power for Take-Back

An option considered was the use of the County's pharmaceutical purchasing power to negotiate contracts. However, after review and consideration, the EPR Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3% of the overall pharmaceutical sales in Los Angeles County.¹⁷

Publicly Financed Take-Back Program

Today in Los Angeles County, publicly financed take-back programs are the only safe options for residents to dispose of sharps and pharmaceuticals. However, these programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County. Currently, the County's program relies on a network of pharmaceutical and sharps waste drop-off locations at Sheriff Stations and designated County health centers; however, these limited locations have faced difficulty with safely handling the volume of pharmaceutical and sharps waste, particularly given the types of waste disposed of by consumers and the volume of waste. The County's HHW Program may not provide a convenient location to every resident in a timely manner to manage their sharps or pharmaceutical waste. Expanding these programs sufficiently would require additional resources; however, as discussed above, the Countywide HHW Program is facing anticipated decreases in funding. Given the limited public take-back options due to funding requirements, the County cannot assume the sole responsibility for developing, financing, advertising, and implementing take-back programs. In addition, a recent study by the City

¹⁶ Ibid.

¹⁷ KFF Total Retail Sales for Prescription Drugs Filled at Pharmacies (KFF Website, Downloaded June 25, 2015)

of San Francisco suggests that residents prefer dropping off pharmaceuticals at pharmacies rather than police stations by a wide margin. 18

Establishing a Privately Financed Take-Back Program

In November 2008, the Los Angeles County Board of Supervisors adopted a resolution supporting the principle of Extended Producer Responsibility (EPR). EPR is an environmental policy approach credited as being officially introduced in Sweden in 1990¹⁹ in which a manufacturer or producer's responsibility for a product is extended to the postconsumer stage of a product's life cycle. Manufacturers would be required, either individually or collectively, to establish a comprehensive take-back program, along with a plan to ensure the program effectively collects the pharmaceutical products at the end of their useful life. In addition to assuming a share of the costs, EPR can lead to better results overall since manufacturers know their product and industry better and can design and operate collection and disposal programs which are more efficient and effective than those implemented by local governments. A take-back program financed by the pharmaceutical industry would share the responsibility for managing unused/expired pharmaceuticals and sharps and relieve the current burden on publicly funded efforts. This program would include handling the shipping costs incurred through the use of a mail-back option for consumers. According to the Product Stewardship Institute, the EPR approach has been successful in managing pharmaceutical and sharps waste for years throughout some European countries, Mexico, and Canada.²⁰

The State Board of Pharmacy is in the process of establishing regulations for pharmaceutical take-back within pharmacies. As the Drug Enforcement Agency regulations also allow take-back within hospitals and long-term care facilities when overseen by a pharmacy, the regulations will include these additional access areas as well.

Generally, EPR programs are more effective when adopted uniformly for a geographically large area, allowing for improved economies of scale for outreach and collection costs while minimizing confusion that may arise over the boundaries of local programs. However, previous attempts to pass Statewide EPR legislation for pharmaceuticals and sharps in California have not been successful. On July 10, 2012, Alameda County was the first County in the nation to adopt an EPR ordinance for pharmaceutical waste at the local level. Alameda County's Safe Drug Disposal ordinance was challenged by the pharmaceutical industry in District Court, and when it was upheld, appealed to the Ninth Circuit Court of Appeals which also upheld the ordinance. On May 26, 2015, the United States Supreme Court decided that it would not review the case, leaving the Ninth Circuit Court decision in

¹⁸ San Francisco's Safe Medicine Disposal Pilot Program Update (San Francisco Public Utilities Commission, Jan. 2013)

¹⁹ The Concepts of Extended Producer Responsibility and Product Stewardship (Institute For Local Self-Reliance Website, Downloaded June 25, 2015)

²⁰ Myths vs. Reality: Extended Producer Responsibility for Pharmaceuticals (Product Stewardship Institute, factsheet downloaded June 17, 2015)

place. Also, this year three additional Counties in California–Santa Clara, San Francisco, and San Mateo-have adopted similar ordinances.

A SUSTAINABLE SOLUTION

Adopting an EPR ordinance to establish a privately financed take-back program for pharmaceutical and sharps waste is a sustainable and effective approach, since it requires the manufacturers, as producers of pharmaceutical products and sharps, to incorporate into the price of their products the cost of managing the products at the end of their useful life. Manufacturers can partner with pharmacies to establish take-back locations, which would be more convenient to residents, and it is anticipated that financing these programs will have minimal impact on the retail costs of pharmaceuticals or sharps.^{21,22}

On October 21, 2014, the Board of Supervisors adopted the Roadmap to a Sustainable Waste Management Future (Roadmap). The Roadmap identifies strategies and initiatives to reduce waste and divert material from landfills. One of the initiatives identified is to advocate for EPR, including exploring the feasibility of establishing a County EPR ordinance for materials such as pharmaceutical and sharps waste.

Additionally, supporting shared responsibility with manufacturers for the impacts and management costs of their products at the end of life is consistent with the County's Legislative Agenda, which states that the County will "support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability." This policy was established following the Board of Supervisors adoption on November 5, 2008, of a resolution "supporting Extended Producer Responsibility and directing the County's Legislative Advocates in Sacramento to actively pursue legislation and Statewide policies that shift end-of-life product management costs from local government to the manufacturers and incentivize the redesign of products that have impacts on public health and the environment."

The overall efforts are in line with the June 2014 County Strategic Plan Goal No. 2, Strategic Initiative 5, Environmentally Sustainable Practices which identifies a specific focus area promoting net-zero waste in order to "optimally manage and reduce solid waste by diverting from waste stream and maximizing recycling opportunities."

²¹ Ibid.

²² Economic Impacts of the B.C. Recycling Regulation (British Columbia, CN Ministry of Environment, August 2008)

^{23 2015-16} State Legislative Agenda, Section 2.7.12 (Los Angeles County, Dec. 2014)

RECOMMENDATION

The Board directed that the Department of Public Works in coordination with the Chief Executive Office, County Counsel, the Sheriff, Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts address the issue of take-back programs for pharmaceutical products. This EPR Working Group recommends the Board adopt a pharmaceutical and sharps waste EPR ordinance in which pharmaceutical manufacturers and producers would develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served.

PHARMACEUTICAL AND SHARPS WASTE EPR ORDINANCE

Working Group recommends that this ordinance require manufacturers/producers of prescription and nonprescription drugs (including controlled and non-controlled substances) as well as sharps to develop product stewardship take-back program(s) to collect and dispose of unused/unwanted pharmaceutical and sharps waste from consumers. Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County's ordinance, but contain other components, such as overthe-counter pharmaceutical waste, as well as requiring other best practices. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the EPR Working Group has considered these risks and believe that they are outweighed by the benefits of achieving the policy goals.

All pharmaceutical manufacturers/producers would be subject to the same requirement to design and implement a take-back program, and they would be able to choose whether to meet these requirements individually or by joining with others. Manufacturers/producers would have the flexibility to design the take-back program to meet performance goals established by the County. The County would be responsible for oversight of the program(s), for ensuring that the program(s) are transparent and readily accessible to the public, and that a thorough outreach program is implemented.

Participation by retail pharmacies, hospitals, and long-term care facilities would be voluntary, and interested pharmacies would work directly with the pharmaceutical producers to join the program. Any pharmacies, hospitals, or nursing homes that choose to participate would provide collection bins for pharmaceutical and sharps waste, contribute floor space and staff time to manage the collected materials and answer consumers' questions. The EPR Working Group recommends that the ordinance authorize pharmaceutical manufacturers/producers to provide financial incentive to participating pharmacies. The EPR Working Group also recommends the ordinance require any retail pharmacy not participating as a collection point, at minimum to advertise options available for proper disposal, including the locations of participating pharmacies and how to make use of mail-back programs.

NEXT STEPS

DRAFT ORDINANCE

Upon the Board's direction, the EPR Working Group will prepare a draft pharmaceutical waste and sharps waste EPR ordinance with the participation of stakeholders. The ordinance would be drafted as a Countywide ordinance, however it is anticipated that each city wishing to participate would need to take additional action, as the ordinance may only be enforceable in a city's jurisdiction after the city takes action to adopt the County ordinance by reference.

Additionally, the EPR Working Group will report back to the Board by October 2, 2015, with findings and recommendations related to items 1-3 of the Board motion as stated on page 4 of this report.

CONDUCT OUTREACH

If the Board directs the EPR Working Group to move forward with drafting an ordinance, the EPR Working Group will initiate stakeholder engagement to the pharmaceutical industry and other stakeholders to solicit their feedback. The EPR Working Group would work together to develop a refined list of stakeholders and host public information meetings. The meetings would be organized to provide industry and other stakeholders with an opportunity to share and discuss their comments and concerns regarding the concept of a pharmaceutical and sharps waste EPR ordinance.

The following target audiences and types of stakeholders have been identified for outreach. A more specific and extensive list will be developed based on the experiences of other Counties that have developed similar ordinances.

Stakeholder Engagement Objectives:

- Communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste
- Obtain feedback from industry and other stakeholders
- Generate awareness about the EPR program

Target Audiences:

- General Public
- Drug Abuse Advocacy Groups
- Waste Management Companies
- Environmental Advocacy Groups
- Senior Citizen Advocacy Groups
- Pharmacy Industry Representatives and Associations
- Pharmaceutical Manufacturers and Associations
- Cities within Los Angeles County
- Veterinarian Organizations
- Health Care Provider Organizations

VII. MISCELLANEOUS

- 78. Additions to the agenda which were posted more than 72 hours in advance of the meeting, as indicated on the supplemental agenda. (12-9995)
- 78-A. Recommendation as submitted by Supervisor Antonovich: Instruct the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, Sheriff, the Directors of Health Services, Internal Services, Mental Health and Public Health, and the County Sanitation Districts to report back within 4 months with the findings and recommendations on the following:

Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education and improving the current management system for unused/expired medications in the County;

Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;

Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;

Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa; and

Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back.

Supervisor Antonovich revised Recommendation Nos. 4 and 5 to request a report back to the Board in 30 days.

On motion of Supervisor Knabe, seconded by Supervisor Antonovich, this item was approved as amended. (15-2619)

Ayes: 5 - Supervisor Solis, Supervisor Ridley-Thomas, Supervisor Kuehl, Supervisor Knabe and

Supervisor Antonovich

Attachments:

Motion by Supervisor Antonovich

Report Video Audio

AGN.	NO.	

MOTION BY MAYOR MICHAEL D. ANTONOVICH

JUNE 2, 2015

Managing unused/expired medications is a growing concern facing the County of Los Angeles. According to the National Community Pharmacists Association, an estimated 200 million pounds of unused or expired prescription drugs are stored in American medicine cabinets. They often end up in the wrong hands where inappropriate use can lead to addiction, abuse, serious injury, and even death. According to a report released by the Department of Public Health, in 2013 there were more than 500 deaths, 3,000 hospitalizations and 5,000 emergency visits associated with prescription and over the counter drug overdose in Los Angeles County.

New studies are also demonstrating that pharmaceuticals have an impact on our environment. The World Health Organization recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources and some drinking-waters." Municipal wastewater treatment plants are not designed to remove the complex compounds in drugs that end up in the sewer system.

Pharmaceuticals delivered via needles pose an additional set of concerns, posing a risk to health professionals as well as public and private employees in law enforcement and waste management that interact with disposed needles and related sharps waste.

These are serious problems impacting the well-being of our communities. In response, the Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely, and anonymously, drop off their expired medications and sharps. The County's Household Hazardous Waste program, managed by Public Works, also collects non-controlled pharmaceuticals and sharps from residents. Unfortunately, the volume of pharmaceuticals is too great for local programs such as this to fully address the problem. We need to do more to increase public awareness of the potential impacts of improper storage and disposal of unused medication and to make it safe and convenient for residents to dispose of unused/expired medications and increase participation.

-MORE-

	MOTION	
SOLIS		
RIDLEY-THOMAS		
KUEHL		
KNABE		
ANTONOVICH		

I, THEREFORE, MOVE that the Board of Supervisors:

Direct the Director of Public Works, in coordination with the Chief Executive Office; County Counsel; the Sheriff's Department; the Departments of Health Services, Internal Services, Mental Health and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- 2. Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an Ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa Clara:
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs; and
- 6. Report back within 4 months with findings and recommendations.

#

MDA:evo pharmaceuticalsdisposai060215

EXHIBIT 3(b)



GAIL FARBER, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

"To Enrich Lives Through Effective and Caring Service"

900 SOUTH FREMONT AVENUE ALHAMBRA, CALIFORNIA 91803-1331 Telephone: (626) 458-5100 http://dpw.lacounty.gov

ADDRESS ALL CORRESPONDENCE TO: P.O. BOX 1460 ALHAMBRA, CALIFORNIA 91802-1460

IN REPLY PLEASE

REFER TO FILE:

EP-4 A4272F

TO:

Each Supervisor

FROM:

October 1, 2015

Gail Farber Mau Farher

Director of Public Works

BOARD MOTION OF JUNE 2, 2015, ITEM 78-A
MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE
IN THE COUNTY OF LOS ANGELES

On June 2, 2015, the Board approved a motion instructing the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, the Sheriff, the Directors of Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the Pharmaceutical Industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1 through 3 and report back in 30 days for items 4 and 5.

Each Supervisor October 1, 2015 Page 2

On July 2, 2015, a report was submitted to the Board in response to items 4 and 5 of the motion. The attached report is in response to items 1-3 of the June 2, 2015, Board motion, and also provides a brief status update regarding the activities undertaken by the Pharmaceutical Working Group in response to the August 11, 2015, Board motion.

The August 11, 2015, Board motion directed the Interim Chief Executive Officer, in collaboration with the County's Sustainability Council and the Pharmaceutical Working group to:

- 1. Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the Pharmaceutical Industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within 6 months with the recommended Ordinance for consideration.

The Board amended the motion to have the stakeholder process occur first before the ordinance is drafted.

The recommended Ordinance, which will be submitted to the Board by February 11, 2016, will take into consideration the findings of the July 2, 2015, Board report "Managing Unused and Expired Medications and Sharps in the County of Los Angeles," feedback received from stakeholders and the public, as well as analyses of EPR ordinances and best practices developed and implemented by other jurisdictions.

If you have any questions regarding this report, please contact me or your staff may contact Shari Afshari at (626) 458-4008.

PH:jl

P:\Secfinal\Pharma EPR Cover Memo 10_2_2015CEO_V3.doc

Attach.

cc: Chief Executive Office (Sachi A. Hamai, Rochelle Goff), County Counsel (Julia Weissman, Grace Chang, Lillian Russell), Executive Office, Department of Health Services, Internal Services Department, Department of Mental Health, Department of Public Health, Sheriff's Department, Sanitation Districts of Los Angeles County

MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

LUANT DE

October 2, 2015

PREPARED BY:

Chief Executive Office
County Counsel
Department of Health Services
Internal Services Department
Department of Mental Health
Department of Public Health
Department of Public Works
Sheriff's Department
Sanitation Districts of Los Angeles County

Table of Contents Introduction and Background	1
Board Motion	1
July 2, 2015, Board Report	1
August 11, 2015, Board Motion	2
June 2, 2015, Board Motion Response	2
Item 1: Options for Reducing Improper Use and Disposal, Increasing Public A and Education, and Improving the Current Management System for Pharmace Sharps Waste	utical and
Item 2: Partner with the Pharmaceutical Industry to Develop a Public A Campaign to Educate Residents on the Importance of How to Properly Store and Unused Medication and the Negative Effects to the Environment When Medication Enters the Waste Stream and Waterways	nd Dispose Medication
Stakeholder Engagement:	3
Item 3: Support and Pursue Extended Producer Responsibility Legislation and Programs for Sharps and Pharmaceuticals at the State Level, Consistent with the Adopted Legislative Agenda and Roadmap to a Sustainable Waste Management	e County's
Assembly Bill 1159	5
Next Steps	5
Appendix	6

Introduction and Background

Board Motion

On June 2, 2015, the Board of Supervisors approved a motion directing the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, the Sheriff, the Directors of Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the Pharmaceutical Industry to develop a public awareness campaign
 to educate residents on the importance of how to properly store and dispose of
 unused medication and the negative effects to the environment when medication
 enters the waste stream and waterways;
- 3. Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1 through 3 and report back in 30 days for items 4 and 5.

The County Departments and Agency listed in the motion formed a Pharmaceutical Working Group (Working Group) to prepare this report, which is in response to items 1 through 3 above. In a report dated July 2, 2015 (see Appendix), the Working Group submitted a response to the Board regarding items 4 and 5 of the motion.

July 2, 2015, Board Report

The July 2, 2015, report to the Board of Supervisors, "Managing Unused and Expired Medications and Sharps in the County of Los Angeles," recognized that while pharmaceuticals play a critical role in treating diseases and saving lives, consumers of pharmaceutical products have limited options for disposal of excess or expired pharmaceutical supplies. In addition, the improper management of discarded sharps waste such as needles, syringes, and lancets can pose a health risk to residents, children, and certain classes of workers such as those that come in contact with waste at municipal solid waste material recovery facilities.

The disposal of pharmaceutical and sharps waste is a public health and safety issue and an environmental issue requiring safe, convenient, and sustainable disposal options for residents in the County of Los Angeles. The report recommended that the Board adopt a

pharmaceutical and sharps waste EPR Ordinance. It was further recommended that the Ordinance be similar to the ordinance adopted by Alameda County with the addition of over-the-counter pharmaceuticals as well as sharps waste. The report noted that while these other provisions have not been legally tested, the Working Group believes that the risks are outweighed by the public health and safety benefits and the environmental protection benefits.

August 11, 2015, Board Motion

In response to the July 2, 2015, report on August 11, 2015, the Board adopted a Motion introduced by Mayor Michael D. Antonovich and Supervisor Hilda L. Solis, and amended by Supervisor Don Knabe, which directed the Interim Chief Executive Officer, in conjunction with the County's Sustainability Council and the Pharmaceutical Working Group to:

- Draft an Ordinance, which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- 2. Initiate stakeholder engagement with the Pharmaceutical Industry and other stakeholders to solicit feedback on the Ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within 6 months with the recommended Ordinance for consideration.

The motion was amended to have the stakeholder process first before the Ordinance is drafted.

June 2, 2015, Board Motion Response

Item 1: Options for Reducing Improper Use and Disposal, Increasing Public Awareness and Education, and Improving the Current Management System for Pharmaceutical and Sharps Waste

The July 2, 2015, report (pages 4-6) included a discussion of existing options for managing pharmaceutical and sharps waste and focused on the broad consensus that take-back and mail-back programs provide for the environmentally safe collection and disposal of unwanted pharmaceutical and sharps waste. The report also noted California's prohibition on disposing of sharps waste in the trash or recycling bins. The report recommended the Board adopt an EPR Ordinance, which manufacturers and producers of pharmaceuticals and sharps develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served. The California Department of Resources, Recycling and Recovery also recommended Product Stewardship as the preferred approach to managing pharmaceutical and sharps waste in their December 2010 report to the legislature, "Recommendations for Home-Generated Pharmaceutical Collection Programs in California." Options for increasing public awareness are further discussed in the next Section of this report.

Item 2: Partner with the Pharmaceutical Industry to Develop a Public Awareness Campaign to Educate Residents on the Importance of How to Properly Store and Dispose of Unused Medication and the Negative Effects to the Environment When Medication Enters the Waste Stream and Waterways

The Working Group recommends that a concerted effort to raise public awareness, in concert with the Pharmaceutical Industry and other stakeholders, be initiated following the adoption of the Ordinance by the Board, which will be submitted for Board consideration on February 11, 2016. This will reduce potential confusion between current, publicly financed programs and future programs that may be implemented.

The July 2, 2015, report recommended that the Ordinance contain provisions, which would allow manufacturers and producers or stewardship organizations the flexibility to design the Take-Back Program to meet performance goals established by the County. Among these performance goals would be an expectation that the Take-Back Program include a robust public awareness campaign. The campaign would need to educate residents on proper storage and disposal of unwanted pharmaceuticals and sharps waste, and the potential ramifications to health and safety of residents as well as the environment if these wastes are not properly disposed. Public awareness of the Take-Back Program will be essential for successful implementation of the program. The Working Group recommends that full implementation of a public awareness program take place after the Ordinance is adopted because it is important to have a safe, convenient and sustainable program in place to facilitate the collection of unwanted pharmaceutical and sharps waste prior to undertaking a significant public awareness campaign about improper disposal. This will also ensure that the public awareness program is funded, since it would be part of the EPR program.

Stakeholder Engagement:

In advance of preparing the draft Ordinance, as directed by the August 11, 2015, motion, the Working Group has initiated a robust stakeholder engagement process and Communications Plan. This plan is aimed at increasing awareness about the importance of proper disposal of pharmaceutical and sharps waste, and current efforts are focused on communicating about the development of a County ordinance with stakeholders and the public at large. The plan includes the following elements:

- **Pharmaceutical Take-Back Webpage** The County has developed a webpage dedicated to providing those interested a central hub for information related to the stakeholder process, including meeting details, and the overall purpose of this effort. The web address is http://publichealth.lacounty.gov/pharma.htm.
- Stakeholder and Public Awareness Meetings As part of the initial process, two meetings took place on September 28, 2015, at the Kenneth Hahn Hall of Administration to allow stakeholders to provide their initial feedback regarding the Board motion. The meeting included representatives from the Pharmaceutical Industry, pharmacies, hospitals, product stewardship advocates, environmental organizations, wastewater agencies, retailers, and sharps manufacturers, which serve as a Technical Advisory Group for the effort and who will be most directly affected by the implementation of the Ordinance. The afternoon meeting included

the general public and other stakeholders. Additional stakeholder and public meetings will take place during the development process of the Ordinance.

- **Webinar** The Working Group has set-up a webinar to increase the audience and facilitate easy access to the meetings live online.
- Dedicated E-mail Address (<u>EPR@lacounty.gov</u>) to Obtain Feedback/Input A specific electronic e-mail address has been set-up so that members of the public, stakeholders, and other organizations will be able to provide comments to the Working Group for their consideration. Comments expressed by the public, and in stakeholder meetings, and through mail and e-mail will be reviewed and considered by the Working Group prior to the final development of the draft Ordinance.
- Creation of a Stakeholder Database The Working Group has developed a stakeholder database, which includes all stakeholder contact information (industry, government, working group, etc.), feedback received at stakeholder meetings as well as which stakeholder provided comments, meeting notes, calendar of meetings, and resource files. The database has been a valuable resource to maintain coordination between several departments involved in the Working Group. The database will provide a mechanism to assure stakeholder feedback is documented in an organized and easily accessible location.
- Announcements of the Public Meetings Flyers have been created to announce
 the initial public meetings. The Working Group expects to continue the use of this
 conventional outreach as well as other mediums for timely meeting announcements
 to the public.
- Invitation to Participate in Meetings with County Representatives Meeting invitations have been extended to stakeholders via e-mail including the pharmaceutical industry and other stakeholders interested in the ordinance development.

Item 3: Support and Pursue Extended Producer Responsibility Legislation and Take-Back Programs for Sharps and Pharmaceuticals at the State Level, Consistent with the County's Adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future

The 2015-16 State Legislative Agenda item 2.7.12 directs the County's Sacramento advocates and County Departments to "Support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability." During the current legislative session only one bill related to EPR and sharps or pharmaceuticals was introduced in the Legislature, as described below.

Assembly Bill 1159

During the first year of the 2015-16 State legislative session, Assembly Bill 1159 (AB 1159) was introduced by Assembly Member Richard Gordon. AB 1159 would require a product stewardship organization to submit a product stewardship plan to the Department of Resources Recycling and Recovery (CalRecycle) by July 1, 2017, for covered products, which are defined as home-generated sharps waste and household batteries. The Stewardship Organization would be required to carry-out the plan as a pilot program until January 1, 2024, and to submit annual reports to CalRecycle describing activities of the program and whether performance standards established by CalRecycle are met.

The County expressed its support to its legislative advocates in Sacramento soon after AB 1159 was introduced by Assembly Member Richard Gordon. AB 1159 is a 2-year Bill at the request of the author in order to provide additional time for debate and general discussion on the merits of the Bill, which may be brought back for legislative consideration in early 2016. The County will continue to express its support for AB 1159, so long as it remains consistent with the County's legislative agenda and will evaluate and support other relevant EPR Bills related to pharmaceutical and sharps waste, as they arise.

Next Steps

As directed by the Board in the August 11, 2015, motion, the Interim Chief Executive Officer, the Sustainability Council, and the Working Group are conducting stakeholder meetings to solicit feedback, analyzing similar ordinances and discussing those ordinances with the various jurisdictions in the State, and reviewing best practices of EPR implementation from around the world, prior to drafting the County's EPR Ordinance.

Upon consideration and adoption of the Ordinance by the Board, regulations will be developed including a product stewardship plan for the Take-Back Program. The stewardship plan for the Pharmaceutical Take-Back Program by manufacturers and producers will include, among other things: (1) collection services; (2) handling and disposal procedures; (3) public education and outreach strategies; and (4) tracking reports of disposal amounts, short-term and long-term goals for collection amounts, and educational and promotional outreach to residents.

APPENDIXA



GAIL FARBER, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

To Enrich Lives Through Effective and Carino Service

900 SOUTH FREMONT AVENUE ALHAMBRA, CALIFORNIA 91803-1331 Telephone (626) 453-7100 http://dpw.lacouruy.gov

ADDRESS ALL CORRESPONDENCE TO P.O. BOX 1460 ALHAMBRA, CALIFORNIA 91809-1460

IN REPLY PLEASE

REFER TO THE

EP-4 A4272

TO:

Each Supervisor

FROM:

July 2, 2015

Gail Farber Law Farker

Director of Public Works

BOARD MOTION OF JUNE 2, 2015, ITEM 78-A
MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE
IN THE COUNTY OF LOS ANGELES

On June 2, 2015, the Board approved a motion introduced by Mayor Michael D. Antonovich, as amended, directing the Director of Public Works, in coordination with the Interim-Chief Executive Officer; County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue Extended Producer Responsibility (EPR) legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5.

Each Supervisor July 2, 2015 Page 2

The attached report is in response to items 4 and 5 of the motion. Below is a summary of the findings and conclusion of the report.

Item 4: Pharmaceutical Take-Back Ordinance

The County Departments and Agency listed in the motion formed a Working Group to evaluate the feasibility of adopting an ordinance similar to the pharmaceutical waste take-back ordinances adopted by the Counties of Alameda (July. 10, 2012), San Francisco (March 17, 2015). San Mateo (May 19, 2015). and Santa Clara (May 28, 2015).

Utilizing the principle of EPR, an environmental policy introduced in Sweden in 1990, these Counties adopted ordinances that mandate drug manufacturers design and implement a safe take-back and disposal program. Based on this premise and for the additional reasons cited below, the Working Group has determined that a similar ordinance is feasible for the County:

- The United States Drug Enforcement Agency promulgated regulations at, inter alia, 21 CFR Parts 1317, et seq. in 2014 allowing the collection of controlled substances at collection receptacles, take-back events, and mail-back programs.
- To date, there is no voluntary or mandatory Statewide product stewardship program for unwanted or expired pharmaceuticals or sharps waste in California.
- Publicly financed take-back programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County.
- The California Medical Waste Management Act allows local jurisdictions to promulgate more stringent requirements to dispose of medical waste pursuant to Health and Safety Code section 117800.
- In May of this year, the United States Supreme Court declined to review a challenge to Alameda County's Drug Disposal Ordinance. The Court's decision upholds the 9th Circuit Court of Appeals' opinion of September 30, 2014, which found that the ordinance, requiring pharmaceutical manufacturers to fund drug take-back programs in the County, did not interfere with interstate commerce or discriminate against out-of-state manufacturers.

Item 5: Utilization of the County's Purchasing Power to Negotiate a Take-Back Program

The Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3 percent of the overall pharmaceutical sales in Los Angeles County.

Each Supervisor July 2, 2015 Page 3

Recommendation

The Working Group recommends the Board adopt an EPR ordinance similar to those adopted by the Counties of Alameda, San Francisco, San Mateo, and Santa Clara requiring manufacturers/producers to develop and finance a product stewardship plan that addresses a take-back program, identifying at a minimum:

- Collection systems and services, including drop-off sites, collection events, and mail-back services;
- Handling and disposal procedures that are safe and in compliance with applicable Federal and State laws;
- Public education and outreach promotion strategies; and
- Tracking reports of disposal amounts, short-term and long-term goals for collection amounts, and education and promotion programs.

Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County, but contain other components, such as over-the-counter pharmaceutical waste. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the Working Group has considered these risks and believes that they are outweighed by the benefits of achieving the policy goals.

Next Steps

Upon the Board's direction, the Working Group will prepare a draft EPR ordinance with participation of stakeholders that ensures the safe and convenient take-back and disposal of sharps and pharmaceutical waste by producers and manufacturers. Additionally, the Working Group will report back to the Board by October 2, 2015, regarding items 1-3 of the June 2, 2015, Board order.

If you have any questions regarding this matter, please contact me or your staff may contact Shari Afshari at (626) 458-4008.

CS:ao

h/adhome/ag/EPD/Pharma EPR Cover Memo

Attach.

cc: Chief Executive Office (Sachi A. Hamai, Rochelle Goff), County Counsel, Executive Office, Department of Health Services, Internal Services Department, Department of Mental Health, Department of Public Health, Sheriff's Department, Sanitation Districts of Los Angeles County

MANAGING UNUSED AND EXPIRED MEDICATIONS AND SHARPS WASTE IN THE COUNTY OF LOS ANGELES

A report on the feasibility of adopting a pharmaceutical take-back ordinance and utilizing the County's purchasing power to negotiate take-back programs

July 2, 2015

PREPARED BY:

Chief Executive Office
County Counsel
Department of Health Services
Internal Services Department
Department of Mental Health
Department of Public Health
Department of Public Works
Sheriff's Department
Sanitation Districts of Los Angeles County

Contents

INTRODUCTION	1
MOTION	1
BACKGROUND	1
Health and Safety Issues	
Environmental Issues	3
Financial Issues	3
OPTIONS FOR MANAGING PHARMACEUTICAL AND SHARPS WASTE	4
DISPOSAL	4
TAKE-BACK AND MAIL-BACK	5
Utilizing the County's Purchasing Power for Take-Back	5
Publicly Financed Take-Back Program	5
Establishing a Privately Financed Take-Back Program	6
A SUSTAINABLE SOLUTION	
RECOMMENDATION	8
PHARMACEUTICAL AND SHARPS WASTE EPR ORDINANCE	8
NEXT STEPS	9
DRAFT ORDINANCE	
CONDUCT OUTREACH	9

INTRODUCTION

MOTION

On June 2, 2015, the Board of Supervisors approved a motion introduced by Mayor Michael D. Antonovich directing the Director of Public Works, in coordination with the Interim Chief Executive Officer; County Counsel; the Sheriff; the Directors of Health Services, Internal Services, Mental Health, and Public Health; and the County Sanitation Districts to:

- Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the pharmaceutical industry to develop a public awareness campaign
 to educate residents on the importance of how to properly store and dispose of
 unused medication and the negative effects to the environment when medication
 enters the waste stream and waterways;
- Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco, and Santa Clara; and
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs.

Report back within 4 months with findings and recommendations for items 1-3 and report back in 30 days for items 4 and 5. The County Departments and Agency listed in the motion formed an Extended Producer Responsibility Working Group (EPR Working Group) to prepare this report, which is in response to items 4 and 5 of the motion.

BACKGROUND

Pharmaceuticals play a critical role in treating diseases and saving lives. However, there are times consumers of pharmaceuticals no longer need the supply that is in their possession – for example, their physician has changed their medication therapy, the medication is expired, or a patient in a long-term care facility has died. Current options for managing this excess pharmaceutical supply, or pharmaceutical waste, are limited. Pharmaceutical waste includes unused and/or expired over-the-counter or prescription tablets, oral liquids and injectable products, but also may contain biomedical or biohazardous waste. For this reason, pharmaceutical waste disposal options must provide for the management of biomedical and biohazardous waste as well as disposal of devices commonly used to

puncture the skin (e.g., syringes/needles) that are also used by consumers to inject pharmaceuticals. The U.S. Environmental Protection Agency (USEPA) states that "reducing, minimizing, or eliminating leftover drugs represents a very significant opportunity to improve both ecological and human health while also reducing expenses associated with medical care and waste treatment." In addition, improper management of discarded sharps waste such as needles, syringes, and lancets can pose a health risk to residents, including certain classes of workers and children.²

The safe disposal of pharmaceutical and sharps waste is a public safety and environmental need that calls for safe, convenient, and sustainable disposal options for residents in Los Angeles County.

Health and Safety Issues

According to the National Community Pharmacists Association (NCPA), an estimated 200 million pounds of unused or expired prescription drugs are stored in medicine cabinets across America.³ Given the limited waste disposal options available and the fact that many County residents are unsure of how to safely and properly dispose of pharmaceutical and sharps waste, there is an opportunity for Los Angeles County to take action to provide additional waste disposal options.

Improperly disposed sharps waste poses an additional set of concerns and risks to health professionals, pharmacists, law enforcement professionals, and the waste management industry as these individuals may unexpectedly encounter disposed needles and other related waste. The USEPA estimates that about 8 million people in the United States use more than 3 billion needles, syringes, and lancets, collectively known as "sharps," each year.4 Once used, these sharps are termed "home generated" medical waste, and by State law,5 are prohibited from disposal in regular trash cans or recycle bins. The volume of home generated sharps waste has been growing in recent years, and many people are unaware of what to do with their used sharps and end up throwing them in the trash despite the law. According to the USEPA "people at the greatest risk of being stuck by used sharps include sanitation and sewage treatment workers, janitors and housekeepers, and children." Much of the home-generated waste is sorted and processed before landfilling, which exposes sanitation workers and others to potentially dangerous conditions. According to the USEPA, all needle-stick injuries are treated as if the needle were infected with a disease. Victims of sharps-related injuries face the cost of post-injury testing, disease prevention measures, and counseling, even if no infection or disease was spread.

¹ Drug Disposal & Stewardship: Ramifications for the Environment and Human Health (USEPA, Sept. 2014)

² Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

³ DisposeMyMeds.org (NCPA, downloaded June 17, 2015)

⁴ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

⁵ California Health and Safety Code §118286

⁶ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

Some diseases can take a long time to appear on test results, leading to months of testing and apprehension.

Environmental Issues

The World Health Organization (WHO) recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources, and some drinking-waters." Pharmaceuticals can enter the environment through multiple pathways, including being poured down the drain, being flushed down toilets, or via trash disposal, which can result in landfill leachate that may enter groundwater. All landfills generate leachate – the product of moisture in the deposited trash and rainfall on the surface of the landfill that collects over time. In landfills operated by the Sanitation Districts of Los Angeles County and most large landfills, the leachate is collected and treated at local wastewater treatment plants. However, municipal wastewater treatment plants in Los Angeles County are not designed to manage or remove all of the complex compounds in pharmaceutical waste, and cannot be cost-effectively retrofitted to do so. The long-term environmental impacts of the presence of pharmaceuticals in groundwater and surface water bodies are unknown; therefore, it is prudent to encourage other methods of disposal.

Financial Issues

The Los Angeles County Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely and anonymously drop off their expired and unused pharmaceutical and sharps waste. In 2013, the Sheriff's program collected about 20,000 pounds of pharmaceutical waste and 26,000 pounds of sharps waste, at a cost of over \$34,000 and \$48,000, respectively, funded through the Sherriff's Department existing budget and personnel. However, this program by itself is simply not adequate to process the volume of pharmaceutical and sharps waste produced in the County.

In addition, the County's Household Hazardous Waste (HHW) Program, managed by Public Works, also collects non-controlled pharmaceutical and sharps waste from residents at weekly HHW collection events and designated collection centers. The \$10 million HHW Program is primarily funded by a Countywide fee collected based on the total amount of solid waste disposed. This funding source is anticipated to substantially decrease as the State proceeds to achieve its policy goal to recycle at least 75% of the waste by 2020, and the County achieves its ambitious waste diversion goals identified in the County's Roadmap to Sustainable Waste Management Future. It is difficult to calculate the exact costs for the collection and management of pharmaceutical and sharps waste from the total HHW Program costs, but they are estimated to be in the range of \$500,000 per year or more. As the County's population continues to increase, demands on these programs will grow, while funding is anticipated to decrease as described above. At the same time, providing for proper management of pharmaceutical and sharps waste for all County residents solely

⁷ Ibid.

⁸ Information sheet: Pharmaceuticals in drinking-water (WHO, 2012)

through the HHW Program would require significant additional resources, which is not financially sustainable in the long term.

OPTIONS FOR MANAGING PHARMACEUTICAL AND SHARPS WASTE

Existing options for managing pharmaceutical and sharps waste are described below:

DISPOSAL

Disposal practices that involve placing medications in household trash, pouring them down the drain, or flushing them down the toilet potentially pose a threat to the environment. The U.S. Food and Drug Administration (FDA) recommends that, if take-back options are not available, certain pharmaceutical waste "that may be especially harmful and, in some cases, fatal with just one dose" should be "flushed down the sink or toilet as soon as they are no longer needed." However, the California Department of Resources Recycling and Recovery (CalRecycle) notes "wastewater treatment plants are not designed to remove pharmaceuticals and studies show that exposure to even low levels of drugs has negative effects on fish and other aquatic species, and also may negatively affect human health. Thus, we recommend households do not dispose of waste medication down the drain or down the toilet." 10

In addition, California Law prohibits the placement of sharps waste in trash or recycling bins, and requires that sharps waste be placed in special container to minimize the risk of injury and prevent leakage or expulsion of waste contents during storage and transport.¹¹ Therefore, home disposal of sharps waste is not an option.

There is broad consensus, including among the FDA,¹² USEPA¹³ and the pharmaceutical industry,¹⁴ that take-back programs that promote incineration disposal methods are the preferred choice for proper disposal of expired or unwanted prescription and over-the-counter medication. The USEPA recommends incineration as the preferred method of disposal to address both environmental concerns and concerns regarding improper use of pharmaceuticals.¹⁵ The USEPA notes "studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing [down the drain/toilet]. Further, some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Incineration of unwanted household pharmaceuticals

⁹ Disposing of Unused Medicines: What You Should Know (FDA, downloaded June 17, 2015)

¹⁰ Household Medication Waste Disposal (CalRecycle website, downloaded June 17, 2015)

¹¹ California Health and Safety Code §§118275-118320

¹² Disposing of Unused Medicines: What You Should Know (FDA website, downloaded June 17, 2015)

¹³ Community Options for Safe Needle Disposal (USEPA, Oct. 2004)

¹⁴ Safe Disposal of Prescription Medication and Environmental Protection (Pharmaceutical Research and Manufacturers of America website, downloaded June 17, 2015)

¹⁵ Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (USEPA Memorandum, Sept. 2012)

will reduce the amount of household pharmaceuticals that are disposed by both flushing and land filling "16".

TAKE-BACK AND MAIL-BACK

Take-back programs are a simple, safe and efficient option to provide for the environmentally safe collection and disposal of pharmaceutical and sharps waste. Through such programs, pharmaceutical and sharps waste are properly contained, incinerated and/or safely disposed. Take-back programs should include a mail-back option, which helps to ensure that the take-back program is accessible to all County residents free of charge, including those who are home bound, live in remote or rural areas, or have a large quantity of pharmaceutical and/or sharps waste that requires disposal. A take-back program with a mail-back option provides for the disposal of pharmaceutical and sharps waste that can be financially, socially, and environmentally sustainable. Three options for implementing a take-back program are discussed below:

Utilizing the County's Purchasing Power for Take-Back

An option considered was the use of the County's pharmaceutical purchasing power to negotiate contracts. However, after review and consideration, the EPR Working Group does not recommend pursuing this strategy. While the County's purchasing power is prominent in many areas based on its sheer volume, most retail pharmaceutical purchases are attributed to the thousands of community and retail pharmacies located within the County. County pharmaceutical purchases make up less than 3% of the overall pharmaceutical sales in Los Angeles County.¹⁷

Publicly Financed Take-Back Program

Today in Los Angeles County, publicly financed take-back programs are the only safe options for residents to dispose of sharps and pharmaceuticals. However, these programs are currently not adequate to manage the amount of unused pharmaceuticals produced in the County. Currently, the County's program relies on a network of pharmaceutical and sharps waste drop-off locations at Sheriff Stations and designated County health centers; however, these limited locations have faced difficulty with safely handling the volume of pharmaceutical and sharps waste, particularly given the types of waste disposed of by consumers and the volume of waste. The County's HHW Program may not provide a convenient location to every resident in a timely manner to manage their sharps or pharmaceutical waste. Expanding these programs sufficiently would require additional resources; however, as discussed above, the Countywide HHW Program is facing anticipated decreases in funding. Given the limited public take-back options due to funding requirements, the County cannot assume the sole responsibility for developing, financing, advertising, and implementing take-back programs. In addition, a recent study by the City

¹⁶ Ibid.

¹⁷ KFF Total Retail Soles for Prescription Drugs Filled at Pharmacies (KFF Website, Downloaded June 25, 2015)

of San Francisco suggests that residents prefer dropping off pharmaceuticals at pharmacies rather than police stations by a wide margin. 18

Establishing a Privately Financed Take-Back Program

In November 2008, the Los Angeles County Board of Supervisors adopted a resolution supporting the principle of Extended Producer Responsibility (EPR). EPR is an environmental policy approach credited as being officially introduced in Sweden in 199019 in which a manufacturer or producer's responsibility for a product is extended to the postconsumer stage of a product's life cycle. Manufacturers would be required, either individually or collectively, to establish a comprehensive take-back program, along with a plan to ensure the program effectively collects the pharmaceutical products at the end of their useful life. In addition to assuming a share of the costs, EPR can lead to better results overall since manufacturers know their product and industry better and can design and operate collection and disposal programs which are more efficient and effective than those implemented by local governments. A take-back program financed by the pharmaceutical industry would share the responsibility for managing unused/expired pharmaceuticals and sharps and relieve the current burden on publicly funded efforts. This program would include handling the shipping costs incurred through the use of a mail-back option for consumers. According to the Product Stewardship Institute, the EPR approach has been successful in managing pharmaceutical and sharps waste for years throughout some European countries, Mexico, and Canada.²⁰

The State Board of Pharmacy is in the process of establishing regulations for pharmaceutical take-back within pharmacies. As the Drug Enforcement Agency regulations also allow take-back within hospitals and long-term care facilities when overseen by a pharmacy, the regulations will include these additional access areas as well.

Generally, EPR programs are more effective when adopted uniformly for a geographically large area, allowing for improved economies of scale for outreach and collection costs while minimizing confusion that may arise over the boundaries of local programs. However, previous attempts to pass Statewide EPR legislation for pharmaceuticals and sharps in California have not been successful. On July 10, 2012, Alameda County was the first County in the nation to adopt an EPR ordinance for pharmaceutical waste at the local level. Alameda County's Safe Drug Disposal ordinance was challenged by the pharmaceutical industry in District Court, and when it was upheld, appealed to the Ninth Circuit Court of Appeals which also upheld the ordinance. On May 26, 2015, the United States Supreme Court decided that it would not review the case, leaving the Ninth Circuit Court decision in

¹⁸ San Francisco's Safe Medicine Disposal Pilot Program Update (San Francisco Public Utilities Commission, Jan. 2013)

¹⁹ The Concepts of Extended Producer Responsibility and Product Stewardship (Institute For Local Self-Reliance Website, Downloaded June 25, 2015)

²⁰ Myths vs. Reality: Extended Producer Responsibility for Pharmaceuticals (Product Stewardship Institute, factsheet downloaded June 17, 2015)

place. Also, this year three additional Counties in California–Santa Clara, San Francisco, and San Mateo-have adopted similar ordinances.

A SUSTAINABLE SOLUTION

Adopting an EPR ordinance to establish a privately financed take-back program for pharmaceutical and sharps waste is a sustainable and effective approach, since it requires the manufacturers, as producers of pharmaceutical products and sharps, to incorporate into the price of their products the cost of managing the products at the end of their useful life. Manufacturers can partner with pharmacies to establish take-back locations, which would be more convenient to residents, and it is anticipated that financing these programs will have minimal impact on the retail costs of pharmaceuticals or sharps.^{21,22}

On October 21, 2014, the Board of Supervisors adopted the Roadmap to a Sustainable Waste Management Future (Roadmap). The Roadmap identifies strategies and initiatives to reduce waste and divert material from landfills. One of the initiatives identified is to advocate for EPR, including exploring the feasibility of establishing a County EPR ordinance for materials such as pharmaceutical and sharps waste.

Additionally, supporting shared responsibility with manufacturers for the impacts and management costs of their products at the end of life is consistent with the County's Legislative Agenda, which states that the County will "support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability."²³ This policy was established following the Board of Supervisors adoption on November 5, 2008, of a resolution "supporting Extended Producer Responsibility and directing the County's Legislative Advocates in Sacramento to actively pursue legislation and Statewide policies that shift end-of-life product management costs from local government to the manufacturers and incentivize the redesign of products that have impacts on public health and the environment."

The overall efforts are in line with the June 2014 County Strategic Plan Goal No. 2, Strategic Initiative 5, Environmentally Sustainable Practices which identifies a specific focus area promoting net-zero waste in order to "optimally manage and reduce solid waste by diverting from waste stream and maximizing recycling opportunities."

²¹ Ibid.

²² Economic Impacts of the B.C. Recycling Regulation (British Columbia, CN Ministry of Environment, August 2008)

^{23 2015-16} State Legislative Agenda, Section 2.7.12 (Los Angeles County, Dec. 2014)

RECOMMENDATION

The Board directed that the Department of Public Works in coordination with the Chief Executive Office, County Counsel, the Sheriff, Health Services, Internal Services, Mental Health, Public Health, and the County Sanitation Districts address the issue of take-back programs for pharmaceutical products. This EPR Working Group recommends the Board adopt a pharmaceutical and sharps waste EPR ordinance in which pharmaceutical manufacturers and producers would develop and fund take-back programs providing collection services that are reasonably convenient and adequately meet the needs of the population being served.

PHARMACEUTICAL AND SHARPS WASTE EPR ORDINANCE

Group recommends that this ordinance Working require manufacturers/producers of prescription and nonprescription drugs (including controlled and non-controlled substances) as well as sharps to develop product stewardship take-back program(s) to collect and dispose of unused/unwanted pharmaceutical and sharps waste from consumers. Ordinances adopted by San Francisco, San Mateo, and Santa Clara were modeled after Alameda County's ordinance, but contain other components, such as overthè-counter pharmaceutical waste, as well as requiring other best practices. As these other ordinances have not been tested legally, there is potential risk of legal challenge associated with including these other components. However, the EPR Working Group has considered these risks and believe that they are outweighed by the benefits of achieving the policy goals.

All pharmaceutical manufacturers/producers would be subject to the same requirement to design and implement a take-back program, and they would be able to choose whether to meet these requirements individually or by joining with others. Manufacturers/producers would have the flexibility to design the take-back program to meet performance goals established by the County. The County would be responsible for oversight of the program(s), for ensuring that the program(s) are transparent and readily accessible to the public, and that a thorough outreach program is implemented.

Participation by retail pharmacies, hospitals, and long-term care facilities would be voluntary, and interested pharmacies would work directly with the pharmaceutical producers to join the program. Any pharmacies, hospitals, or nursing homes that choose to participate would provide collection bins for pharmaceutical and sharps waste, contribute floor space and staff time to manage the collected materials and answer consumers' questions. The EPR Working Group recommends that the ordinance authorize pharmaceutical manufacturers/producers to provide financial incentive to participating pharmacies. The EPR Working Group also recommends the ordinance require any retail pharmacy not participating as a collection point, at minimum to advertise options available for proper disposal, including the locations of participating pharmacies and how to make use of mail-back programs.

NEXT STEPS

DRAFT ORDINANCE

Upon the Board's direction, the EPR Working Group will prepare a draft pharmaceutical waste and sharps waste EPR ordinance with the participation of stakeholders. The ordinance would be drafted as a Countywide ordinance, however it is anticipated that each city wishing to participate would need to take additional action, as the ordinance may only be enforceable in a city's jurisdiction after the city takes action to adopt the County ordinance by reference.

Additionally, the EPR Working Group will report back to the Board by October 2, 2015, with findings and recommendations related to items 1-3 of the Board motion as stated on page 4 of this report.

CONDUCT OUTREACH

If the Board directs the EPR Working Group to move forward with drafting an ordinance, the EPR Working Group will initiate stakeholder engagement to the pharmaceutical industry and other stakeholders to solicit their feedback. The EPR Working Group would work together to develop a refined list of stakeholders and host public information meetings. The meetings would be organized to provide industry and other stakeholders with an opportunity to share and discuss their comments and concerns regarding the concept of a pharmaceutical and sharps waste EPR ordinance.

The following target audiences and types of stakeholders have been identified for outreach. A more specific and extensive list will be developed based on the experiences of other Counties that have developed similar ordinances.

Stakeholder Engagement Objectives:

- Communicate the need to provide safe, convenient, and sustainably financed take-back
 options for consumers to properly dispose of pharmaceutical and sharps waste
- Obtain feedback from industry and other stakeholders
- Generate awareness about the EPR program

Target Audiences:

- General Public
- Drug Abuse Advocacy Groups
- Waste Management Companies
- Environmental Advocacy Groups
- Senior Citizen Advocacy Groups
- Pharmacy Industry Representatives and Associations
- Pharmaceutical Manufacturers and Associations.
- Cities within Los Angeles County
- Veterinarian Organizations
- Health Care Provider Organizations

VII. MISCELLANEOUS

- 78. Additions to the agenda which were posted more than 72 hours in advance of the meeting, as indicated on the supplemental agenda. (12-9995)
- 78-A. Recommendation as submitted by Supervisor Antonovich: Instruct the Director of Public Works, in coordination with the Interim Chief Executive Officer, County Counsel, Sheriff, the Directors of Health Services. Internal Services, Mental Health and Public Health, and the County Sanitation Districts to report back within 4 months with the findings and recommendations on the following:

Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education and improving the current management system for unused/expired medications in the County;

Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;

Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;

Investigate the feasibility of adopting an ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa; and

Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back.

Supervisor Antonovich revised Recommendation Nos. 4 and 5 to request a report back to the Board in 30 days.

On motion of Supervisor Knabe, seconded by Supervisor Antonovich, this item was approved as amended. (15-2619)

Ayes:

5 - Supervisor Solis, Supervisor Ridley-Thomas,

Supervisor Kuehl, Supervisor Knabe and

Supervisor Antonovich

Attachments:

Motion by Supervisor Antonovich

Report Video Audio

AGN.	NO.	

MOTION BY MAYOR MICHAEL D. ANTONOVICH

JUNE 2, 2015

Managing unused/expired medications is a growing concern facing the County of Los Angeles. According to the National Community Pharmacists Association, an estimated 200 million pounds of unused or expired prescription drugs are stored in American medicine cabinets. They often end up in the wrong hands where inappropriate use can lead to addiction, abuse, serious injury, and even death. According to a report released by the Department of Public Health, in 2013 there were more than 500 deaths, 3,000 hospitalizations and 5,000 emergency visits associated with prescription and over the counter drug overdose in Los Angeles County.

New studies are also demonstrating that pharmaceuticals have an impact on our environment. The World Health Organization recently reported that "a number of studies found trace concentrations of pharmaceuticals in wastewater, various water sources and some drinking-waters." Municipal wastewater treatment plants are not designed to remove the complex compounds in drugs that end up in the sewer system.

Pharmaceuticals delivered via needles pose an additional set of concerns, posing a risk to health professionals as well as public and private employees in law enforcement and waste management that interact with disposed needles and related sharps waste.

These are serious problems impacting the well-being of our communities. In response, the Sheriff's Department has set up collection and drop-off boxes at 21 stations where residents can safely, and anonymously, drop off their expired medications and sharps. The County's Household Hazardous Waste program, managed by Public Works, also collects non-controlled pharmaceuticals and sharps from residents. Unfortunately, the volume of pharmaceuticals is too great for local programs such as this to fully address the problem. We need to do more to increase public awareness of the potential impacts of improper storage and disposal of unused medication and to make it safe and convenient for residents to dispose of unused/expired medications and increase participation.

-MORE-

	MOTION
SOLIS	
RIDLEY-THOMAS	
KUEHL	
KNABE	· · · · · · · · · · · · · · · · · · ·
ANTONOVICH	

I, THEREFORE, MOVE that the Board of Supervisors:

Direct the Director of Public Works, in coordination with the Chief Executive Office; County Counsel; the Sheriff's Department; the Departments of Health Services, Internal Services, Mental Health and Public Health; and the County Sanitation Districts to:

- 1. Investigate options for reducing improper use and disposal of unused/expired medications, increasing public awareness and education, and improving the current management system for unused/expired medications in the County;
- Partner with the pharmaceutical industry to develop a public awareness campaign to educate residents on the importance of how to properly store and dispose of unused medication and the negative effects to the environment when medication enters the waste stream and waterways;
- Actively support and pursue extended producer responsibility legislation and take-back programs for sharps and pharmaceuticals at the State level, consistent with the County's adopted Legislative Agenda and Roadmap to a Sustainable Waste Management Future;
- 4. Investigate the feasibility of adopting an Ordinance similar to the pharmaceutical take-back ordinance adopted by the Counties of Alameda, San Mateo, San Francisco and Santa Clara;
- 5. Investigate the feasibility of utilizing the County's purchasing power to negotiate producer/pharmacy take-back programs; and
- 6. Report back within 4 months with findings and recommendations.

#

MDA:evo pharmaceuticalsdisposal060215

EXHIBIT 4

CalRecycle - Sharps Collection Locations in Los Angeles County

Facility Name	Address	City	ZIP	Telephone	Sup Dist.	Unincorporated	Sheriff's	Sup Dist.	Sup Dist. City Name (GIS)
		(Mail Location)	Code			Area	Sharps Program	(GIS)	
1 Altadena Sheriff's Station	780 E. Altadena Dr.	Altadena	91001	91001 (626) 798-1131	5	Altadena	No	5	Unincorporated
2 Anderson Memorial Senior Citizen Ctr.	828 S. Mesa St.	San Pedro	90731	90731 (310) 548-7596	4		No	4	Los Angeles
3 Antelope Valley Environmental Collection 1200 W. City Ranch Rd. Ctr. (AVECC)	1200 W. City Ranch Rd.	Palmdale	93551	93551 (661) 947-7197	2		No	5	Palmdale
4 Antelone Valley Health Ctr.	335 E. Avenue K6 Ste. B	Lancaster	93535	93535 (661) 723-4526	5		No	5	Lancaster
		Los Angeles	90018	(323) 733-1946	2		No	2	Los Angeles
6 Boyle Heights Senior Citizen Ctr.	2839 E. 3rd St.	Los Angeles	90033	(323) 264-5757	2		No	2	Los Angeles
7 Canoga Park Senior Citizen Ctr.	7326 Jordan Ave.	Canoga Park	91303	91303 (818) 340-2633	3		No	3	Los Angeles
8 Carson Sheriff's Station	21356 S. Avalon Blvd.	Carson	90745	90745 (310) 830-1123	2		No	2	Carson
9 Central Health Ctr.	241 N. Figueroa St.	Los Angeles	90012	90012 (213) 240-8203	1		No	1	Los Angeles
10 Century Sheriff's Station	11703 S. Alameda St.	Lynwood	90262	90262 (323) 568-4752	2		Yes	2	Lynwood
11 City of Agoura Hills door-to-door	Call for appointment.	Agoura Hills	91301	91301 (818) 597-7314	3		No	c	Agoura Hills
program						i		,	2
12 City of Arcadia Public Works Service	11800 Goldring Rd.	Arcadia	91006	91006 (800) 449-7587	2		No	2	Arcadia
13 City of Glendale Environmental	780 Flower St.	Glendale	91201	91201 (818) 548-4030	4		No	4	Glendale
14 Claude Pepper Senior Citizen Ctr.	1762 S. La Cienega Blvd.	Los Angeles	90035	(310) 559-9677	3		No	3	Los Angeles
15 Common Ground	2401 Lincoln Blvd.	Santa Monica	90405	90405 (310) 314-5480	3		No	3	Santa Monica
16 Compton Sheriff's Station	301 S. Willowbrook Ave.	Compton	90221	(#10) 605-6500	2		Yes	2	Compton
17 Costello Senior Citizen Ctr.	3121 E. Olympic Blvd.	Los Angeles	90023	(213) 485-9143	1		No	1	Los Angeles
18 Crescenta Valley Sheriff's Station	4554 N. Briggs Ave.	La Crescenta	91214	91214 (818) 248-3464	5	La Crescenta	Yes	2	Unincorporated
19 Curtis R. Tucker Health Ctr.	123 W. Manchester Blvd.	Inglewood	90301	90301 (310) 419-5325	2		No	2	Inglewood
20 East Los Angeles Sheriff's Station	5019 E. Third St.	Los Angeles	90022	90022 (323) 264-4151	1	East L.A.	Yes	1	Unincorporated
21 East Los Angeles: Washington Blvd. S.A.F.E. Collection Ctr.	2649 E. Washington Blvd.	Los Angeles	90021	90021 (800) 988-6942	1		No No	T	Los Angeles
22 EDCO Recycling and Transfer Ctr.	2755 California Ave.	Signal Hill	90755	90755 (562) 997-1122	4	:	No	4	Signal Hill
23 El Sereno Senior Citizen Ctr.	4818 Klamath Pl.	Los Angeles	90032	(323) 222-2040	1		No	П	Los Angeles
24 Fairfax Senior Citizen Ctr.	7929 Melrose Ave.	Los Angeles	90046	(323) 653-1824	3		No	3	Los Angeles
25 Felicia Mahood MPC	11338 Santa Monica Blvd.	Los Angeles	90025	(310) 479-4119	3		No	3	Los Angeles
26 Glassell Senior Citizen Ctr.	3750 Verdugo Rd .	Los Angeles	90062	(323) 550-8809	1		No	Н	Los Angeles
27 Glendale Health Ctr.	501 N.Glendale Ave.	Glendale	91206	91206 (818) 500-5762	5		No	2	Glendale
28 Harbor St Maintenance Dist. Yard,	1400 N. Gaffey St.	San Pedro	90731	90731 (800) 773-2489	4		No	4	Los Angeles
Mulching Facility AND SAFE Collection									-
29 Highland Park Senior Citizen Ctr.	6152 N. Figueroa St.	Los Angeles	90042	90042 (323) 256-6866	-1		No		Los Angeles
30 Hollywood Wilshire Health Ctr.	5205 Melrose Ave.	Los Angeles	90038	90038 (323) 769-7800	-		No		Los Angeles
31 Homeless Healthcare Los Angeles	512 East Fourth St.	Los Angeles	90057	90057 (213) 617-8408	1		No	1	Los Angeles

CalRecycle - Sharps Collection Locations in Los Angeles County

					onb pier	STATE OF THE STATE			Carlo Carlo Carlo Carlo Carlo
		(Mail Location)	Code			Area	Sharps	(GIS)	
							Program		
32 Industry Sheriff's Station	150 N. Hudson Ave.	Industry	91744	91744 (626) 330-3322	1		Yes	1	Industry
33 Jim Gilliam Senior Citizen Ctr.	4000 S. La Brea Ave.	Los Angeles	80006	90008 (323) 291-5969	2		No	2	Los Angeles
34 Joslyn Senior Ctr.	660 N. Mountain Ave.	Claremont	91711	91711 (909) 399-5488	1		No	=	Claremont
35 Lakewood Sheriff's Station	5130 Clark Ave.	Lakewood	90712	90712 (562) 623-3500	4		Yes	4	Lakewood
36 Lancaster Sheriff's Station	501 W. Lancaster Blvd.	Lancaster	93534	93534 (661) 948-8466	5		Yes	2	Lancaster
37 Las Palmas Senior Citizen Ctr.	1820 N. Las Palmas Ave.	Los Angeles	90028	90028 (323) 465-7787	3		No	3	Los Angeles
38 Lincoln Heights Senior Citizen Ctr.	2323 Workman St.	Los Angeles	90031	90031 (323) 225-9339	1		No	1	Los Angeles
39 Lincoln Park Senior Citizen Ctr.	3501 Valley Blvd.	Los Angeles	90031	(213) 847-1726	1		No	1	Los Angeles
40 Lomita Sheriff's Station	26123 S. Narbonne Ave.	Lomita	90717	(310) 539-1661	4		Yes	4	Lomita
41 Los Angeles City Hall East	200 N. Spring St.	Los Angeles	90012	(213) 473-3231	1		No	1	Los Angeles
42 Los Angeles City Hall South	111 E. First St.	Los Angeles	90012	(213) 485-2121	1		No	1	Los Angeles
43 Los Angeles Department of Public Works	Call for more information.	Los Angeles	91803	91803 (888) 253-2652	1		Yes	0	
44 Los Angeles: Los Angeles-Glendale (LAG)	4600 Colorado Blvd.	Los Angeles	68006	90039 (800) 988-6942	33		No	3	Los Angeles
S.A.F.E. Collection Ctr.									
45 Malibu/Lost Hills Sheriff's Station	27050 Agoura Hills Rd.	Calabasas	91301	91301 (818) 878-1808	3		Yes	33	Calabasas
46 Marina Del Rey Sheriff's Station	13851 Fiji Way	Marina Del Rey	90292	90292 (310) 482-6000	4	Marina Del Rey	Yes	4	Unincorporated
47 Martin Luther King Jr. Ctr.	11833 Wilmington Ave.	Los Angeles	90059	90059 (323) 568-8100	2	Wilmington	No	2	Unincorporated
48 Mid Valley Senior Citizen Ctr.	8801 Kester Ave.	Panorama City	91402	91402 (818) 893-3700	3		No	3	Los Angeles
49 Monrovia Health Ctr.	330 W. Maple Ave.	Monrovia	91016	91016 (626) 256-1642	2		No	2	Monrovia
50 Montecito Heights Senior Citizen Ctr.	4545 Homer St.	Los Angeles	90031	90031 (213) 485-8549	-		No	1	Los Angeles
51 Nicole Bernson S.A.F.E. Collection Ctr.	10241 Balboa Blvd.	Northridge	91325	(800) 998-6942	c		No	3	Los Angeles
52 North Hollywood Senior Citizen Ctr.	11430 Chandler Blvd.	No. Hollywood	91601	(818) 763-7651	e		No	3	Los Angeles
53 Norwalk Sheriff's Station	12335 Civic Center Dr.	Norwalk	90650	(562) 863-8711	4		Yes	4	Norwalk
54 Pacoima Health Ctr.	13300 Van Nuys Blvd.	Pacoima	91331	(818) 896-1903	3		No	3	Los Angeles
55 Palmdale Sheriff's Station	750 Avenue Q	Palmdale	93550	(661) 272-2400	5		Yes	2	Palmdale
56 Pan Pacific Senior Citizen Ctr.	141 S Gardner St.	Los Angeles	90036	(323) 935-5705	3		No	3	Los Angeles
57 Pico Rivera Sheriff's Station	6631 Passons Blvd.	Pico Rivera	09906	(562) 949-2421	1		Yes	-1	Pico Rivera
58 Playa del Rey: Hyperion Treatment Plant	7660 W. Imperial Highway	Playa del Rey	90293	(310) 648-5000	4		No	4	Los Angeles
59 Pomona Health Ctr.	750 S Park Ave.	Pomona	91766	91766 (909) 868-0259	1		No	1	Pomona
60 Porter Ranch Pharmacy	19950 Rinaldi St.	Porter Ranch	91326	91326 (818) 360-1915	2		No	2	Los Angeles
61 Robert M. Wilkinson Multipurpose	8956 Vanalden Ave.	Northridge	91324	91324 (818) 756-7741	m		N 0	æ	Los Angeles
Senior Ctr.	and thaleth 2070	Can Dimac	91773	(909) 450-2700	٠		Yes	ۍ	San Dimas
Santa Clarita Sheriff's Station	23740 W. Magic Mtn. Pkwv.	Valencia	91355		2		Yes	5	Santa Clarita
6. Slauson Senior Citizen Ctr.	5306 S. Compton Ave.	Los Angeles	90011	(323) 846-5392	2		No	2	Los Angeles

CalRecycle - Sharps Collection Locations in Los Angeles County

	Facility Name	Address	City	ZIP	Telephone	Sup Dist.	Sup Dist. Unincorporated Sheriff's Sup Dist. City Name (GIS)	Sheriff's	Sup Dist.	City Name (GIS)	
			(Mail Location)	Code			Area	Sharps	(GIS)		_
								Program			
65	65 South Health Ctr.	1522 E 102nd St.	Los Angeles	90005	90002 (323) 563-4053	2	Athens	No	2	Unincorporated	
99	66 South Los Angeles Sheriff's Station	1310 W. Imperial Hwy.	Los Angeles	90044 (90044 (323) 820-6700	2	Athens	Yes	2	Unincorporated	
29	67 Sun Valley SAFE	11025 Randall St.	Sun Valley	91352 (91352 (800) 773-2489	3		No	3	Los Angeles	
99	68 Sunland Senior Citizen Ctr.	8640 Fenwick St.	Sunland	91040 (91040 (818) 353-9571	5		No	5	Los Angeles	
69	69 Temple Sheriff's Station	8838 E. Las Tunas Dr.	Temple City	91780	91780 (626) 285-7171	5		Yes	5	Temple City	
70	70 Van Nuys City Hall	6262 Van Nuys Blvd.	Van Nuys	91401 (91401 (818) 756-8121	3		No	3	Los Angeles	
71	71 Vineyard Recreation Ctr.	2942 Vineyard Ave.	Los Angeles	90016	90016 (323) 732-2469	2		No	2	Los Angeles	
72	72 Walnut Sheriff's Station	21695 E. Valley Blvd.	Walnut	91789	91789 (909) 595-2264	1		Yes	1	Walnut	
73	73 Watts Senior Citizen Ctr.	1657 E. Century Blvd.	Los Angeles) 20006	90002 (323) 564-9440	2		No	2	Los Angeles	
74	74 West Hollywood Sheriff's Station	780 N. San Vicente Blvd.	W. Hollywood) 69006	90069 (310) 855-8850	3		Yes	3	W. Hollywood	
75	75 West Los Angeles: UCLA S.A.F.E.	550 Charles E. Young Dr.	Los Angeles) 52006	90025 (800) 988-6942	3		Yes	cc	Los Angeles	
	Collection Ctr.										
26	76 Westchester Senior Citizen Ctr.	8740 Lincoln Blvd.	Los Angeles	90045	90045 (310) 649-3317	2		No	2	Los Angeles	
77	77 Whittier Health Ctr.	7643 S. Painter Ave.	Whittier) 20906	90602 (562) 464-5350	4		No	4	Whittier	

3/8/2016

EXHIBIT 5(a)



County of Los Angeles CHIEF EXECUTIVE OFFICE

Kenneth Hahn Hall of Administration 500 West Temple Street, Room 713, Los Angeles, California 90012 (213) 974-1101 http://ceo.lacounty.gov

April 23, 2013

Board of Supervisors GLORIA MOLINA First District

MARK RIDLEY-THOMAS Second District

ZEV YAROSLAVSKY Third District

DON KNABE Fourth District

MICHAEL D. ANTONOVICH Fifth District

To:

Supervisor Mark Ridley-Thomas, Chairman

Supervisor Gloria Molina Supervisor Zev Yaroslavsky Supervisor Don Knabe

Supervisor Michael D. Antonovich

From:

William T Fujioka

Chief Executive Officer

SACRAMENTO UPDATE

Executive Summary

This memorandum contains Pursuit of County Positions on the following product stewardship Legislation:

- AB 403 (Stone). This measure would require businesses that sell medical sharps to establish a produce stewardship plan for the end-of-life management of home-generated medical sharps.
- AB 488 (Williams). This measure would require producers of non-rechargeable household batteries to develop and implement a plan to collect and manage batteries sold in the State.
- SB 727 (Jackson). This measure would require producers of pharmaceutical products sold in the State to develop and implement a program to collect, transport, and process home-generated pharmaceutical drug waste.

Unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers, the Sacramento advocates will support AB 403, AB 488, and SB 727.

Pursuit of County Position on Legislation

AB 403 (Stone), which as amended on April 8, 2013, would require businesses that sell medical sharps to establish a product stewardship plan for the end-of-life management of home-generated medical sharps. Specifically, this bill would: 1) establish the Safe Home-Generated Sharps Recovery Program for home-generated hypodermic needles, syringes with needles attached, pen needles, intravenous needle, or any other similar device intended to self-inject medication at home; 2) require the producers of injection devices to develop and implement a program to collect, transport, and process homegenerated sharps to be overseen by the Department of Resource Recovery and Recycling (DRRR); 3) require, on or before April 15, 2015, medical sharp producers or a stewardship organization designated by medical sharps producers to submit a medical sharps stewardship plan to DRRR; 4) require DRRR to review and approve the plans by January 1, 2016 and to post on its website a list of producers for which the Department has approved a plan; 5) establish administrative civil penalties for any person who violates the requirement of this bill; and 6) direct penalty fees to be deposited into the Safe Sharps Disposal Penalty Account to be used, upon appropriation by the Legislature, to enforce the bill's requirements.

Existing law prohibits a person from knowingly placing home-generated sharps waste in trash or recycling containers and requires that home-generated sharps waste be transported to designated collection centers in sharps containers approved by the local enforcement agency. Existing law also requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.

AB 403 would require, on or before April 1, 2015, medical sharps producers or a stewardship organization designated by medical sharps producers to submit a plan to DRRR to do all of the following: 1) include the development and implementation of a recovery program to reduce the generation and manage the collection, transporting, processing, disposal of home generated medical sharps; 2) include provisions to meet collection rates of 25 percent and 20 percent to be met in 2016 and 2017, respectively. In subsequent years, the plans will be required to meet collection rates established by DRRR; 3) include a mechanism to provide sufficient funding to carry out the program; 4) include education and outreach for consumers, the medical community, and retailers that would promote the collection of home-generated sharps; 5) provide for a home-generated sharps collection point to be established in every county in the State, and that the number of home-generated sharps collection points is equal to at least one for every 25,000 people in the State; 6) require that the funding mechanism be an amount that cumulatively will adequately fund the program; and 7) require that home-generated medical sharps producers, and not

consumers, are responsible for implementing the home-generated sharps stewardship program.

According to the Department of Public Works (DPW), despite existing law making it illegal to dispose of home-generated sharps waste in trash or recycling containers, local jurisdictions were not mandated to implement new collection programs for home-generated sharps waste. However, local governments, by default, have carried the financial burden of managing home-generated sharps collection programs. In an effort to assist residents comply with the law, DPW took a proactive role and launched the County Home-Generated Sharps Waste Management Program in July 2008. Through this program, DPW partners with several cities, County departments, Goodwill stores, and other public/private organizations to provide locations throughout the County for residents to obtain sharps containers free of charge, as well as locations to dispose of filled sharps containers properly free of charge. In addition, the County offers a free mail-back program to qualified elderly and disabled residents.

The Department indicates that the total cost to operate the sharps program since its inception has been approximately \$500,000. This includes the purchase of sharps waste containers, advertising, administrative costs, and costs to administer contracts for the collection at Sheriff's stations. DPW recommends support of AB 403 because it would place responsibility directly on producers of injection devices to develop and implement a program to collect, transport, and process home-generated sharps, thereby reducing and potentially eliminating the costs involved in administering the County's program as well as freeing up DPW staff to work on other environmental programs.

The Department of Public Health also recommends support of AB 403 because it would help reduce the majority of illegally disposed syringes and sharps at no net cost to the County.

This office, the Department of Public Works, and the Department of Public Health support AB 403. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers, the Sacramento advocates will support AB 403.

AB 403 is sponsored by the California Product Stewardship Council and supported by: Californians Against Waste; California State Association of Counties; the City of Torrance; Clean Water Action; Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force; Rural County Representatives of California; Sierra Club California; and Waste Management, among others. The bill is

opposed by: AdvaMed; BayBio; BIOCOM; California Healthcare Institute; PhRMA, Silicon Valley Leadership Group; and TechNet.

AB 403 passed the Assembly Environmental Safety and Toxic Materials Committee by a vote of 5 to 2 on April 16, 2013. This measure now proceeds to the Assembly Appropriations Committee.

AB 488 (Williams), which as amended on April 8, 2013, would: 1) require, by January 1, 2015, a producer or a household battery stewardship organization created by one or more producers of a household battery to submit to the Department of Resources Recycling and Recovery (DRRR) a household battery stewardship plan, which would be required to include specified elements; 2) require the DRRR to review a household battery stewardship plan submitted to the department within 30 days after receipt and to approve or disapprove the plan, as specified; 3) prohibit a producer, wholesaler, or retailer, on and after April 1, 2015, from selling a household battery unless the plan for that battery is approved by the department; 4) require a producer or the household battery stewardship organization to implement the household battery program pursuant to the household battery stewardship plan, including achieving a specified collection rate; 5) require each producer or household battery stewardship organization implementing a household battery stewardship plan to prepare and submit an annual report and a plan to pay the department a plan review fee, as determined by the department, when submitting the plan to the department and to pay an administrative fee, as determined by the department, when submitting the annual report; 6) provide for the imposition of administrative civil penalties upon a wholesaler or retailer selling household batteries in violation of the bill; 7) authorize the fees and penalties to be expended, upon appropriation by the Legislature, to cover the department's program implementation costs and incentives to enhance recyclability and redesign efforts and to reduce environmental and safety impacts of batteries; and 8) allow a producer or organization that is implementing an approved plan and incurring specified costs to bring a civil action to recover costs, damages, and fees from another producer for failure to comply with the bill's provisions.

As of February 8, 2006, the Department of Toxic Substances Control (DTSC) has classified both rechargeable and single use batteries as "universal waste" (or "u-waste") and banned them from being disposed of in landfills under the California Waste Rule. Existing law also requires retailers of rechargeable batteries to have in place a system for the acceptance and collection of rechargeable batteries.

AB 488 would require producers of single-use primary household batteries or stewardship organizations created by producers to submit a single-use primary household battery stewardship plan to the DRRR. AB 488 would also require battery

producers to fund and operate the stewardship plan to properly manage batteries sold in California, and to increase collection and recycling of batteries 25 percent by 2019.

The Department of Public Works reports that each year, approximately 3 billion dry-cell batteries are purchased to power items such as cell phones, radios, watches, and other products. These batteries are a concentrated source of heavy metals such as lead, mercury, cadmium and nickel and, if improperly disposed, may have a negative impact on the environment or cause serious health risks to humans and animals. DPW indicates local governments are currently held responsible for ensuring the proper collection and management of u-waste, and that the 2006 classification of batteries as u-waste imposed an additional unfunded mandate on local governments to collect and manage household batteries.

In an effort to educate and encourage Los Angeles County residents to properly dispose of their household batteries, DPW partnered with the Los Angeles County Public Library to offer residents free and convenient locations to properly dispose of common household batteries such as AA, AAA, C cells, D cells, 9-volt, rechargeable and "button" cell batteries (e.g., watch, camera, hearing aid, etc.) at designated libraries throughout the County. Additionally, the County offers collection mechanisms for batteries along with other hazardous household items at mobile collection events and designated collection sites throughout the County. DPW estimates that these efforts cost approximately \$100,000 each year, in addition to the costs that the County incurs to properly manage batteries purchased for use by County departments.

The Department of Public Works recommends support of AB 488 because it would help reduce the environmental impact of improper disposal of batteries in the County. Additionally, the bill would significantly reduce the County's current expenditures to properly manage and dispose of batteries.

The Department of Public Health also recommends support of AB 488 because it would help reduce the environmental and safety impacts associated with the improper disposal of household batteries.

This office, the Department of Public Works, and the Department of Public Health support AB 488. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers, the Sacramento advocates will support AB 488.

AB 488 is sponsored by the California Produce Stewardship Council and supported by: the California State Association of Counties; Californians Against Waste; City of Covina; City of Torrance; Green Cities California; Napa County Board of Supervisors; Rural County Representatives of California; Santa Barbara County; Sierra Club California; and Sonoma County, among others. The bill is opposed by: AdvMed; BayBio; California Healthcare Institute; California Manufacturers and Technology Association; Silicon Valley Leadership Group; and TechAmerica, among others.

AB 488 passed the Assembly Natural Resources Committee by a vote of 6 to 3 on April 15, 2013. This measure has been referred to the Assembly Appropriations Committee.

SB 727 (Jackson), as amended on April 3, 2013, would establish the Drug Abuse Prevention and Safe Disposal Program and would: 1) require producers, on or before January 1, 2015, to submit a stewardship plan, which must address both solid and liquid pharmaceuticals to DRRR; 2) require producers to consult with stakeholders when developing the plan; 3) require the plan to address coordination with existing local collection systems; 4) require a minimum of collection sites, including at least one collection service within 10 miles of a resident in the State by 2016 with a 20 percent increase in collection service by 2017; 5) require DRRR to post a list of producers who have submitted a plan on their website; 6) require producers to submit an annual report to DRRR on or before April 1, 2016, and every year thereafter; and 7) authorize DRRR to impose an administrative civil penalty on a person who violates the bill's requirements or impose a fine on a producer or stewardship organization if a stewardship plan is not submitted by January 1, 2015. DRRR would be authorized to expend moneys generated from these fines and penalties, upon appropriation by the Legislature, to enforce the bill's requirements.

Existing law requires every city and county in the State to prepare a Household Hazardous Waste Element and provide for the management of household hazardous waste (HHW) generated by the residents in the jurisdiction. Existing law also declares that cities and counties provide for the collection of HHW generated by residential households to ensure proper handling and disposal of the materials in order to prevent contamination. The law further requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to DRRR, a plan supporting the safe collection and proper disposal of specified waste devices.

SB 727 would require the producers of pharmaceuticals to develop and implement a program to collect, transport, and process home-generated pharmaceutical drug waste to reduce the costs, public health, and environmental impacts of the illegal and unsafe

disposal of this type of medical waste. "Home-generated pharmaceutical drug waste" is a prescription or over-the-counter human or veterinary drug that is a waste derived from a household, including, but not limited to, a multifamily residence.

The Department of Public Works reports that improper disposal of household hazardous waste may pose threats to solid waste workers who unknowingly may handle trash containing toxic chemicals and the general public who may come into contact with groundwater and surface water contamination resulting from the disposal of HHW in the sewer system, sanitary landfills, or storm water systems.

The Department of Public Works recommends support of SB 727 because it would protect the public's health and safety by reducing improper disposal of pharmaceutical wastes which reach landfills or contaminate soil and groundwater. By improving the availability of free and convenient options for residents to manage their expired or unused pharmaceutical, the provisions of SB 727 would also reduce the costs associated with the County's "No Drugs Down the Drain" program, which accepts pharmaceutical waste from residents at HHW collection events, designated collection centers and participating Sheriff's stations.

The Department of Public Health recommends support of SB 727 because it would reduce the environmental impact of improperly disposed home-generated pharmaceutical drugs and would shift responsibility for funding and management of disposal of these products from local governments to producers.

This office, the Department of Public Works, and the Department of Public Health support SB 727. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local government to producers, the Sacramento advocates will support SB 727.

SB 727 is sponsored by the California Product Stewardship Council and Clean Water Action, and supported by: the California State Association of Counties; California Association of Retired Americans; Californians Against Waste; City of Covina; City of Torrance; Community Prevention of Alcohol and Drug Problems; County of Santa Barbara; Environmental Working Group; Monterey Regional Waste Management Authority; National Coalition Against Prescription Drug Abuse; Natural Resources Defense Council; Sacramento Regional County Sanitation District; San Francisco Public Utilities Commission; Sonoma County Water Agency; Sonoma County Waste Management Authority; West Contra Costa Integrated Waste Management; and Yolo

County Waste Advisory Committee, among others. There is no registered opposition to the bill at this time.

SB 727 is scheduled for hearing in the Senate Environmental Quality Committee on May 1, 2013.

We will continue to keep you advised.

WTF:RA MR:AO:ma

c: All Department Heads
Legislative Strategist
Local 721
Coalition of County Unions
California Contract Cities Association
Independent Cities Association
League of California Cities
City Managers Associations
Buddy Program Participants



County of Los Angeles CHIEF EXECUTIVE OFFICE

Kenneth Hahn Hall of Administration 500 West Temple Street, Room 713, Los Angeles, California 90012 (213) 974-1101 http://ceo.lacounty.gov

March 24, 2014

Board of Supervisors GLORIA MOLINA First District

MARK RIDLEY-THOMAS Second District

ZEV YAROSLAVSKY Third District

DON KNABE Fourth District

MICHAEL D. ANTONOVICH Fifth District

From:

To:

William T Fujioka

Chief Executive Officer

Supervisor Gloria Molina

Supervisor Don Knabe, Chairman

Supervisor Mark Ridley-Thomas

Supervisor Michael D. Antonovich

Supervisor Zev Yaroslavsky

SACRAMENTO UPDATE

Executive Summary

This memorandum contains a report on the following:

Pursuit of County Position on Legislation to Support SB 1014 (Jackson). This measure would, among other provisions, enact the Home-Generated Pharmaceutical Waste Collection and Disposal Act to provide for the collection and disposal of home-generated pharmaceutical waste. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability, the Sacramento advocates will support SB 1014.

Pursuit of County Position on Legislation

SB 1014 (Jackson), which as introduced on February 13, 2014, would enact the Home-Generated Pharmaceutical Waste Collection and Disposal Act (Act). SB 1014 would require a producer of certain pharmaceuticals to submit a product stewardship plan for the disposal of home-generated pharmaceutical waste to the California Department of Each Supervisor March 24, 2014 Page 2

Resources Recycling and Recovery (DRRR) by July 1, 2015. This bill would define "home-generated pharmaceutical drug waste" as a prescription or over-the-counter (OTC) human or veterinary drug that is a waste and is derived from a household, including, but not limited to, a multi-family residence or household.

Under SB 1014, the product stewardship plan (Plan) must contain certain elements with regard to the collection and disposal of home-generated pharmaceutical waste which would conveniently and adequately serve the residents of the State. Upon submission of the Plan, a pharmaceutical producer will be required to pay a fee, set by the DRRR. The DRRR will deposit the fees into the Home-Generated Pharmaceutical Waste Program Account, which this bill would create in the Integrated Waste Management Fund. These fees, upon appropriation, would be used to enforce the program. Once the Plan is approved, an entity operating a Plan would be required to take certain actions with regard to the disposal of home-generated pharmaceutical waste and to promote product stewardship programs to consumers, pharmacists, retailers of covered pharmaceuticals, and health care practitioners as to the proper and safe method to dispose of home-generated pharmaceutical waste.

SB 1014 would require a product stewardship plan to include, among other provisions, a description of how collection sites for home-generated pharmaceutical waste may be placed at appropriate retail stores, including pharmacies, and authorize pharmacies to accept the return of these products from a consumer. Development of these plans is intended to help ensure that vulnerable populations are better protected from the risk of unnecessary poisoning due to the improper and/or careless disposal of drugs and illegal resale of drugs, and that the State's drinking water sources are less contaminated by the presence of unwanted and/or expired drugs.

The Department of Public Health (DPH) indicates that there were 8,265 drug-related deaths between 2000 and 2009, and that approximately 61 percent of those deaths involved a commonly abused prescription/over-the-counter drug. DPH further indicates that in 2009 there were 3,048 hospitalizations and 5,382 emergency department visits for prescription/OTC drug overdose among County residents. According to DPH, SB 1014 would create a vehicle to safely dispose of pharmaceuticals based on a producer responsibility model that addresses the public health problems of stockpiling unwanted/expired drugs in the home. DPH notes that these medications can become a prime source for drug abusers. In addition, the disposal of these unwanted/expired drugs down the drain threatens water quality and the public's health and safety.

Each Supervisor March 24, 2014 Page 3

The Department of Public Works (DPW) indicates that SB 1014 is expected to significantly reduce costs currently borne by the County by establishing a producer-funded collection and disposal system which might eventually eliminate the need for the County to provide a separate collection program for pharmaceutical waste. DPW further indicates that SB 1014, if enacted, would protect the public's health and safety by reducing the amount of pharmaceutical waste that reaches landfills.

The Sheriff's Department indicates that prescription drug abuse and hospitalizations for overdoses have skyrocketed in recent years and that the lack of a consistent or convenient disposal option for unwanted pharmaceuticals continues to be a source that fuels the prescription drug abuse epidemic.

This office, the Department of Public Health, the Department of Public Works, and the Sheriff's Department support SB 1014. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability, the Sacramento advocates will support SB 1014.

SB 1014 is co-sponsored by: Alameda County; City and County of San Francisco; California Alliance of Retired Americans; California Product Stewardship Council; and Clean Water Action. SB 1014 is supported, among others, by: Butte County Public Health Department; California State Association of Counties; Cities of Chula Vista, Livermore, Sacramento, and Torrance; County of Santa Clara; Los Angeles County Sheriff's Department; Marin County Board of Supervisors; and the Napa County Board of Supervisors. There is no registered opposition to the bill at this time.

SB 1014 is similar in nature to **County-supported SB 727** of **2013** which failed to move out of the Senate by January 31, 2014, which was the deadline for bills to move out of the house of origin, pursuant to Joint Rule 56.

SB 1014 is scheduled for hearing in the Senate Environmental Quality Committee on March 26, 2014.

We will continue to keep you advised.

WTF:RA MR:VE:RM:ma

c: All Department Heads Legislative Strategist

N/Sacramento Updates 2014/sacto 032414



County of Los Angeles CHIEF EXECUTIVE OFFICE

Kenneth Hahn Hall of Administration 500 West Temple Street, Room 713, Los Angeles, California 90012 (213) 974-1101 http://ceo.lacounty.gov

April 27, 2015

Board of Supervisors HILDA L. SOLIS First District

MARK RIDLEY-THOMAS Second District

SHEILA KUEHL Third District

DON KNABE Fourth District

MICHAEL D. ANTONOVICH Fifth District

To:

Mayor Michael D. Antonovich

Supervisor Hilda L. Solis

Supervisor Mark Ridley-Thomas

Supervisor Sheila Kuehl Supervisor Don Knabe

From:

Sachi A. Har

Interim Chief Executive Officer

SACRAMENTO UPDATE

Executive Summary

This memorandum contains pursuits of County position on the following measures:

- Pursuit of County Position to Support AB 1159 (Gordon). This measure would establish the Product Stewardship Pilot Program, which would require producers and product stewardship organizations of covered products, either home-generated sharps waste or household batteries, to develop and implement a product stewardship plan. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability, the Sacramento advocates will support AB 1159.
- Pursuit of County Position to Oppose SB 119 (Hill) Unless Amended. This measure would make several changes to the State's subsurface installation excavation laws and create an Authority to enforce these laws and assess civil penalties for violations of their provisions. Therefore, unless otherwise directed by the Board, consistent with existing policy to: 1) oppose measures that restrict local control over the public rights-of-way; and 2) minimize the adverse impact of State actions, the Sacramento advocates will oppose SB 119 unless

amended to: 1) clarify the term "excavation" so that it does not place an undue burden on routine road and shoulder grading activities, or post-storm debris removal; and 2) remove the requirement that an excavator, when the excavation is complete, eliminate or camouflage any temporary markings that remain for 45 days or more after a project is completed.

Pursuit of County Position on Legislation

AB 1159 (Gordon), which as amended on April 21, 2015, would establish the Product Stewardship Pilot Program, which would require producers and product stewardship organizations of covered products, either home-generated sharps waste or household batteries, to develop and implement a product stewardship plan by July 1, 2017. The product stewardship plan must include specified elements, including strategies to achieve performance standards and a funding mechanism to provide sufficient funding to carry out the plan. AB 1159 would also impose administrative civil penalties for persons who violate provisions of the bill.

According to the author of AB 1159, home-generated sharps waste and household batteries are widely used. However, there is a lack of convenient disposal and recycling opportunities for consumers for these products which have significant and indisputable end-of-life impacts. The author also states that the regulations established by AB 1159 would be performance-based instead of "command and control," meaning that the product manufacturers would be given certain performance goals for the program, but would be left to develop the compliance mechanisms in the most cost-effective and efficient manner possible and meet the goals set by the State.

The California Integrated Waste Management Act of 1989 requires the reduction, recycling, and reuse of solid waste generated in the State to the maximum extent feasible in an efficient and cost-effective manner to conserve water, energy, and other natural resources. State law also requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.

The Department of Public Works (DPW) reports that extended producer responsibility (EPR), or product stewardship, is a principle which seeks to encourage manufacturers to redesign their products to minimize waste while holding manufacturers accountable for their products at the end of their useful life. By holding manufacturers accountable, EPR ideally encourages improvements in product design that promote environmental

sustainability while also creating a convenient way for product consumers to properly dispose of the items at the end of their useful life. DPW notes that the County has been a consistent supporter of EPR, adopting a resolution and policy in 2008, and is a board member of the California Product Stewardship Council which is a leading advocate for EPR.

The Department of Public Works indicates that, per California regulations, local governments are responsible for ensuring the proper collection and management of universal waste (U-Waste), which includes household batteries. However, local governments do not receive funding from the State to handle disposal. In an effort to educate and encourage Los Angeles County residents to properly dispose of their household batteries, DPW partners with the County of Los Angeles Public Library to offer free battery collection containers for the proper collection of household batteries at designated libraries throughout the County. Other County collection mechanisms for household hazardous waste (HHW) include mobile collection events and permanent centers. The County spends over \$100,000 each year managing efforts related to household battery collection, in addition to the costs to properly manage batteries purchased by County departments.

The Department of Public Works also reports that SB 1305 (Chapter 64, Statutes of 2006) made it illegal to dispose of home-generated sharps waste in the trash or recycling containers, and requires that all home-generated sharps waste be transported to a collection center in a sharps container approved by the local enforcement agency. DPW notes that while local jurisdictions were not mandated to implement new collection programs for home-generated sharps waste, many jurisdictions began providing for the collection of home-generated sharps waste as part of their residential services in order to offer residents a convenient method to comply with the law. In July 2008, DPW launched the Home-Generated Sharps Waste Management Program, a partnership with the Department of Public Health and Sheriff's Department, to provide additional locations for residents to drop off sharps waste in addition to mobile events and permanent collection centers. These sites also serve as distribution points for free sharps waste containers, and 11 cities, as well as Goodwill stores, have partnered with the County to expand our distribution points for free sharps waste containers.

The Department of Public Works notes that, despite these efforts, the County has identified the need to further reduce the environmental and social impacts of the improper disposal of household hazardous waste, including batteries and homegenerated medical sharps. DPW indicates that, if enacted, AB 1159 would mitigate the environmental impact and health risks associated with the end-of-life of these products, as well as reduce some of the costs of managing the County's HHW program, by placing responsibility directly on producers of these products to develop and implement

program to collect, transport, and process these materials. DPW reports that local governments and taxpayers pay an average of \$800 per ton to manage household battery waste. If enacted, AB 1159 would significantly reduce the County's costs in managing household battery waste, which is currently \$100,000 annually, as well as its cost to operate the County's sharps collection program, which averages \$100,000 per year (this includes the purchase of sharps waste containers, advertising, administrative costs, and proper disposal of the sharps collected).

This office and the Department of Public Works support AB 1159. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that places greater emphasis on producer/manufacturer responsibility for the environmental impact of their products and the waste that is produced, and shifts end-of-life management and financial responsibilities from local governments to producers, in order to reduce public costs and encourage improvements in product design that promote environmental sustainability, the Sacramento advocates will support AB 1159.

Support of AB 1159 is consistent with the County's support of **AB 403 of 2013**, which would have required producers of non-rechargeable household batteries to develop and implement a plan to collect and manage batteries sold in the State, and County-supported **AB 488 of 2013**, which would have required businesses that sell medical sharps to establish a product stewardship plan for the end-of-life management of homegenerated medical sharps. AB 403 was held in the Senate Environmental Quality Committee. AB 488 was held in the Assembly Appropriations Committee.

AB 1159 is supported by Californians Against Waste, California Product Stewardship Council, Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force, and Recycle Smart (Central Contra Costa Solid Waste Authority). There is no opposition on file at this time.

AB 1159 is scheduled to be heard by the Assembly Environmental Safety and Toxic Materials Committee on April 28, 2015.

SB 119 (Hill), which as amended on April 20, 2015, would make several changes to the State's subsurface installation excavation laws and create the California Underground Facilities Safe Excavation Authority to enforce these laws and assess civil penalties for violations of their provisions. Specifically, SB 119 would:

1) expand the definition of a subsurface installation to include any underground or submerged duct, pipeline, or structure;

- 2) require an excavator to delineate the area to be excavated in white paint before notifying the appropriate regional notification center of a planned excavation;
- 3) require an operator of a subsurface installation to locate and mark its subsurface installations before the start of excavation and to maintain and preserve all plans and records for any known subsurface installations; and
- 4) prohibit an excavator that damages a subsurface utility installation due to an inaccurate field mark from liability for damages, replacement costs, or other expenses, provided that the excavator complied with the provisions described above, among other provisions.

According to the author of SB 119, excavators in California are less likely than the national average to call the State's two regional notification centers to obtain marking of underground utilities, such as, gas and electric lines, before beginning an excavation or digging project. This, combined with mismarked utility subsurface installations, increases the risk of injuries to excavators and the public, and results in damage to underground utilities.

The Department of Public Works reports that, as currently amended, SB 119 would provide very little benefit to the public and minimal, if any, improvement in worksite safety to excavators. The DPW Road Maintenance Division (DPW-RMD) reports that SB 119 would be impractical for routine dirt road and shoulder grading activities. The requirement to mark every utility would require DWP-RMD to physically dig a trench, by hand (or vacuum if approved), 4-inches deep, minimum 4-feet wide, for the entire length of each road project. This would require digging by hand for miles for every utility indicated to be excavated that is located in the shoulder area of a road. Furthermore, the requirement would impose a serious burden on agencies that perform surface grading or smoothing of dirt shoulders or roads in the course of routine maintenance.

The Department of Public Works Road Maintenance Division also notes that redefinition of the term "excavation" in the bill would place an undue burden on agencies that maintain roadways and sidewalks because it could eliminate the use of power tools or equipment from grinding, cutting, or removing pavement or sidewalks. The DPW-RMD also notes that SB 119 does not take into account the need to remove material which has been deposited onto the surface due to storms. In order to re-open roadways impacted by mud, rocks, or other debris deposited during storms, this material must be immediately removed down to the original graded surface. As currently amended, SB 119 would require notification to the Dig Alert system for removal post-storm mud and rocks, or a pile of dirt which is placed onto the side of the roadway for construction purposes.

The Department of Public Works requests the following amendments to SB 119:

- clarify the definition of the term "excavation" so that it does not place an undue burden on routine road and shoulder grading activities and to take into account the need to remove material which has been deposited onto the surface due to storms; and
- remove the provision that would require an excavator to eliminate or camouflage any temporary markings that remain for 45 days or more after a project is completed, unless a local ordinance indicates otherwise.

This office and the Department of Public Works oppose SB 119 unless amended. Therefore, unless otherwise directed by the Board, consistent with existing policy to:
1) oppose measures that restrict local control over the public rights-of-way; and 2) to minimize the adverse impact of State actions, the Sacramento advocates will oppose SB 119 unless amended as noted above.

This position is also consistent with the County position to oppose AB 1514 of 2012, which would have increased civil penalties for violations of excavations laws. That bill was held in the Assembly Appropriations Committee in May 2013.

SB 119 is supported by Underground Service Alert of Southern California, and several organizations (including AT&T, Pacific Gas and Electric, and Southern California Gas Company) support the bill if amended. The following organizations oppose SB 119 unless amended: the California Landscape Contractors Association, California Farm Bureau Federation, California Fresh Fruit Association, Western Agricultural Processors Association, and Western Growers.

SB 119 is scheduled to be heard by the Senate Judiciary Committee on April 28, 2015.

We will continue to keep you advised.

SAH:JJ:MR VE:AO:ma

c: All Department Heads Legislative Strategist

EXHIBIT 5(b)









CONSUMER HEALTHCARE PRODUCTS ASSOCIATION









CALIFORNIA HEALTHCARE

March 13, 2014

The Honorable Hannah-Beth Jackson State Capitol, Room 5080 Sacramento, CA 95814

> RE: SB 1014 (Jackson) Position: Oppose

Dear Senator Jackson:

On behalf of the above-listed entities, we respectfully inform you of our opposition to SB 1014. This bill would require pharmaceutical manufacturers to fund and administer a new state program to specially collect and dispose of certain unused pharmaceutical products.

Secure disposal is a complex issue and the legislation, as drafted, is impractical and will have numerous unintended consequences, including possibly increasing healthcare costs. Most importantly, this legislation will not meet the program's stated "goals" of reducing trace amounts of pharmaceuticals in the environment, and it has not been demonstrated that such programs reduce the abuse of unused medicines. Additionally, <u>several safe and secure wavs already exist to dispose of unused medicines:</u>

1) Voluntary Take Back Programs: The pharmaceutical industry has long supported voluntary drug take back programs such as the Drug Enforcement Administration's (DEA) Eighth National Prescription Drug Take Back Day on April 26, 2014. In addition, industry supports other community-based programs that involve law enforcement and patient education about adherence and encourage in-home disposal of unused medicines, such as the American Medicine Chest Challenge (AMCC). The AMCC emphasizes the importance of

- taking medicines as prescribed and not sharing medicines with others. It also offer an online search tool and iPhone or Android App that you can install that allows consumers to use their zip code to find the nearest law-enforcement run drop off location.
- 2) Active Facilities in California: There are currently 317 statewide active facilities that accept home-generated medications for proper treatment. Consumers can access a complete listing of these facilities and their locations by going to www.calrecycle.ca.gov and then proceed to the Facility listings. Also, many pharmacies have partnered with law enforcement agencies to operate take back events, often located at the participating pharmacies. In addition, at least one large chain store operates a voluntary mail program for people who want to dispose of unused medicines. The pharmaceutical industry does recommend that any voluntary program compile information that would allow the program's operators to evaluate the program's impact on abuse of prescription drugs as well as the program's environmental impact.

Drug take back programs do not address the issue of pharmaceuticals in the environment.

Scientists generally agree that the majority of the trace amounts of pharmaceuticals in the environment are from human use and metabolite of medicines—not from the improper disposal of medicines. Industry partners have conducted research that evaluated whether detectable levels of pharmaceuticals in the environment pose a risk to human health, evaluated methods for the effective disposal of human medicines, and they continue to study the potential effects of human pharmaceuticals and their metabolites in surface waters on aquatic life. Additionally, many technical experts have contributed to the on-going scientific research in the area of pharmaceuticals in water. The studies conducted to date, published in peer-reviewed journals, which include work on sensitive subpopulations, suggest that it is highly unlikely that the very small quantities of pharmaceuticals detected in the environment would be harmful to human health. 1,2,3,4

Research demonstrates that household trash disposal is effective for disposing of unused medicines.

3) Several programs already in place are accomplishing the same goal of removing unused medicines from the home.

SMARxT DISPOSALTM (<u>www.SMARxTdisposal.net</u>) is a cooperative program developed by the U.S. Fish and Wildlife Service, the American Pharmacists Association, and PhRMA, that provides guidance to consumers on the proper disposal of unused prescription and over-the-counter medications. SMARxT DISPOSALTM also raises awareness about the potential environmental impacts from improperly disposed medications. This national campaign unites

¹ Christensen, F.M. Pharmaceuticals in the environment – A Human Risk?, Reg. Toxicol. & Pharmacol., 28, 212-221. (1998)

² Schwab, et al. Human pharmaceuticals in US surface waters: A human health risk assessment. Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, Pages 296-312 (August, 2005)

³ Webb, et al. *Indirect human exposure to pharmaceuticals via drinking water*, Toxicology Letters, 142, 157-167. (2003)

⁴ Mons, M.N., (2003) Pharmaceuticals and drinking water supply in the Netherlands, Kiwa N.V. Water Research.

diverse interests from the health care profession, pharmaceutical manufacturers, and conservation community and provides simple steps for patients to mix their unused medicines with an undesirable substance to avoid diversion and throw them away in the trash, in contrast to flushing them or pouring them down the sink.

Increasing the Cost of Pharmaceuticals

Placing new, considerable, mandated cost pressures on the industry is inconsistent with the Legislature's and manufacturers' shared goal of keeping medicine affordable. It is unavoidable that the legislation's mandates will lead to substantial costs that will eventually impact a manufacturer's cost of doing business—resulting in higher drug prices for everyone.

SB 1014 includes fees, penalties, and other mandated costs that will unquestionably result in higher prices for prescription and non-prescription medications across the United States. Not only are manufacturers required to cover all the costs associated with administering, operating, collecting, transporting, and disposing of returned products, but companies are likewise required to cover the costs borne by the State in administering and enforcing the provisions of the program itself.

What is more, there are far better, documented programs that exist to aggressively combat prescription drug abuse, such as comprehensive outreach and education programs that help to inform patients of the importance of taking their medications as prescribed; thereby cutting down significantly on the number of unused medications at the outset. For example, Prescription Drug Monitoring Programs (PDMPs) provide prescribers with a tool to reduce "doctor shopping" by allowing the healthcare provider to quickly review the medication history for the patient and what was recently prescribed and/or filled.

A Rigid Program with Tight Bureaucratic Controls

SB 1014 has been heralded as a solution with flexibility—one in which industry can design their programs individually and in accordance to their own needs. However, as we read the bill, we see innumerable specific mandates on companies, strict directives, and the threat of being determined non-compliant if the Department does not approve the company's plan.

While we object to the underlying premise that manufacturers, alone within the supply chain, are responsible, we also note that the bill does not provide the flexibility that supporters say it provides. With the Department carrying all of the power to direct the company to use their preferred method of collection, accept and reject a company's plan, as well as impose penalties as leverage—companies are left with little, if any, flexibility in the development and implementation of stewardship programs.

Treatment Compliance

As mandated by SB 1014, companies must submit an annual report to the Department, detailing their total sales data for pharmaceuticals to compare with their collection data. It is impossible to forecast the amount of drugs that will be collected—it is counterintuitive to the treatment of

disease. The Department will actually penalize companies if patients are compliant with the drug treatment regimens, thus minimizing the amount of medicines that would be discarded at a drug take back collection site. If the Department determines that the number of pharmaceuticals being used by patients is not compatible with their assumption as to how many pharmaceuticals should be returned to collection sites, the Department may find the company to be non-compliant.

As SB 1014 is attempting to find a solution for "end-of-life management" of pharmaceuticals, we believe it ignores the fact that the end-of-life for most drugs is ingestion by a patient and therefore the medicine is not returnable to a collection sites.

For these reasons, we respectfully oppose SB 1014.

Sincerely,

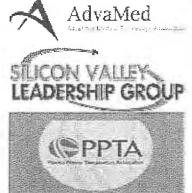
BayBio
BIOCOM
California Healthcare Institute—CHI
Consumer Healthcare Products Association (CHPA)
California Manufacturers and Technology Association (CMTA)
Generic Pharmaceutical Association (GPhA)
Pharmaceutical Researchers and Manufacturers of America (PhRMA)
TechNet

We believe product stewardship programs must include a broad base of stakeholders as opposed to the punitive approach focused on manufacturers established by AB 403. Any equitable, fair and effective program by comparison must involve shared responsibility among all affected parties ranging from end users to waste haulers, health care facilities, all taxpayers and other beneficiaries of these products.

For these reasons, we strongly oppose AB 403









१ छात्र इतिरामक <u>करह</u>



CALIFORNIA HEALTHCARE INSTITUTE

April 10, 2013

TO: Members, Assembly Environmental Safety and Toxics Committee

SUBJECT: AB 403 (Stone): Solid waste: home-generated sharps.

Oppose- As Amended April 8, 2013 Set For Hearing - April 16, 2013

On behalf of the identified organizations we respectfully inform you of our opposition to AB 403 regarding "home generated sharps."

The development, distribution and use of sharps and related medical devices, which provide life-saving medications to patients, is a complex process. This process involves many stakeholders, including medical device manufacturers, wholesalers, distributors, hospitals, medical providers, local governments, public health officials, waste haulers, health care organizations, long-term care facilities, patients, and other beneficiaries. Placing the responsibility for end-of life disposal of sharps solely on any manufacturer as defined in the amended bill places an unfair burden on a single stakeholder and will hamper an important and fast-growing California based industry. Further, a study from the April 3, 2013 Journal of Public Health Advance Access calls into question the need for disposal programs like the one in this bill. During the past twenty years, the number of Americans who self-inject medications has dramatically increased. Despite this, the number of needle-stick injuries, and associated medical costs, remain extremely low. [1]

AB 403 Creates Tremendous Cost Pressures in Healthcare

AB 403 establishes a large, statewide bureaucracy that is fully funded by medical device manufacturers. The program is rigid, specific, and punitive. The bill holds medical device manufacturers responsible for all the Department of Resources Recycling and Recovery's (Department) administrative, operational, and capital costs associated with oversight of this untested program. Per the bill, medical device manufacturers must fully reimburse the Department for all of its expenses to administer and enforce the program. This alone amounts to a sizable tax on device manufacturers. But, to comply with the specific mandates in AB 403, the medical device industry will also have additional costs. These additional cost burdens, as specified by the bill include:

- Developing and administering marketing and educational outreach materials for distribution throughout the supply chain
- Establishment of collection sites throughout the state, located at a minimum of one collection site per every 5,000 people
- Hiring independent auditors to detail and review the stewardship plans' financing methods
- Responsibility for all costs associated with the transport and disposal of collected products
- Administrative penalties of \$1,000 per day if the Department finds a company is in violation of the program
- \$10k per day penalty if the Department finds the company is in negligent violation

The exorbitant costs imposed on sharps manufacturers will negatively impact the health care delivery system and are not commensurate with the value to patients, particularly when take back programs exist. Also, though the bill suggests otherwise, the financial impact to health systems especially Medi-Cal and patients will prove substantial via increased costs for these vital tools necessary for patient self-care.

AB 403 Allows For Medical Devices to Be Banned

Authority to approve or deny the sale of medical devices is granted today solely to the federal Food and Drug Administration (FDA) based on a device's safety and efficacy to patients. Obtaining FDA marketing clearance can take years, after the many more years already spent in research and development. This bill, however, changes this dynamic, thereby threatening the safety of patients. Under AB 403, the state Department of Resources, Recycling, and Recovery—a non-medical entity—will have new and FDA-like authority to allow or disallow the sale of medical devices containing sharps.

Section 47117 states: "(a) A producer or retailer shall not sell or offer for sale in this state home-generated sharps to a person in this state unless the producer of those home-generated sharps is in compliance with this article."

The willingness of state waste officials to grant the authority for a medical device containing a sharp to be sold or not based on arbitrary and subjective decisions is a dangerous precedent to patient safety. Granting this authority will prevent patients from obtaining vital and necessary medical devices with sharps to manage chronic disease for reasons not related to safety and efficacy of a product. AB 403 could create serious and long-term obstacles to vital medical care and impede patient compliance with their treatments ordered by physicians and medical professionals.

AB 403 Mandated Collection Rates Not Practical

The mandated collection rates established in the bill are wholly impractical, unworkable and fail to recognize existing statute. An example, federal and state health privacy laws protect the identity of patients using medical devices containing sharps. Therefore, manufacturers cannot contact patients to request the return of used sharps. Further, once a product is distributed to a wholesaler or other intermediary, ownership and control of the sharp by a manufacturer is lost. This means a manufacturer cannot force or compel the patient to dispose of the sharp according to the company's wishes. Given this reality it is not practical to penalize, fine and threaten the banning of a product if a patient does not return the sharp. Because the mandated collection rates and severe penalties are impractical and do not recognize the manufacturer does not have control over the patient's actions, we believe AB 403 is infeasible.

CONCLUSION - OPPOSE AB 403











CONSUMER HEALTHCARE PRODUCTS ASSOCIATION











April 17, 2013

The Honorable Hannah-Beth Jackson State Capitol, Room 5080 Sacramento, CA 95814

RE: SB 727 (Jackson)
Position: Oppose

Dear Senator Jackson:

On behalf of the above-listed entities, we respectfully write to inform you of our opposition to SB 727. As you know, the bill seeks to create a new state recycling program that is fully funded by drug manufacturers.

SB 727 establishes a new, expansive statewide program and mandates that pharmaceutical companies pay for 100% of the Department's costs to administer the new program.

The presumed costs to implement SB 727 are considered tremendous and non-absorbable, which is why the bill mandates that impacted companies must prove they have a dedicated funding stream to pay for the new state program.

On page 8, Line 28 the bill states: "The plan shall demonstrate sufficient funding for the stewardship program as described in the plan, including a funding mechanism for securing and dispersing funds to cover administrative, operational, and capitol costs."

In addition to fully funding the new statewide program, the companies are also be subject to new, harsh penalties.

Under the bill, the Department may impose a civil penalty for violations--\$1,000 per violation per day. If the Department finds the company to be negligent, the company may be additionally fined \$10,000 per day per violation. Further, a third fine may be imposed by the Department if the company is not listed on the Department's website--\$2,500 on the first day and will increase by 50 percent with interest each day thereafter until a plan is submitted.

In addition to fully funding the new statewide program and being subject to severe penalties, the impacted companies are also responsible for all costs associated with the implementation of their mandated stewardship plan. These costs include establishing collection sites of 1 within every 10 miles per person in the state, the related CEQA compliance costs, as well as costs related to liability, transportation, processing, disposing of the product.

Placing new, considerable cost pressures onto the industry is inconsistent with the Legislature's and the manufacturers shared goal to keep the cost of medicine affordable.

Another practical consideration that makes SB 727 unreasonable is the issue of patient drug compliance. Often physicians request patients to finish and complete an entire prescription. However, under SB 727, the more patients that comply with their physician's direction, the greater the penalty for the drug company, because the company will not be able to collect the amount of unused medicine required as there should be none left.

As mandated by SB 727, companies must submit an annual report to the Department, detailing their total sales data for pharmaceuticals to compare with their collection data. If the Department determines that the number of pharmaceuticals being used by patients is not compatible with their assumption as to how many pharmaceuticals should be returned to collection sites, the Department may find the company to be non-compliant.

As SB 727 is attempting to find a solution for "end-of-life management" of medicines, we believe it ignores the fact that the end-of-life for most drugs is ingestion by the patient and therefore the medicine is not returnable to a collection sites.

Finally, it is not practical to penalize a manufacturer based on whether or not a patient chooses to utilize a collection site. We do not support the use of performance measurements or "goals" as

mandated in Section 47125 (k), particularly those that are used to enforce strict penalties regardless of manufacturer compliance. Furthermore, we believe that penalizing manufacturers for the actions, or non-actions, of patients is a violation of due process. If patients refuse to return their unused medications, the manufacturer should not be penalized as it is beyond their control.

For the reasons outlined, we must respectfully oppose SB 727.

Sincerely,

TechNet
California Healthcare Institute (CHI)
Silicon Valley Leadership Group
Pharmaceutical Researchers and Manufacturers of America
CalChamber
California Manufacturers and Technology Association
BayBio
BIOCOM
Generic Pharmaceutical Association (GPhA)
Consumer Healthcare Products Association

EXHIBIT 6

We are doing a short survey to find out how adults in Los Angeles County get rid of their unwanted medicines and sharps (syringes, needles, and lancets). We also want to know how people would prefer to get rid of medicines, needles and sharps in the future. Thank you in advance for your contribution to this study.

Consent/Privacy

The survey is anonymous. We do not ask your name, address, e-mail or telephone number and we will not track your IP address. Your responses will be kept strictly confidential. You can skip any questions that you do not want to answer.

- 1. By checking 'Yes', you confirm that you are:
- · Aged 18 or older, and
- · Live in Los Angeles County, and
- · Are willing to take part in this survey

Yes

Medicines 2. Are there any medicines in your home that are out of date, or are no longer needed? (By medicines' we mean prescription and over-the-counter drugs, including pills, patches and liquids. Please include medicines for you, your family members and your pets) Ne Don't Know Yes	MEDICINES A	ND SHAKE I	JISPUSAL -	CONSUME!	N SURVET	1998	F 59
medicines we mean prescription and over-the-counter drugs. including pills, patches and liquids. Please include medicines for you, your family members and your pets) No Den't Know Yes	Medicines						
medicines we mean prescription and over-the-counter drugs. including pills, patches and liquids. Please include medicines for you, your family members and your pets) No Den't Know Yes							
Don't Know Yes	'medicines' we m	nean prescription	on and over-the	e-counter dru	gs. including p		е
Yes	No						
	Don't Know						
	Yes						
					6		

Waiting for a drug collection day Don't know what to do with them Haven't thought about it Haven't gotten around to getting rid of them Other (please specify)		or a household member, nee	d them again		
Haven't thought about it Haven't gotten around to getting rid of them Other (please specify)					
Haven't gotten around to getting rid of them Other (please specify)					
	Other (please specify)				

oply)			
Take to a hazardous v	vaste disposal site or collection event		
Flush down the toilet of	or put down the drain		
Throw away in the tra	sh after mixing with wet coffee grounds, kitty litter, or similar		
Throw away in the tra	sh as they are		
Take to a drop-off bin	outside a sheriff's or police station		
Mail in a pre-paid enve			
Keep at home			
I don't usually have ar	v left-over medicine		
Other (please describe			
Do you believe that	putting medicine down the toilet or sink is harmful for the	e environment?	
	putting medicine down the toilet or sink is harmful for the	e environment?	
No	putting medicine down the toilet or sink is harmful for the	e environment?	
No Don't Know	putting medicine down the toilet or sink is harmful for the	e environment?	
No Don't Know Yes	putting medicine down the toilet or sink is harmful for the		
No Don't Know Yes			
No Don't Know Yes Do you believe that			
No Don't Know Yes Do you believe that			
No Don't Know Yes Do you believe that No Don't Know			
No Don't Know Yes Do you believe that No Don't Know			
No Don't Know Yes Do you believe that No Don't Know			
No Don't Know Yes Do you believe that No Don't Know			

MEDICINES AND SE	HARP DISPUSAL	- CON	SUMER SUR	/ET		
SHARPS						
7. Do you, or anyone in		medica	ıl sharps (e.g. sy	yringes, needl	es. lancets	to give
medicine or test blood s	sugar)					
No						
Don't Know						
Yes						

Never					
Don't Know					
Sometimes					
Always					
What are all the ways that you, or a f	amily member, dispose	of the used	sharps?(select	all that ap	ply)
Take to a clinic					
Put down the toilet or sink					
Throw in the trash		2			
Take to a hazardous waste disposal site or	collection event				
Put in a drop-off bin outside a sheriff's or po	alian atatian				
					- 2
Send to a mail-back program					
Keep at home					
Keep at home Other (please describe)					
Other (please describe)					
Other (please describe)					

Future	Dis	posal	Pre	fei	rences
---------------	-----	-------	-----	-----	--------

	e County is working to increase the number of ways for people to dispose of wanted medicines and sharps.
	If all the options listed below were available free of charge, which $\underline{\text{ONE}}$ option would you prefer to use lispose of your medicines and/or sharps:
	Drop-off bin outside sheriff's or police station
	Drop-off bin at a local pharmacy
Ö	Drop-off bin at a clinic
	Pre-paid mail-back envelope or box
	Hazardous waste disposal site or collection event
Othe	er (please specify)
	If all the options listed below were available free of charge, which OTHER options would you be willing see to dispose of your medicines and/or sharps: (select all that apply) Drop-off bin outside a sheriff's or police station Drop-off bin at a local pharmacy Drop-off bin at a clinic Pre-paid mail-back envelope or box
	Drop-off bin at a local pharmacy

One of the ways that has been suggested for people to dispose of unwanted medicines and sharps is to place them in drop-off bins in pharmacies.

	think that is a good again am undecided on whe	ether that would be a good approach.	
		that approach, as follows	
3. If	the pharmacies	are located in stores that sell fresh food, which of the	following best describe
our	response to this	suggestion?	
) [think that is a good ap	proach.	
) [am undecided on whe	ether that would be a good approach.	
1	have concerns about	that approach, as follows	
		*	

14.	Age			
	18-29			
	30-39			
	40-49			
	50-59			
Ö	60-69			
	70+			
15.	Gender			
	Male			
¥	Female			
0	Transgender			
16.	Zip Code of Residence:			
	Homeless			
	Zip Code:			
17.	Which race/ethnicity do you identify as?			
0	African American/Black			
	Asian			
	American Indian/Alaskan Native			
	Hispanic/Latino			
0	Mixed/Multi-ethnic			
	Native Hawaiian or other Pacific Islander			
	White/Non-Hispanic			
0	Other (please specify)			
	**			

			I, at	
	3			
2.2				

Thank you.

We appreciate your time and feedback.

More information

To learn how to dispose of medicines and sharps in LA County call 1 (888) CLEAN-LA or visit the Department of Public Works Household Hazardous Waste website.

Please note that it is against the law to dispose of sharps in the trash or toilet. Free sharps boxes and drop-off facilities are available. In addition, there is a sharps mail-back disposal program for elderly and disabled residents.

For information on disposal options nationally visit the No Drugs Down the Drain website.

For more information about efforts to increase the number of ways to dispose of unwanted medicines and sharps in LA County please visit the County's Pharmaceutical_Take-Back_website.

Share your story!

If you have a story about harm from unwanted medicines or sharps that you are willing to share, please email EPR@LACOUNTY.GOV or call (213) 240-8144

EXHIBIT 7(a)

California Take-Back Programs

Alameda County

On July 24, 2012, Alameda County adopted the Safe Drug Disposal Ordinance. This ordinance is based on the successful Extended Producer Responsibility (EPR) program in British Columbia, operated by many of the same pharmaceutical companies doing business in the United States. This precedent-setting ordinance was the first in the nation to hold pharmaceutical companies responsible for the safe collection and disposal of unused medications from the public. It was unsuccessfully challenged by the pharmaceutical industry in December of 2012 and the United States Supreme Court ultimately denied the request to hear the case on May 26, 2015. Two Stewardship Plans have been approved. On November 15, 2015, Alameda County also adopted an ordinance to require the development of a stewardship program for sharps waste.

San Francisco City/County

In 2010, San Francisco introduced a Safe Drug Disposal Ordinance. However, in 2012 the city chose instead to accept \$110,000 from the Pharmaceutical Research and Manufacturers of America (PhRMA) and Genentech to fund a pilot project to collect data on the issue. In August 2013, the same two organizations provided another payment of \$125,000 to fund the pilot project an additional year. The pilot program was well-utilized, with over 37,000 pounds collected in the first 26 months. The pilot data indicated that residents overwhelmingly preferred taking unwanted drugs to pharmacies rather than law enforcement locations. Following the success of the pilot program as well as the unsuccessful lawsuit by PhRMA against Alameda County, San Francisco adopted their own EPR ordinance on March 17, 2015, with an effective date of April 25, 2015.

Marin County

On August 11, 2015, the Marin County Board of Supervisors adopted the Safe Drug Disposal Ordinance. The ordinance went into effect on September 11, 2015. The Safe Drug Disposal Ordinance is intended to address harm to human and environmental health related to unused drugs by establishing collection sites at a minimum of 25, geographically and conveniently located sites throughout the county. Additionally, the public will be educated about proper drug disposal, the drug disposal program, and mail-back alternatives.

Santa Clara County

On June 23, 2015, the Santa Clara County Board of Supervisors adopted the Safe Drug Disposal Ordinance. The ordinance requires easy, efficient and convenient opportunities for all residents to dispose of their medicines to help reduce the risks to health and the environment linked to unsafe drug disposal. The ordinance requires manufacturers of products, too hazardous to be disposed of through the municipal waste stream, to take financial and logistical responsibility for their products safe disposal.

Pharmaceutical Drugs and Sharps Take-Back Programs in Other Jurisdictions

Santa Cruz County

On December 8, 2015, the Santa Cruz County Board of Supervisors unanimously adopted the Safe Drug and Sharps Disposal Ordinance. The ordinance went into effect on January 8, 2016, and is intended to: 1) significantly increase convenient disposal options for residents' unwanted drugs; 2) enable collection of larger quantities of unwanted drugs; and 3) reduce the risks to public safety, health, and the environment.

San Mateo County

On April 28, 2015, the San Mateo County Board of Supervisors adopted on consent the Safe Medicine Disposal Ordinance which went into effect on May 28, 2015. Under the program, medicine manufacturers will fully fund a medicine collection program, making it easier for the public to choose the safest way to dispose of their unwanted medicines. The goals of the ordinance are to increase public safety and reduce water pollution.

National Take-Back Program

King County, Washington

On June 20, 2013, the King County Board of Health passed the Secure Medication Return Rule & Regulation to create a drug take-back program for King County's residents. The program promotes the safe disposal of unused prescription and over-the-counter drugs, and will be funded and operated by the drug manufacturers. On November 27, 2013, four groups of major drug manufacturers sued the County. The suit was dismissed following the U.S. Supreme Court's decision not to hear industry's legal challenge to the Alameda County Safe Drug Disposal Ordinance. On October 16, 2015, King County approved the Return Meds LLC stewardship plan which includes over 100 pharmacies that will participate as collection sites for the program.

International Take-Back Programs

Belgium - Bonusage

This program was first implemented in the Brussels region in 2002. The program is organized through a partnership of pharmaceutical wholesalers, manufacturers, and pharmacies. It is funded by wholesalers, who pay for collection, storage and transportation; and manufacturers who pay for incineration of the collected materials based on market share. Medicines managed through this program increased 33% from 2000 to 2011.

France – Cyclamed

The Cyclamed program started in 1993 as a voluntary program before becoming mandated by law in 2007. The program is fully funded by the pharmaceutical industry, and all pharmacies are mandated to take back medicines. In 2013, almost 15,000 tons of medication were collected nationally.

Pharmaceutical Drugs and Sharps Take-Back Programs in Other Jurisdictions

Hungary – Recyclomed

The Recyclomed program began collecting medicines in 2005 after legislation mandated a national program. Funding is provided by drug manufacturers and all pharmacies are mandated to host take-back bins. By 2011, there were over 4,000 locations nationally.

Portugal – <u>Sistema Integrado de Gestão de Resíduous de Embalagens de Medicamentos</u> (SIGREM)

This program is administered by the nonprofit VALORMED, SIGREM and was implemented in 2001. Funding is provided by pharmaceutical manufacturers and distributors, as well as the national pharmacy association. Although participation is voluntary, over 99% of pharmacies served as take-back locations in 2011.

Spain - SIGRE Medicines and the Environment

This program is administered by the nonprofit SIGRE, and has been in operation since 2003. Funding and operation of the take-back program is provided by the manufacturers. Collection bins are located exclusively at pharmacies, with over 21,000 participating take-back locations in 2014. Results indicate that over 70% of households utilize the system.

Canada - Medications Return Programs

This producer funded and operated program started voluntarily in British Columbia (B.C.) over 15 years ago and since has become mandated. The program has expanded beyond B.C. and now operates in most provinces.

Mexico – <u>Sistema Nacional De Gestión De Residuous De Envases Y Medicamentos</u> (<u>SINGREM</u>)

This program is administered by Mexico's National Chamber of the Pharmaceutical Industry (CANIFARMA). The SINGREM program began collecting medicines in 2010 in several Mexican states with funding supplied by CANIFARMA. In 2014, the program underwent a major national expansion to include all cities with 100,000 or more inhabitants. As of 2014, there were 4,000 collection locations in 22 states.

Brazil - Descarte Consciente

This program is administered by <u>Brazil Health Service</u>. Descarte Consciente was implemented in 2010 with funding provided by the pharmaceutical industry. Collection is located at pharmacies but is not mandatory. In 2013 the program collected 22 tons of medicines.

Pharmaceutical Drugs and Sharps Take-Back Programs in Other Jurisdictions

Colombia - Punto Azul

This program is administered by Colombia's National Association of Entrepreneurs (<u>ANDI</u>). The Punto Azul program began collecting medicines in 2010 with funding supplied by pharmaceutical manufacturers and importers. Collection is located at pharmacies and large supermarkets but is not mandatory. In 2014 there were over 685 locations nationally covering 43% of the population.

4/12/16

EXHIBIT 7(b)

Pharmaceutical Take-Back Ordinance Comparison Chart

Question	Alameda County (excludes Berkeley) 1.5 million Residents Adopted July 24, 2012	San Francisco City/County 822,000 Residents Adopted March 17, 2015	Santa Clara County 1.9 million Residents Adopted June 23, 2015	San Mateo County 758,500 Residents Adopted April 28, 2015	King County, Washington 2.1 million Residents Adopted June 20, 2013	Marin County 260,750 Residents Adopted August 11, 2015	Los Angeles County 1.1 Unincorporated Area Residents, 10.0 Million Residents County-wide
What is the status of the other take-back programs?	Two stewardship plans have been approved. A contract between Alameda MED-Project LLC and Alameda County Sheriff was finalized in July 2015 for the Sheriff to assist with drug take-back events. Negotiations are underway for fixed drop-boxes to be placed at the Sheriff's offices. Similar contracts expected to be negotiated with the remaining law enforcement agencies in the County. Currently, controlled substances are accepted at the Sheriff's offices. Additionally, Alameda County recently adopted an ordinance for a sharps EPR program as well.	Stewardship plan is due March 26, 2016.	Stewardship plan is due June 23, 2016.	Stewardship plan is due April 28, 2016.	Two plans have been submitted. One of the plans, submitted by Return Meds LLC, was approved on October 16, 2015 and is set to launch June 9, 2016.	Stewardship plan is due August 11, 2016.	Ordinance is Scheduled to be introduced for consideration by the Board of Supervisors on March 29, 2016. If adopted by the Board, the Ordinance effective date would be May 5, 2016. Stewardship Plans would be due February 1, 2017.
How are producers/ manufacturers as "Responsible Stewards" defined?		"A manufacturer engaged in the Manufacture of a Covered Drug sold in the City, including a brandname or generic Drug." Does not include retailers whose store label appears on packaging and repackagers if the Manufacturer is identified. Also exempts pharmacists who compound or repackage for a consumer and wholesalers who are not also the Manufacturer.	"A manufacturer engaged in the Manufacture of a Covered Drug sold in the County, including a brand-name or generic Drug." Does not include: Retailers whose store label appears on packaging and repackagers if the Manufacturer is identified. Also exempts pharmacists who compound or repackage for a consumer and wholesalers who are not also the Manufacturer.	"A manufacturer engaged in the Manufacture of a Covered Drug sold in the City, including a brandname or generic Drug." Does not include: retailers whose store label appears on packaging and label appears on packaging and label appears on packaging and label appears on consumer is pharmacists who compound or repackage for a consumer and wholesalers who are not also the Manufacturer.	"Producer" means a mandatcurer of a covered drug sold in or into King County, including brand-name or generic drug." Does not include: Retailers whose store label appears on packaging and repackagers if the Manufacturer is identified. Also exempts pharmacists who compound or repackage for a consumer and wholesalers who are not also the Manufacturer.	"A manufacturer engaged in the Manufacture of a Covered Drug sold in the County, inducing a brand-name or generic Drug." Does not include: Retailers whose store label appears on packaging and repackagers if the Manufacturer is identified. Also exempts pharmacists who compound or repackage for a consumer and wholesalers who are not also the Manufacturer.	"Responsible Steward" shall mean a Manufacturer regaged in the Manufacture 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 is also a Manufacturer."
Are retail pharmacies serving as collection sites for the	Retail pharmacy participation is planned for Phase II of the program which will begin in July 2016.	Prior to the EPR ordinance, San Francisco had a voluntary drug take-back program which included retail pharmacies.	N/A	N/A	Yes, over 100 retail pharmacies have been identified as being interested in participating in the program.	N/A	Retail pharmacy participation is encouraged.
Are over-the- counter medications covered?	No	Yes	Yes	Yes	Yes	Yes	Yes
Are vitamins and supplements covered?	No	No	No	ON	No	ON	NO :
Are controlled substances	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Pharmaceutical Take-Back Ordinance Comparison Chart

Are sharps covered?	Yes	No	No	No	NO	No	Yes
Do producers pay 100% of costs?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Does it have convenience standards, and if so what?	No, but an explanation of how the system will be convenient and adequate to serve the needs of residents is required in the plan, including the locations where envelopes for mail-back program are available.	Yes – each Supervisorial District must have at least 5 drop-off sites geographically distributed to provide reasonably convenient and equitable access. If this ramor be achieved due to lack of drop-off sites, periodic collection events and/or mail-back services shall be provided.	Yes, must provide equitable access in all Supervisorial Districts. One dirop-off district. One district. No less than 10 per district. In ot feasible, those areas must be served through periodic collection events and/or mail-back service.	Yes, must provide equitable access in all Supervisorial Districts. One drop-off site/20,000 residents in each district. No least han 5 per district. If not feasible, those areas must be served through periodic collection events and/or mail-back service.	No, but must be convenient on an ongoing, year-round basis to adequately serve the needs of covered entities and designed to consider equitable opportunities for all King County residents; includes the use of mail-back services and/or collection events.	Ves, must be geographically distributed to provide reasonably convenient access throughout the County and at no time can there be fewer than 25 drop-off sites throughout the County. Plan must describe any mail-back services that will be provided.	Yes, in each Unincorporated Community and in each Participating City with at least one Potential Authorized Collector, each Stewardship Plan shall provide at least one Collection Site for Unwanted Covered Drugs, at least one Collection Site for Unwanted Sharps, and for every 30,000 County residents at least one additional Collection Site for Unwanted Covered Drugs and at least one additional Collection Site for Unwanted Sharps. "Collection sites shall be geographically distributed to geographically distributed for minimum requirements are not met, the Stewardship Plan shall provide for (a) monthly collection events and/or (b) mailers to consumers in those areas unon requires."
Does it require prepaid mail-back services where applicable?	Yes	Yes	Yes	Yes	Yes	Yes	Yes (see above.)
Does it require a public education outreach program?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Will pharmacies be required to (1) host bins, or (2) advertise the program?	OV.	No, but they have a separate Drug Disposal Information ordinance that requires pharmacies to display ads for the collection program.	O _N	ON	No	No, but plan must give preference for pharmacies and law enforcement agency locations.	Pharmacies are not required to host bins; however they are required to post display materials explaining how and where members of the public may safely and lawfully dispose of Unwanted Covered Drugs and Unwanted Sharos.
Does it allow producers to charge visible fees?	NO	No	No	No	No	ON	No

Pharmaceutical Take-Back Ordinance Comparison Chart

Yes	Los Angeles County Department of Public Health	of Nine months after the effective date of the Ordinance.	No, but the Ordinance is written to allow Participating Cities for whom the County Health Officer serves as their Health Officer to adopt the requirements of the Ordinance into their respective municipal codes.	Within three months of approval of a Stewardship Plan(s).	
Yes	Marin County Environmental Health Services	One year after effective date of ordinance.	Yes	Three months after plan is approved.	Annual, within six months after end of first twelve-month period.
Yes	King County Department of Public Health	One year after rule is adopted.	Yes	Three months after plan approved. Three months after plan is approved.	Annual, within six months after end of first twelve-month period.
Yes	San Mateo County Environmental Health Division of San Mateo's Health System.	One year after ordinance passed.	Yes	Three months after plan is approved.	Annual, within six months after end of first twelve-month period.
Yes	County of Santa Clara Consumer and Environmental Protection Agency	One year after ordinance passed.	Yes	Ordinance does not indicate.	Annual, within six months after end of first twelve-month period.
Yes	Department of Environment	One year after ordinance passed.	Yes	Three months after plan approved.	Annual, within six months after end of first twelve-month period.
Yes	Alameda County Environmental Heaith	One year after ordinance passed.	Yes, except cities which have their own health officer.	Plan must indicate start date for collection program.	Annual, July 1
Does it provide oversight regulatory fees to reimburse costs incurred by the public agency?	Which entity implements and enforces the requirements?	When is a plan due for review?	Does the ordinance cover incorporated cities within the county?	When must program begin?	Program reporting frequency

Pharmaceutical Take-Back Ordinance Comparison Chart

administrative, criminal, and/or civil penalty/fine?		the following:	the following:	the following:	Yes. The Ordinance provides for the following:	Yes. The Ordinance provides for the following:	Yes. The Ordinance provides for the following:
criminal, and/or civil penalty/fine?	Administrative: Administrative citation for non-)))	,	,
dvil penalty/fine?	compliance which includes a written warning	Administrative: An initial 30-day	Administrative: An initial 30-	Administrative: A 30 day warning	Administrative: (1) A written	Administrative: The Director	Administrative fine: If after a
	and gives violator 30 days to comply. If violator	written compliance warning is	day written compliance warning	is issued for non-compliance to	warning is sent to a producer not	shall send a written warning to	Notice of Violation is issued and
	fails to comply and correct violations, the	issued to a violator. If after 30	is issued to a violator. If after 30	the violator. If after 30 days, the	participating in the stewardship	the Person or Persons who	the Person or Persons fail to
	County may impose administrative fines.	days, violator fails to comply, the	days, violator fails to comply,	violator fails to come into	plan, and may be assessed a	violates the ordinance or	come into compliance or correct
		Director may impose	the Director may impose	compliance, administrative fines	penalty.	adopted regulations. The	all violations, the Director may
	Civil Penalty: Any Person in violation will be	administrative fines for violations.	administrative fines/penalties	may be issued as follows: (1) not		violator has 30 days after	impose administrative fines for
	liable for a civil penalty of up to \$1,000 per day		for violations.	exceeding one hundred dollars	(2) If it is determined that a	receiving the warning to come	violations of the Ordinance or any
	per violation, depending on the nature of the	Criminal Fine: Any Person who		(\$100) for a first violation; (2) two	stewardship plan is not in	into compliance. If a violator	regulation adopted pursuant to
	violation. Each day shall constitute a separate	knowingly and willfully violates the	Criminal Fine: Any Person who	hundred dollars (\$200) for a	compliance with the approved	fails to come into compliance,	this chapter and/or Los Angeles
	violation.	requirements of the ordinance or	knowingly and willfully violates	second violation; and (3) five	plan, the Director may send the	the Director may impose	County Code.
		any adopted rule or regulation is	the requirements of the	hundred dollars (5500) for the	producer or group of producers	administrative lines set forth in	
	Criminal Fine: Any Person who knowingly and	guilty of a misdemeanor. A	ordinance or any adopted	third and each subsequent	participating in the plan a written	the regulations adopted	Criminal Fine: Any Person who
	willfully violates the requirements of the	conviction is punishable by a fine	regulation is guilty of a	violation. If the fine is not paid	warning indicating the	pursuant to the ordinance.	knowingly and willfully violates
	ordinance or adopted rule or regulation is guilty	of not less than fifty (\$50) dollars	misdemeanor, and is punishable	within 30 days of the notice, the	noncompliance, and a warning that		the requirements of the
	of a misdemeanor, and may be prosecuted. A	and not more than five hundred	by a fine of not less than five	Director may use any lawful	penalties may be assessed for	Criminal Fine: Any Person who	Ordinance or any rule or
	conviction is punishable by a fine of not less	(\$500) for each day per violation,	hundred dollars (\$500) for each	means for collecting the fine,	noncompliance. The producer or	knowingly and willfully violates	regulation adopted pursuant to
	than fifty dollars (\$50) and not more than five	or by imprisonment in the County	day per violation, or by	including instituting an action in	group of producers has 30 days to	the requirements of the	the Ordinance is guilty of a
	hundred dollars (\$500) per day per violation or	Jail for a period not to exceed six	imprisonment in the County jail,	any court of proper jurisdiction.	comply, after which a penalty may	ordinance or adopted regulation	misdemeanor and upon
	by imprisonment in Alameda County Jail for a	(6) months or by both fine and	or by both fine and		be assessed. The Director is not	is guilty of a misdemeanor and	conviction thereof is punishable
	period not to exceed six (6) months, or by both	imprisonment.	imprisonment.	Criminal Fine: Any Person who	precluded from suspending an	upon conviction is punishable	by a fine of not less than fifty-
	a fine and imprisonment.			knowingly and willfully violates	approved plan if a violation of the	by a fine of not less than fifty	dollars (\$50) and not more than
		Civil Penalty: Any Person in	Civil Penalty: Any Person in	the requirement of the ordinance	ordinance or an approved plan	dollars (\$50) and not more than	one-thousand (\$1,000) for each
		violation of the ordinance is also	violation of the ordinance is also	is guilty of a misdemeanor, and	creates, in the Director's judgment,	five hundred dollars (\$500) per	day per violation, or by
		liable to the City for a civil penaity	liable to the County for a civil	upon conviction thereof is	an immediate hazard.	day for each day of violation, or	imprisonment for a period not to
		in an amount not to exceed one	penalty in an amount not to	punishable by a fine of not less		by both imprisonment for a	exceed six (6) months, or by both
		thousand dollars (\$1,000) per day	exceed one thousand dollars	than fifty dollars (\$50) and not	Civil Penalty: A violation of the	period not to exceed six (6)	such fine and imprisonment.
		per violation.	(\$1,000) per day per violation.	more than five hundred dollars	ordinance is subject to a civil	months, or by both fine and	
				(\$500) for each day per violation,	penalty of up to two thousand	imprisonment.	Civil Penalty: Any Person in
				or by imprisonment for a period	dollars (\$2,000) and may be		violation of the Ordinance or any
				not to exceed six (6) months, or by	assessed against a producer or	Civil Penalty: Any Person in	rule or regulation adopted
				both fine and imprisonment.	group of producers. Each day	violation of the ordinance or	pursuant to the Ordinance shall
					upon which a violation occurs or is	any rule or regulation shall be	be liable to the County for a civil
				Civil Penalty: Any Person in	permitted to continue constitutes	liable to the County for a civil	penalty in an amount not to
				violation of the ordinance is also	a separate violation.	penaity in an amount not to	exceed one thousand dollars
				liable to the County for a civil		exceed one thousand dollars	(\$1,000) per day per violation.
				penalty in an amount not to		(\$1,000) per day per vibiation.	Each day in which the violation
				exceed one thousand dollars			continues shall constitute a
				(\$1,000) per day per violation.			separate violation.

EXHIBIT 8

EPR Pharmaceuticals and Sharps Technical Advisory Group Roster

Invited Participants

- 1) Pharmaceuticals industry (name-brand drug manufacturers)
 - Marissa Watkins, Pharmaceutical Research and Manufacturers of America (PhRMA)
 - Reese Isbell, California Life Science Association (represent sharps and pharmaceuticals manufacturers)
 - Ritchard Engelhardt, Biotechnology Industry Organization
 - Victor Law, San Gabriel Valley pharmacist and State Board of Pharmacy
- 2) Generic drug manufacturers Brynna M. Clark, Generic Pharmaceutical Association (GPhA)
- 3) Over the counter drug manufacturers Carlos Gutierrez, Consumer Healthcare Products Association (CHPA)
- 4) Sharps manufacturers Carrie Hartgen, Advanced Medical Technology Association (AdvaMed)
- 5) Pharmacies
 - Tony Park, California Pharmacists Association (CPhA)
 - Steve Gray, Kaiser Permanente
- 6) Retailers
 - Angie Manetti, California Retailers Association (CRA)
 - Laura Peralta, California Grocer's Association (CGA)
- 7) Hospitals Jaime Garcia, Hospital Association of Southern California (HASC)
- 8) EPR Advocacy Organization Heidi Sanborn, National Stewardship Action Council (NSAC)
- 9) <u>Consumer/Patient Advocacy Organization</u> Vishnu Subramaniam, *California Alliance for Retired Americans (CARA)*
- 10) Environmental Organizations
 - Andria Ventura, Clean Water Action
 - Leslie Tamminen, Seventh Generation Advisors
- 11) Wastewater Agencies David Pedersen, California Association of Sanitation Agencies (CASA)
- 12) Solid Waste and Recycling Industry
 - Susanne Passantino, Republic Services
 - Ron Saldana, LA County Small Haulers Association

Invited Observers

- Tracy Rafter and Linda Bermudez, Los Angeles County Business Federation (BizFed)
- MaryAnne Bobrow, California Society of Health System Pharmacists (CSHSP)
- Steven C. Anderson, National Association of Chain Drug Stores (NACDS)
- John T. Sherrer, National Community Pharmacists Association (NCPA)
- Eve Bukowski, California Life Science Association
- Jennifer Kurrie, Walgreens
- Rita Speck, Kaiser Permanente
- John G. Waffenschmidt, Covanta Energy Corporation
- Hal Dash and Brandon Stephenson, Cerrell and Associates (PR firm representing PhRMA)
- Howard Sunkin, Ek & Ek (PR firm representing generic drug manufacturers)
- Kerrie Randolph, Arnie Berghoff & Associates (PR firm representing GPhA)
- John R. Valencia, Wilke, Fleury, Hoffelt, Gould & Birney, LLP (PR firm representing Grifols)
- Angela Blanchard and Elizabeth Gallenagh, *Political Solutions LLC (PR firm representing wholesale distributors)*
- Tom Erickson, Sharps Disposal Consultant

EXHIBIT 9

Los Angeles County EPR Pharmaceuticals and Sharps Ordinance Objective, Program Goals, and TAG Purpose

On August 11, 2015, the Los Angeles County Board of Supervisors adopted a Motion authored by Mayor Antonovich and Supervisor Solis, directing "the Interim Chief Executive Officer, in collaboration with the County's Sustainability Council and the Pharmaceutical Working Group to:

- 1. Draft an ordinance which requires manufacturers and producers of prescription and nonprescription drugs and sharps to develop product stewardship take-back programs to collect and dispose of unused/unwanted pharmaceutical and sharps waste from County residents;
- Initiate stakeholder engagement with the pharmaceutical industry and other stakeholders to solicit feedback on the ordinance; communicate the need to provide safe, convenient, and sustainably financed take-back options for consumers to properly dispose of pharmaceutical and sharps waste; and generate awareness about the collection program that will be created; and
- 3. Return to the Board within six months with the recommended Ordinance for consideration."

The Board also approved a friendly amendment to the motion by Supervisor Knabe, encouraging approval of the motion and clarifying that "the stakeholder process occur first before the ordinance is drafted."

Objective

Ensure all County residents have access to safe, convenient, and sustainably financed collection and take-back options for properly disposing unwanted pharmaceutical and sharps waste.

Program Goals

- Promote extended producer responsibility principles, which pertain to the proper management of products at the end of their useful life. These principles include, but are not limited to:
 - Ensuring the proper collection and disposal of waste, including potentially harmful products;
 - Creating a mechanism for shared logistical and financial responsibility for safe drug and sharp disposal programs;
 - Ensuring convenience for the public, including take-back options at no cost to the resident at the end of life of the product; and
 - Ensuring effective outreach and education for residents and other stakeholders.
- Ensure all elements of the program are consistent with the Drug Enforcement Administration Disposal Act as stipulated within the framework of the Controlled Substances Act, and all other applicable federal, State, and local laws and regulations.

Technical Advisory Group (TAG) Purpose

- Engage in a constructive dialogue regarding potential components of a draft EPR ordinance.
- Provide input and feedback on best practices of EPR programs for unwanted pharmaceuticals and sharps waste from around the world, including within California.

EXHIBIT 10

List of Support and Opposition to the Los Angeles County's Draft Pharmaceutical Drugs and Sharps Take-Back Ordinance as of April 14, 2016

Cities Supporting the Ordinance (Total 30)

SD1: Total 10	SD2: Total 4	SD3: Total 3	SD4: Total 7	SD5: Total 6
City of Azusa	City of Carson	City of Malibu	City of Avalon	City of Alhambra
City of Bell	City of Compton	City of W. Hollywood	City of Downey	City of Covina
City of Bell Gardens	City of Culver City	City of Santa Monica	City of Lakewood	City of Glendale
City of Claremont	City of Inglewood		City of La Mirada	City of Monrovia
City of Huntington Park			City of Norwalk	City of Palmdale
City of La Puente			City of Signal Hill	City of S. Pasadena
City of Rosemead			City of Torrance	
City of South Gate				
City of Vernon				
City of Whittier				
*City of Los Angeles is loc	cated in all five Count	y Supervisorial Districts.	_	<u> </u>

^{*} Resolution supporting the County's Ordinance was introduced by Council members Paul Koretz and David E. Ryu, on 2/26/16: Pending in the Rules, Elections, Intergovernmental Relations and Neighborhood Committee.

Other Agencies and Entities Supporting the Ordinance

- 1 Alameda County, Nate Miley, Supervisor, District 4
- 2 Athens Services
- 3 ASCON Corporation
- 4 Blue Shield of California
- 5 California Association of Sanitation Agencies (Waste Water Treatment Agencies)
- 6 California Nurses Association
- 7 California Product Stewardship Council (Product Stewardship Advocates)
- 8 CalRecycle
- 9 California Refuse Recycling Center
- 10 Coalition of Supporters containing over 16 agencies (Environmental, Consumer, Retired, and Drug Abuse
- 11 Covanta Energy LLC
- 12 East Bay Sanitary Co., Inc.
- 13 Gray Panthers of San Francisco (Social Justice/Human Rights Advocates)
- 14 Heal the Bay (Water Quality)
- 15 Kern Refuse, Inc. (Waste Management)
- 16 Las Virgenes-Triunfo Joint Powers Authority (Water Quality)
- 17 League of California Cities, Los Angeles County Division (Regional Association)
- 18 Letters from private individuals
- 19 Los Angeles Alliance for a New Economy (LAANE) and Teamsters Local 396
- 20 Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force
- 21 Los Angeles County Waste Management Association
- 22 Marin Sanitary Service
- 23 Metropolitan Recycling LLC (Recycler)
- 24 National Stewardship Action Council (Product Stewardship Advocates)
- 25 Robert Kennedy Jr., Waterkeeper Alliance, Natural Resources Defense Council

List of Support and Opposition to the Los Angeles County's Draft Pharmaceutical Drugs and Sharps Take-Back Ordinance as of April 14, 2016

- 26 San Gabriel Valley COG (Regional Association)
- 27 Sierra Energy
- 28 Southern California Disposal & Recycling Center
- 29 State Senator Ben Allen
- 30 State Senator Hanna-Beth Jackson
- 31 State Senator Tony Mendoza
- 32 Surfrider Foundation (Environment)
- 33 Tarzana Treatment Centers
- 34 Turlock Recycling

List of Entities Opposing the Ordinance

- 1 Advanced Medical Technology Association (Sharps)
- 2 Biocom (Pharmaceuticals and Biotech)
- 3 Biotechnology Innovation Organization (Biotech)
- 4 Bristol-Myers Squibb (Pharmaceuticals)
- 5 Consumer Healthcare Products Association (Over-the-counter medications)
- 6 Civil Justice Association of California (Various lobbyists for tort reform)
- 7 California Life Sciences Association (Drugs and Sharps)
- 8 Generic Pharmaceutical Association (Generic Drugs)
- 9 Los Angeles Area Chamber of Commerce (Businesses)
- 10 Pharmaceutical Research and Manufacturers of America (Drugs and Biotechnology)
- 11 Product Management Alliance
- 12 Southern California Biomedical Council (Biomedicine)

Other Interested Agencies

- 1 California Grocers Association (Chain and Independent Supermarkets)
- 2 California Retailers Association (Retail Establishments)
- 3 Healthcare Distribution Management Association (Healthcare Distributors)
- 4 Hospital Association of Southern California (Hospitals)
- 5 Los Angeles County Business Federation (Businesses)

EXHIBIT 11

Key Elements to be Addressed Based on Existing Extended Producer Responsibility (EPR) Pharmaceutical Take-Back Ordinances in California

- 1. Determine which products are included in the take-back program, for example:
 - Prescription medicines
 - Over-the-counter medicines
 - Generic medicines
 - Sharps
- 2. Define terms that are used throughout the ordinance such as manufacturer, producer, wholesaler, and repackager.
- 3. Determine funding of a stewardship take-back program, including administration and oversight.
- 4. Determine elements of a stewardship take-back program plan, which will include the safe and legal collection, transportation, and disposal of unwanted products.
- 5. Determine the review and approval process for product stewardship plans.
- 6. Determine the education and outreach requirements for product stewardship plans.
- 7. Establish requirements for reporting to the public agency overseeing the program.
- 8. Determine how the ordinance is implemented and enforced including the establishment of regulations and fees.
- 9. Determine miscellaneous, additional provisions.

Outline of a Proposed LA County EPR Pharmaceutical Take-Back Ordinance

- 1. Declaration of Findings:
 - Board of Supervisors to make factual findings precipitating the drafting of a proposed ordinance.
- 2. Title of Ordinance
- 3. Definitions: see current definitions set forth in the Alameda and San Francisco, and King County, Washington. Key definitions include, but not limited to:
 - Collector
 - Covered drug
 - Drug
 - Manufacture/Manufacturer
 - Repackager
 - Producer
 - Sharp
 - Wholesaler
- 4. Stewardship Plan Participation:
 - Sets forth requirements for who must participate in the program.
 - Establishes the Stewardship Plan approval process.
 - Sets forth the timeline for participants to submit a Stewardship Plan.
- 5. Stewardship Plan Components (note, the ordinance will establish Stewardship Plan criteria and guidelines; manufacturers will be required to design their respective plans to meet established guidelines):
 - Sets forth components required in each product stewardship plan.
 - Establishes collection requirements including requirement for drop-off locations and mail-back options.
 - Establishes convenience metrics.
 - Establishes success metrics.
- 6. Stewardship Program Promotion and Educational Outreach:
 - Sets forth requirements for the education and outreach components of the Plan.
 - Requires assessment of program to determine public awareness and how effectiveness will be evaluated.
 - Establishes language requirement of promotional and educational materials.

7. Disposal of Covered Drugs:

- Sets forth requirements for disposal of covered drugs, to ensure environmental and human health is protected.
- Establishes criteria for final disposal technologies such as protections in the following areas: worker health and safety; monitoring of any emissions or waste (e.g., air emissions, etc.), and overall impact on the environment and human health.

8. Stewardship Plan Reporting Requirements:

- Sets forth reporting requirements including due dates and content of reports.
- Sets forth County requirements to make reports available to the public.

9. Stewardship Program - Administrative and Operational Costs:

- Establishes Producer responsibility to pay costs associated with program, including, but not limited to collection, transportation, disposal, etc.
- Establishes Producer responsibility to pay administrative costs of the program including, but not limited to review and approval of stewardship plans, review of program reports, and enforcement.
- Sets forth that Producer shall not charge or pass costs on to end-users/consumers.

10. Regulations and Fees:

• Gives County authority to adopt regulations governing the implementation of the proposed ordinance.

11. Enforcement:

• Sets forth how the County may enforce the ordinance.

12. Adherence to State and Federal Law:

• Sets forth that ordinance must be in compliance and have no conflict with State or federal laws.

13. Additional Provisions:

• Sets forth miscellaneous, additional provisions.

Los Angeles County Extended Producer Responsibility Pharmaceuticals and Sharps Waste Ordinance Matrix of Potential Roles and Responsibilities

Stakeholder/ Partner	Potential Role/Responsibility
Producers	Develop Program Plan Pay for and implement Program Drovide periodic reports summerizing Program
Pharmacies/ Retailers (including mail- order pharmacies)	 Provide periodic reports summarizing Program Voluntarily participate in Program (serve as collection site and/or distribute mail back envelopes/containers) OR- Share information regarding nearby take-back/mail-back locations
Hospitals/Clinics	 Help educate customers Voluntarily participate in Program (serve as collection site and/or distribute mail back envelopes/containers) OR
	 Share information regarding nearby take-back/mail-back locations Help educate patients
Medical/Sharps Waste Disposal Service Providers	Provide for collection and proper disposal of collected pharmaceutical and sharps waste, in compliance with relevant laws and regulations
Non-profits	Share information regarding proper management of products/EPR program to residents in the County
Sherriff's Department/Law Enforcement	 Host collection events Host kiosks Assist participants in complying with DEA requirements
Department of Public Health	Review and approve Stewardship PlansEnforce ordinance
Department of Public Works/ Other County Agencies	 Host collection events Conduct outreach and education

PHARMACEUTICAL TAKE-BACK

A DOSAGE FOR CHANGE





LA County Overview



A MESSAGE FROM THE HEALTH OFFICER
Prescription and non-prescription drugs play a
critical role in treating diseases and saving lives.
However, unused and expired
medications must be properly discarded so
that they do not pose a risk to others.
According to the National Community

Pharmacists Association, an estimated 200 million pounds of unused or expired prescription drugs are stored in medicine cabinets across America. This situation provides easy access and an opportunity for the abuse of these medications by others for whom they were not intended.

In LA County from 2000 to 2009, there were 8,265 drug-related deaths. Public health statistics show that 61 percent of those deaths involved a commonly abused prescription or over-the-counter drug. Of note, nearly 75 percent of residents who misuse prescription drugs obtain them from relatives or friends. Deaths and illnesses caused by the abuse of prescription opioids are of national concern. The number of deaths each year from prescription opioids is now greater than the deaths from heroin, cocaine, and benzodiazepine drugs combined.

It is also very important that needles, syringes, lancets, and other medical products are disposed of properly. While the use and disposal of these items is closely regulated in healthcare facilities, there is no regulatory oversight of their use in the home. Studies show that these items are routinely placed into the trash. Improper disposal practices may result in needlestick and other injuries that can expose others to bloodborne illnesses such as hepatitis B, hepatitis C, and HIV. Many residents are unsure of safe disposal methods, and proper disposal services are limited.

These situations represent a significant public health problem. There is an opportunity for LA County to implement additional disposal options that will protect the health and safety of our residents. The Board of Supervisors recently passed a motion directing the Pharmaceutical Working Group, made up of several County departments, to draft an Extended Producer Responsibility ordinance. In the proposed ordinance, manufacturers and producers would develop and fund convenient collection services for LA County residents.

The principle behind the ordinance is to protect public health and assure public safety. Safe drug and sharps disposal is an important social need that requires a permanent and sustainable solution. The Pharmaceutical Working Group is reaching out to the producers of drugs, needles, syringes and other medical products as well as stakeholders in the community to gather suggestions and concerns about drafting such an ordinance. After this information has been collected, the group will draft an ordinance, share this for further comment, and then provide this to the Board of Supervisors for its consideration.

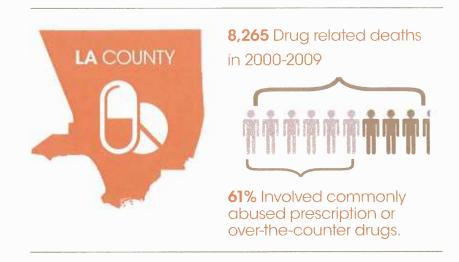
Problem

MEDICATION MISUSE

Prescription drug abuse has become one of the fastest-growing public health concerns in the United States and Los Angeles County. Nearly 75 percent of residents who use prescription drugs inappropriately, obtain them from relatives or friends.

According to the CDC, there is a national epidemic of prescription opioid abuse that takes about 15,000 lives each year in the U.S. Deaths from prescription opioids are greater than deaths from heroin, cocaine, and benzodiazepine drugs combined each year.

Public Health statistics in LA County show that there were 8,265 drug-related deaths in Los Angeles County between 2000-2009; 61 percent of those deaths involved commonly abused prescription or over-the-counter drugs.



SHARPS WASTE

Disposal of needles, syringes, lancets, and other medical products are not regulated in the home, while these same products used in health care facilities are strictly regulated. Home-generated medical waste is routinely placed into the trash, which poses a public health risk.

"Given the limited waste disposal services available and the fact that many County residents are unsure of how to safely and properly dispose of pharmaceutical and sharps waste, there is an opportunity for Los Angeles County to take action to provide additional waste disposal options through this ordinance," said Jeffrey Gunzenhauser, MD, MPH, Interim Health Officer for Los Angeles County. "It is prudent to encourage other methods of disposal."

Sustained collaboration between the public and private sectors is essential.

How to Manage Your Medications

It's important to properly store medications (pharmaceuticals) that are currently being used and to safely dispose of unused/expired medication.

What is considered medication?

- Prescription drugs
- Over-the-counter medications
- Aspirin, ibuprofen, etc.
- Birth control pills
- Hormone replacement drugs

AVOID Flushing
Unwanted
Medications

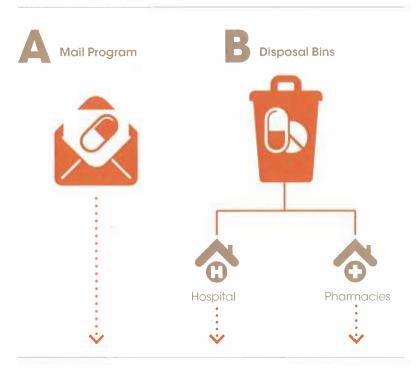


How to properly dispose of medications

Do not flush unused, unwanted, and expired medications down the toilet or put them in the drains. Always make sure to keep medication out of reach of children and pets. Unused, unwanted, and expired medications can be taken to one of the County's free Household Hazardous Waste collection events, designated Sheriff's stations or to one of the City of Los Angeles' SAFE Centers. Event schedule and locations can be found on the CleanLA.com website.

When disposing of medication, make sure to remove all labels with personal information and recycle the containers at home. Place unneeded pills into a plastic container or bag.

MEDICATION COLLECTION OPTIONS



Extended Producer Responsibility (EPR)

EPR is an environmental protection policy approach that recognizes a manufacturer or producer's responsibility to steward a product through the post-consumer stage of a product's lifecycle.

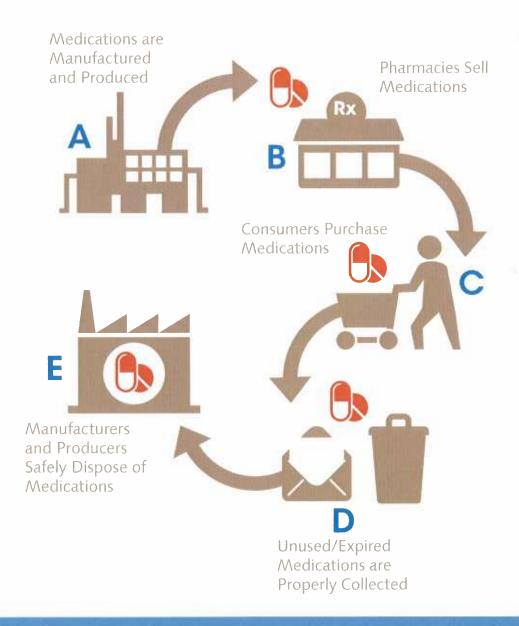
• EPR provides producers an *incentive to design* their products to be less hazardous and/or *easier to manage/recycle* at the end of their useful life.

 The EPR approach has been successful in managing pharmaceutical (unused/expired medication) waste for years throughout some European countries, Mexico, and Canada.

Sustainable Solution

Take-back programs are a *convenient*, efficient, and environmentally safe collection and disposal option for pharmaceutical and sharps waste.

 A take-back program financed by the pharmaceutical industry would manage the safe collection and disposal of unused/expired pharmaceuticals and relieve the current burden from publically funded efforts.



Creating a **Healthier** LA County



GET INVOLVED

Learn more at: publichealth.lacounty.gov

- facebook.com/lapublichealth
- twitter.com/lapublichealth



EXHIBIT 12

Federal and State Regulatory/Recommendation Comparison Chart

Drug Enforcement Agency (DEA) Rule for Disposal of Controlled Substances	Federal Drug Administration (FDA) Recommendations on How to Dispose of Unused Medicines	Environmental Protection Agency (EPA) Recommendations for Collecting and Disposing of Unwanted Medicines
Istration as a collector: Allowable types of collectors: pharmacies; long-term care facilities, ehospitals/clinics with onsite pharmacies, law enforcement locations and elocation events where law enforcement is present.	Tanster Unused Medicine to Authorized Collectors for Disposal: Medicine take-back programs are preferable method to safely dispose. Recommend DEA National Prescription Drug Take-back events or local law enforcement sponsored take-back programs.	What to do with unwanted medicines: Do not flush expired or unwanted prescription drugs down the drain or tollet unless the label or accompanying information instructs to do so.
Submit a written request to the DEA; no fee is required for modification of entire registration for pharmacies.	Contact local waste management authorities.	First choice: EPA encourages the public to take advantage of pharmaceutical take-back collection programs that accept prescription
	Dispose of unreceded interdules to DEA registered confectors (retain pharmacies, hospitals or clinic pharmacies, law enforcement locations, or mail-host programs).	or over-the-counter drugs.
Collection receptacles must be securely placed in the immediate proximity to where an employee can see the receptacle from the pharmacy counter.	Disposa in Household Trash:	conscious way to dispose of unwanted medicines. May include a local enforcement agency, retail pharmacy,
	If no medicine take-back program or DEA-authorized collectors are available:	hospital or clinic. Recommends that household pharmaceuticals collected
	O Mix medicines with unpalatable substance such as dirt, kitty	
Once the opaque liner (device to collect/store medications that is within the receptacle) is removed from receptacle, liner must be sealed and stored	litter, or used coffee grounds. Place in a container such a sealed plastic bag.	 EPA prefers that the collected household pharmaceuticals be sent to a permitted hazardous waste combustor, but when
until prompt destruction can occur.	Throw in household trash. Remove personal information	that is not feasible, at a minimum they should be sent to a large or small municipal waste combustor.
The installation and removal of the inner liner must be performed by, or	4	Second Choice: Put medicines into a disposable container with a lid.
מר ובפאר ואס בוולוסאבא מו חוב מתווסודגמ	Recommended for small number of medicines that may be especially	such as an empty margarine tub, or into a sealable bag. O Mix drues with an undesirable substance, such as cat litter or
	infinition and potentially later with one dose. If no take-back program option is available, recommended to flush down	used coffee grounds.
Strict record keeping requirements, including keeping track of when each liner is transferred to and from the receptacles.	the sink or toilet as they are no longer needed. FDA remains committed to working with other federal agencies and medicine manufacturers to develop alternative, safe disposal policies.	 Conceal or remove any personal information, including Rx number, on the empty containers by covering it with permanent marker or duct tape, or by scratching it off.
If transferred to a person registered to destroy controlled substances, two collection site employees must witness loading on to transportation vehicle. If being transferred to non-registered location, two collection site employees must accompany the transporting of substance and witness the destruction.		 Proper Disposal Benefits: Prevents poisoning of children and pets. Deters misuse by teenagers and adults. Keeps medicines from entering streams and rivers when poured down the drain or flushed down the toilet.
Sealed and numbered liner may be sent via common carrier to registered destruction location. DEA's states in the Notice for Proposed Rulemaking that disposal by flushing down a toilet or sink and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds, and depositing in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard.		

EXHIBIT 13

1. What is the objective of this ordinance?

Response: The primary objective of this ordinance is to ensure that all County residents have access to safe, convenient, and sustainably financed collection and take-back options for properly disposing unwanted pharmaceutical and sharps waste. The safe disposal of pharmaceuticals and sharps waste helps protect public health and safety and the environment.

2. Why is a take-back program necessary for pharmaceuticals and sharps?

Response: Currently, there are limited options for the proper disposal of unwanted or expired pharmaceuticals and supplies. It is estimated that each year in the United States, 200 million pounds of pharmaceutical waste is generated, and that much of that waste ends up in medicine cabinets in homes or disposed of through sewer or waste systems¹. In addition, the lack of convenient options to discard sharps waste such as needles, syringes, and lancets can pose a health risk to residents, particularly children and sanitation workers.

3. Does this draft ordinance apply to the entire County, or only the unincorporated areas?

Response: The ordinance will only apply to the County Unincorporated areas. However, all 85 cities for which Public Health is the Health Officer may adopt the Ordinance upon approval by their respective City Councils. Thus far, almost 30 cities have provided support letters to the County and have expressed interest in joining the program. The three cities that have their own Public Health Department, (Long Beach, Pasadena, and Vernon), would have to pass their own ordinances, if interested.

4. Are other take-back ordinances, such as in Alameda County, successful?

Response: It is too early to determine the success of these other ordinances as implementation of Extended Producer Responsibility (EPR) programs have not yet begun for most Counties in California that have adopted similar EPR ordinances. This is in part due to litigation, specifically "Pharmaceutical Research and Manufacturers of America v. County of Alameda." However, EPR programs for pharmaceuticals have been very successful in other countries such as Canada, Mexico, Belgium, France, Hungary, Portugal, Spain, Brazil, and Colombia. Alameda, Marin, Santa Clara, Santa Cruz, and San Mateo Counties, and the City and County of San Francisco, and King County, Washington, have approved ordinances; and Alameda County and King County have Stewardship Plans developed by industry which are anticipated to be successful.

5. Will pharmacies be required to host collection bins?

Response: The preliminary draft ordinance <u>does not</u> mandate pharmacies or any other entities to serve as a collector (host a collection bin for either pharmaceutical or sharps waste). Throughout the stakeholder process County staff representatives have stressed that hosting a bin is voluntary, since the pharmacy and retailer associations, including, the California Retailers Association,

¹ DisposeMyMeds.org (National Community Pharmacists Association, downloaded November 24, 2015)

since the pharmacy and retailer associations, including, the California Retailers Association, California Pharmacists Association, and California Grocers Association have indicated that some locations may have constraints that prevent them from being able to serve as a collector. However, it should be noted that there is already voluntary participation at many pharmacies, clinics, hospitals, and other locations throughout the country, including 1,600 independent pharmacies as reported by the National Community Pharmacists Association Foundation. Walgreens pharmacies have a sharps take-back program in San Francisco, and Kaiser Hospitals have collection bins for sharps. Additionally, Walgreens announced on February 9, 2016 that they will be adding collection bins at 500 locations in 39 states, and that California will be the first state to have collection bins.

6. Can the program be successful if pharmacies choose not to host collection bins?

Response: As stated above, pharmacies and hospitals are already hosting collection bins and indicated an interest in participating in a Stewardship Program in the County. In addition, Stewardship Plans are intended to be flexible, offering a range of collection options. Responsible Stewards can host their own locations, host monthly collection events, and provide mail-back services. The federal Drug Enforcement Agency (DEA) regulations specify five categories of take-back options for pharmaceutical waste, including mail-back programs, pharmacies, hospitals with pharmacies, long-term health care facilities, and law enforcement. There are no regulations pertaining to hosting a sharps collection bin so these could potentially be located in a broader area of locations.

7. What will the role of pharmacies be?

Response: Each pharmacy will have an integral role in this program, even if they choose not to serve as a collector and host a bin. At a minimum, pharmacies and any business selling drugs to the public will display educational materials approved by the County, explaining how and where residents may conveniently, safely and lawfully dispose of unwanted drugs and sharps.

8. What drugs are included in the draft ordinance?

Response: The Draft Ordinance defines "Covered Drugs" which includes prescription, non-prescription, brand name, generic drugs, and controlled substances. It does not include vitamins or supplements, herbal-based remedies and homeopathic drugs, products, or remedies.

9. Why can't residents simply dispose unwanted pharmaceuticals and sharps in the trash or flush them down the drain?

Response:

Although pharmaceuticals are not prohibited from being flushed down the toilet or drain,
 Waste Water Treatment Plants (WWTPs) are not designed to manage or remove all of the

complex compounds found in pharmaceutical waste. As a result, flushing medications contributes to an increase in concentrations of medications in surface, ground, and drinking water. The long-term effects of these pollutants are unknown; therefore it is prudent to encourage other methods of collection and disposal.

- Similarly, disposing of pharmaceuticals in the trash is currently not prohibited; however, medications that end up in landfills may leach into the groundwater or the landfill's leachate, which is treated via WWTPs not designed to treat pharmaceuticals, as discussed above. Additionally, medications thrown in the trash are susceptible to improper diversion or accidental poisonings.
- The disposal of sharps in the trash or flushing is prohibited by state law (<u>California Health and Safety Code 118286</u>). This is because there is a serious health risk to children, workers who collect and sort waste, and the general public from improper disposal of sharps. Unfortunately, some people flush sharps down the drain, which is hazardous for the WWTPs. Recently, local beaches were temporarily closed due to sharps washing ashore following discharges from WWTPs. Therefore, the federal Environmental Protection Agency and the federal Food and Drug Administration have both identified local take-back programs as the "first choice" or "best option" for safely and conveniently collecting these products.

10. <u>Since pharmaceuticals enter the environment through excreted human waste, how will this ordinance prevent pharmaceuticals from entering the environment?</u>

Response: There are many factors that influence the amount of pharmaceuticals in the environment. This ordinance is intended to decrease the amount of unwanted and unused pharmaceuticals and sharps waste that enter the environment by substantially increasing the collection and proper disposal. The fact that there are other sources of pollution beyond the scope of this Draft Ordinance does not mean we should not attempt to reduce pollution from sources that can be affected by this Ordinance.

11. <u>Do the DEA regulations or Draft California Board of Pharmacy (BoP) regulations preclude</u> retail pharmacies from serving as collection sites?

Response: **No.** The purpose of the DEA regulations, which were promulgated following the passage of the Secure and Responsible Drug Disposal Act of 2010, was to *facilitate* additional options for the collection of all pharmaceuticals, including controlled substances, through take-back events, mail-back programs, and collection receptacle locations, including pharmacies. The regulations serve to reduce the potential for returned pharmaceuticals to be improperly diverted. The Draft BoP Regulations are not yet finalized, but the current draft closely mirrors the DEA pharmaceutical take-back regulations.

12. Is outreach and education the best way to deal with proper disposal?

Response: Education and outreach are very important components of any successful effort, but cannot solve the problem alone. Once safe and convenient disposal options are available, education and outreach to residents on where and how they may safely and lawfully dispose of unwanted drugs and sharps will be critical to the success of a comprehensive multifaceted EPR program. Along with the three disposal options (collection sites, mail-back services, and collection events), the draft Ordinance also includes a requirement that the Responsible Steward(s) or Stewardship Organization(s) conduct outreach and education materials to pharmacies, health care facilities, veterinary facilities, and other prescribers for their own education and for dissemination to residents.

13. What will be the financial impact to the consumer of this program?

Response: The ordinance prohibits Responsible Stewards from charging consumers a point-of-sale or point-of-collection fee.

14. What is the estimated unincorporated area cost and County-wide cost of the program that will be borne by the Responsible Steward(s) or Stewardship Organizations?

Response: The County estimates that the unincorporated area annual cost would be \$3.2 million, and the County-wide annual cost would be \$16.0 million, which is approximately 0.018 percent, or about $1/50^{th}$ of 1 percent of the pharmaceutical industries annual profits (\$89.3 billion).

ATTACHMENT III

Los Angeles County Pharmaceutical Drugs and Sharps Collection and Disposal Stewardship Ordinance CEQA FINDINGS

The Board of Supervisors finds that the Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance ("Ordinance") is categorically exempt from the California Environmental Quality Act ("CEQA") pursuant to Section 15307 (Class 7) and 15308 (Class 8) of the CEQA Guidelines because it consists of a regulatory action that will assure the maintenance, restoration or enhancement of a natural resource or the maintenance, restoration, enhancement or protection of the environment. Furthermore, none of the exceptions contained in Section 15300.2 of the CEQA Guidelines applies. The Board of Supervisors makes the following specific findings:

A. Pathways to the Environment From Disposing Medication in the Trash or Toilet

- 1. Without a convenient take-back alternative, most Los Angeles County residents will dispose of unwanted pharmaceuticals either down the toilet or sink, or in their household trash. Pharmaceuticals disposed in this fashion may end up in surface waters, groundwater, soil, drinking water and even the food supply through several different pathways.¹
- 2. When pharmaceuticals are flushed down the toilet or poured down the sink, they end up in the wastewater stream. Wastewater treatment plants ("WWTPs") produce treated effluent that may be discharged to surface waters or in some cases may be beneficially reused. WTTPs also produce a byproduct known as biosolids. Some biosolids are disposed in landfills, and others are beneficially used as fertilizer or compost.²
- 3. WWTPs are not designed to remove pharmaceuticals.³ Pharmaceutical compounds have been detected in treated effluent and in receiving waters where WWTPs discharge, including rivers and streams.⁴ Research is ongoing to determine the impacts of such

HOA.2016279.1

¹ See Recommendation on Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (EPA Memorandum, September 2012), found at http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\$file/14833.pdf; *Pharmaceuticals in Drinking Water* (World Health Organization 2012); found at http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085 eng.pdf?ua=1.

² CalRecycle. Organic Materials Management Biosolids. Found at: http://www.calrecycle.ca.gov/organics/biosolids/ (January 6, 2016); California Association of Sanitation Agencies. Biosolids Program. Found at http://www.casaweb.org/biosolids/ (January 13, 2016).

³ CalRecycle, Household Medication Waste Disposal, found at http://www.calrecycle.ca.gov/homehazwaste/Medications/household.htm; Pharmaceuticals in Drinking Water (World Health Organization 2012; Bendz, David, Nicklas A. Paxeus, Timothy R. Ginn and Frank J. Loge, "Occurrence and fate of pharmaceutically active compounds in the environment, a case study: Höje River in Sweden," Journal of Hazardous Materials (2005) 122:195-204.

⁴ See, for instance, Kostich, Mitchell S., Angela L. Batt and James M. Lazorchak, U.S. Environmental Protection Agency, "Concentrations of Prioritized Pharmaceuticals in Effluents from 50 Large Wastewater Treatment Plants in the US and Implications for Risk Estimation," United States Environmental Protection Agency (January 2014), found at http://www.epa.gov/sites/production/files/2014-09/documents/50 large wwtp effluent.pdf; Sengupta, Ashmita, J. Michael Lyons, Deborah J. Smith, Jorg E. Drewes, Shane A. Snyder, Ann Heil, and Keith A. Maruya, "The Occurrence and Fate of

- pharmaceuticals on aquatic life.⁵ Moreover, flows from unlined rivers and streams can infiltrate and reach groundwater.
- 4. Because pharmaceuticals have been found in the effluent of WWTPs, questions have been raised about the presence of these compounds in biosolids, which provides an additional pathway to the environment, such as when they are applied to the land as fertilizer or compost.⁶
- 5. Pharmaceuticals that are disposed in household trash are at risk of being improperly diverted and either abused or accidentally consumed by children and pets. To the extent that these pharmaceuticals end up in landfills, they may ultimately end up in the liquid that drains from landfills (leachate), where they may directly impact groundwater or be diverted to a WWTP.⁷
- 6. Recycled water taken from municipal wastewater sources is a vital resource for managing scarce water resources, particularly in times of drought. Recycled water is used for a variety of purposes such as irrigation, industrial use, and groundwater recharge. Reducing the amount of pharmaceuticals that are discharged to WWTPs helps support the continued use of this vital resource.
- 7. In addition, wastewater from onsite wastewater treatment (septic) systems and some small treatment plants is discharged to seepage pits and leach fields where it percolates to the groundwater.
- 8. According to the United States Environmental Protection Agency ("EPA"), "studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing. Further, some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems." 10

2

HOA.2016279.1

Chemicals of Emerging Concern in Coastal Urban Rivers Receiving Discharge of Treated Municipal Wastewater Effluent," Environmental Toxicology and Chemistry, Vol. 33, No. 2, pp. 350-358 (2014).

⁵ Household Medication Waste Disposal (CalRecycle website); Onesios, K. M., Yu, J. T. & Bouwer, E. J. Biodegradation and removal of pharmaceuticals and personal care products in treatment systems: a review. Biodegradation 20, 441–466 (2009).

⁶ USGS, Land Application of Municipal Biosolids, found at http://toxics.usgs.gov/regional/emc/municipal biosolids.html.

⁷ J. Masoner, D. Kolpin, E. Furlong, I. Cozzarelli & J. Gray, Landfill leachate as a mirror of today's disposable society: Pharmaceuticals and other contaminants of emerging concern from landfills in the coterminous United States, U.S. Geological Survey, October 2015.

⁸ State Water Resources Control Board, Recycled Water Policy, found at http://www.waterboards.ca.gov/water_issues/programs/water_recycling_policy. Los Angeles County Sanitation Districts, Water Reuse Program, found at http://www.lacsd.org/waterreuse.

⁹ Association of California Water Agencies, California's Water: Water Recycling Imitates Nature, found at http://www.wrd.org/engineering/groundwater-replenishment-spreading-grounds.php.

¹⁰ Recommendation on Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs (EPA Memorandum, September 2012), *supra*.

- 9. According to the World Health Organization ("WHO"), pharmaceuticals have been detected in the water cycle, including surface waters, wastewater, groundwater and to a lesser extent, drinking water, which "has raised concerns among stakeholders, such as drinking water regulators, governments, water suppliers and the public, regarding the potential risks to human health from exposure to traces of pharmaceuticals via drinking water."
- 10. The most straightforward way to minimize the risk posed by the flushing and trash disposal of pharmaceuticals is to reduce the quantity of pharmaceuticals that are discarded in this fashion. 12
- B. Take-Back Programs Reduce the Entry of Pharmaceuticals and Sharps into the Environment
- 11. According to the United States Congress, "[d]rug take-back programs are . . . a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water."¹³
- 12. The WHO supports take-back programs as a way to promote the "proper disposal of unwanted and excess medicines and reduce the environmental impact of pharmaceuticals entering our environment, including water sources.¹⁴
- 13. The EPA encourages the public to utilize pharmaceutical take-back collection programs that accept prescription or over-the-counter drugs to dispose of unwanted medications. According to the EPA, "these programs offer a safe and environmentally-conscious way to dispose of unwanted medicines." ¹⁵
- 14. The Federal Food and Drug Administration ("FDA") recommends use of take-back programs as the preferred option for disposal of unwanted or expired medications. Only if a take-back option is not available does the FDA recommend disposal in household trash after following a multi-step process (consisting of crushing pills and adding

HOA.2016279.1 3

¹¹ Pharmaceuticals in Drinking Water (World Health Organization 2012), supra.

¹² January 19, 2016 Comments by the Los Angeles County Sanitation Districts in support of the Los Angeles County Pharmaceutical and Sharps Collection and Disposal Stewardship Ordinance, Bound, Jonathan P. and Nikolaos Vouvoulis, "Household Disposal of Pharmaceuticals as a Pathway for Aquatic Contamination in the United Kingdom, Environmental Health Perspectives (Vol. 113, No. 12, Dec. 2005), pp. 1705-1711; see also *Pharmaceuticals in Drinking Water* (World Health Organization 2012), *supra*, noting that "preventing pharmaceuticals from entering the water supply cycle during their production, consumption (i.e. excretion) and. *disposal* is a pragmatic and effective means of risk management."

¹³ The Secure and Responsible Drug Disposal Act of 2010, PL 111–273 [S 3397] October 12, 2010.

¹⁴ Pharmaceuticals in Drinking Water (World Health Organization 2012), supra.

¹⁵EPA website, at http://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines.

- undesirable substances, such as cat litter or used coffee grounds, to it), and flushing certain high-risk substances down the drain. ¹⁶
- 15. However, pharmaceuticals disposed via trash, even if they are altered in the manner recommended by the FDA, may pose an acute hazard for people and pets and may potentially facilitate entry of pharmaceutical residuals into the environment.¹⁷ An additional hazard associated with this manner of disposing medications in the trash is that identifying information is not available, and if someone were to accidentally (or intentionally) recover and ingest the medicine, it would be difficult to assist them without that information.¹⁸
- 16. On January 22, 2016, a coalition of over 50 public agencies, environmental organizations, and other interested stakeholders signed a letter urging the FDA, "[t]o protect public health and environmental quality," to "end its recommendation that certain medications be disposed by flushing, and to clarify that secure medicine take-back programs provide the best disposal method for leftover household medications." 19
- 17. Improperly disposed sharps pose a danger to children, pets, and particularly to sanitation workers who risk needle-stick injuries during trash collection, during the process of sorting trash from recyclables at materials recovery facilities, and at landfills.²⁰ In addition, sharps that are improperly flushed down the toilet can wash up on our beaches. For example, one incident involved hypodermic needles and other debris discharged from a pipe leading to the Hyperion Treatment Plant overflowed into a storm drain, and years later, in September 2015, this material washed up on Dockweiler State Beach.²¹
- 18. Although it is illegal for residents to dispose their sharps waste in trash or recycling receptacles, many people still improperly dispose of their sharps waste due to the lack of convenient, affordable options for legal disposal. Making proper sharps disposal more convenient and less costly to consumers will reduce the incidence of improper disposal and improve operations that sort recyclables in the solid waste stream.
- 19. The Ordinance requires responsible stewards of covered drugs and sharps, (as defined and set forth in the Ordinance), to provide safe and convenient locations for residents to

HOA.2016279.1 4

¹⁶ Federal Food and Drug Administration, "Disposal of Unused Medicines: What You Should Know." Found at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm (January 13, 2016).

¹⁷ Daughton, Christian G. and Ilene S. Ruhoy, "Environmental Footprint of Pharmaceuticals: The Significance of Factors Beyond Direct Excretion to Sewers," <u>Environmental Toxicology and Chemistry</u> (2009) Vol. 28, No. 12, p. 2511.

¹⁸ Ibid, p. 2513

¹⁹Robert F. Kennedy, Jr., et al, Letter to Commissioner Stephen Ostroff, M.D. of the Federal Food and Drug Administration, RE: FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal (January 22, 2016).

²⁰ Community Options for Safe Needle Disposal (EPA 2004).

²¹ Sharon McNary, "Sewer Plant Hid Syringes and Other Waste for Years Before Dockweiler Beach Spill," KPCC, December 2, 2015. Found at: http://scprv4-staging.scprdev.org/news/2015/12/02/55985/sewer-plant-hid-syringes-and-other-waste-for-years/.

drop off unwanted medication and sharps, as well as provide mail back options and collection events. Providing a safe, sustainable alternative method for residents of Los Angeles County to dispose of these products, other than placing them in the trash or flushing them, will reduce the amount of these items that enter the waste stream and end up in surface water, groundwater and drinking water or on beaches.

20. There are no unusual circumstances per Section 15300.2 (c) of the CEQA Guidelines because, among other things, several other counties in California, including Alameda²², San Mateo,²³ Santa Clara,²⁴ Marin²⁵, San Luis Obispo²⁶ and Santa Cruz²⁷ counties, as well as the City and County of San Francisco,²⁸ have adopted take-back programs similar to the one set forth in the Ordinance, to provide a safe, convenient and sustainable means for consumers to take-back unwanted medication and to protect the environment from the deleterious impacts associated with flushing these medications and disposing them in the trash. Santa Cruz County's ordinance also provides for the take-back of sharps,²⁹ and Alameda County ³⁰ adopted an ordinance providing for the take-back of sharps.

HOA.2016279.1 5

²² Alameda County Safe Drug Disposal Ordinance, Chapter 6.53 of the Alameda County Code of Ordinances; see also http://www.acgov.org/aceh/safedisposal.

²³ "County of San Mateo Safe Medicine Disposal Ordinance, Chapter 4.116 of the San Mateo County Code of Ordinances, see also http://smchealth.org/EPR.

 $^{^{24}}$ Santa Clara County Ordinance Code, Division B11, Chapter XX – Safe Drug Disposal, see also $\underline{\text{https://www.sccgov.org/sites/rwr/Pages/safemeds.aspx}} \ .$

²⁵ Marin County Safe Drug Disposal Ordinance, Chapter 7.90 of the Marin County Code of Ordinances; see also http://www.marincounty.org/depts/cd/divisions/environmental-health-services/safe-drug-disposal-ordinance.

²⁶ San Luis Obispo Integrated Waste Management Authority Ordinance No. 2015-1, see also http://www.slocounty.ca.gov/Assets/PW/Garbage+and+Recycling/Medication+Take+Back+-+English.pdf.

²⁷ Santa Cruz County Safe Drug and Sharps Disposal, Chapter 7.95 of the Santa Cruz County Code; see also https://www.sccgov.org/sites/rwr/Pages/safemeds.aspx.

²⁸ San Francisco Safe Drug Disposal Stewardship Ordinance, Chapter 22 of the San Francisco Environment Code; see also http://sfenvironment.org/article/business/safe-drug-disposal-stewardship-ordinance.

²⁹ Santa Cruz County Safe Drug and Sharps Disposal, Chapter 7.95 of the Santa Cruz County Code.

³⁰ Alameda County Safe Consumer Generated Sharps Disposal Ordinance, Chapter 6.54 of the Alameda County Code of Ordinances.

Bibliography

Alvarez, D.A., K.A. Maruya, N.G. Dodder, W. Lao, E.T. Furlong, and K.L. Smalling. 2014. Occurrence of contaminants of emerging concern along the California coast (2009-10) using passive sampling devices *Marine Pollution Bulletin* 81:347-354.

Alvarez-Munoz, D. et al., Occurrence of pharmaceuticals and endocrine disrupting compounds in macroalgaes, bivalves, and fish from coastal areas in Europe. Environmental Research Vol. 143(B) (2015).

Andreu, V., Presence of pharmaceuticals and heavy metals in the waters of a Mediterranean coastal wetland: Potential interactions and the influence of the environment, SCIENCE OF THE TOTAL ENVIRONMENT VOL. 540 (2016).

Arnold, Kathryn E., et al., *Medicating the environment: assessing risks of pharmaceuticals to wildlife and ecosystems*, PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY (2014).

Backhaus, Thomas & Karlsson, Maja, Screening level mixture risk assessment of pharmaceuticals in STP effluents, WATER RESEARCH VOL. 49 (2014).

Batt, Angela L., et al., Evaluating the Extent of Pharmaceuticals in Surface Waters of the United States Using a National-Scale Rivers and Streams Assessment Survey, Environmental Toxicology and Chemistry, Vol. 9999 (2015).

Behr, R., et al., *Preliminary Characterization of the Pharmaceutical Content of Municipal Solid Waste Landfill Leachate from three landfills in Maine*, MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION (2009).

Bendz, David, et al., Occurrence and fate of pharmaceutically active compounds in the environment, a case study: Hoje River in Sweden, JOURNAL OF HAZARDOUS MATERIALS. VOL. 122 (3), 195-204 (2005).

Blair, Benjamin D., et al, *Pharmaceuticals and personal care products found in the Great Lakes above concentrations of environmental concern*, CHEMOSPHERE Vol. 93 (9) (November 2013).

Boix, Clara, et al., Biotransformation of pharmaceuticals in surface water and during waste water treatment: Identification and occurrence of transformation products, JOURNAL OF HAZARDOUS MATERIALS. VOL. 302 (2016).

Bound, Jonathan P. & Voulvoulis, Nikolaos, *Household Disposal of Pharmaceuticals as a Pathway for Aquatic Contamination in the United Kingdom*, ENVIRONMENTAL HEALTH PERSPECTIVES Vol. 113(12) (2005).

Burkina, Viktoriia, et al., Effects of pharmaceuticals present in aquatic environment on Phase I metabolism in fish, Environmental Toxicology and Pharmacology Vol. 40(2) (2015).

Butkovskyi, A., et al., Fate of pharmaceuticals in full-scale source separated sanitation system, WATER RESEARCH, VOL 85. (2015).

California Association of Sanitation Agencies, Biosolids, (January 13, 2016) available at http://www.casaweb.org/biosolids.

California Research Bureau, Common Pharmaceuticals in CA Water, ENVIRONMENTAL SCIENCES CRB SHORT SUBJECTS (March 2014).

California Research Bureau, *Pharmaceuticals in Water: An Overview,* ENVIRONMENTAL SCIENCE SERIES CRB SHORT SUBJECTS (March 2014).

CalRecycle, Organic Materials Management Biosolids, available at http://www.calrecycle.ca.gov/organics/biosolids. Cook, Sherri M. et al, Life Cycle Comparison of Environmental Emissions from Three Disposal Options for Unused Pharmaceuticals, Environ. Sci. Technol., Vol 46 (10), pp 5535–5541 (2012).

Cook, Sherri M. et al, Life Cycle Comparison of Environmental Emissions from Three Disposal Options for Unused Pharmaceuticals, Environ. Sci. Technol., Vol 46 (10), pp 5535–5541 (2012).

Cunningham, Virginia, et al. , Effects of Human Pharmaceuticals on Aquatic Life: Next Steps, Environ. Sci. Technol, Vol. 40 (11), pp 3456–3462 (2006).

Daughton, Christian (U.S. EPA Office of Research and Development) Comment on "Life cycle comparison of environmental emissions from three disposal options for unused pharmaceuticals," Environ. Sci. Technol., Vol 46 (15), pp 8519–8520 (2012).

Daughton, Christian, *Eco-directed sustainable prescribing: feasibility for reducing water contamination by drugs*, SCIENCE OF THE TOTAL ENVIRONMENT 493, 392-404 (2014).

Daughton, Christian, Environmental Footprint of Pharmaceuticals: The Significance of Factors beyond Direct Excretion to Sewers, ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY, Vol. 28(12), 2495-2521 (2009).

Daughton, Christian, Environmental Stewardship and Drugs as Pollutants, LANCET, 360, 1035-1036 (2002).

de Solla, S.R., et al., Bioaccumulation of pharmaceuticals and personal care products in the unionid mussel Lasmigona costata in a river receiving wastewater effluent, CHEMOSPHERE Vol. 146 (2016).

Dodder, N.G., K.A. Maruya, P.L. Ferguson, R. Grace, S. Klosterhaus, M.J. La Guardia, G.G. Lauenstein, and J. Ramirez. 2014. Occurrence of contaminants of emerging concern in mussels (*Mytilus* spp.) along the California coast and the influence of land use, storm water discharge, and treated wastewater effluent. *Marine Pollution Bulletin* 81:340-346.

Fernandez, C. & E.M. Beltran, *Pharmaceuticals Effects in the Environment*, ENCYCLOPEDIA OF TOXICOLOGY (3d ed. 2014).

Garcia-Santiago, Xela, et al., Risk assessment of persistent pharmaceuticals in biosolids: Dealing with uncertainty, JOURNAL OF HAZARDOUS MATERIALS VOL. 302 (2016).

Glassmeyer, Susan T., et al., U.S. Environmental Protection Agency, *Disposal practices* for unwanted residential medications in the United States, ENVIRONMENTAL INTERNATIONAL 35, 566-572 (2008).

Godfrey, E. et al., *Pharmaceuticals in on-site sewage effluent and ground water, Western Montana*, GROUND WATER (May-June 2007).

Gurke, Robert, et al., Occurrence and removal of frequently prescribed pharmaceuticals and corresponding metabolites in wastewater of a sewage treatment plant, SCIENCE AND THE TOTAL ENVIRONMENT, Vol. 532 (2015).

Heberer, T. et al., From municipal sewage to drinking water: fate and removal of pharmaceutical residues in the aquatic environment in urban areas, WATER SCIENCE AND TECHNOLOGY VOL. 46(3) 81-88 (2002).

Hernando, M.D., et al., Environmental risk assessment of pharmaceutical residues in wastewater effluents, surface waters and sediments, TALANTA 69 (2006).

Kennedy Jr., Robert F., et al, Letter to Commissioner Stephen Ostroff, M.D. of the Federal Food and Drug Administration, RE: FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal (January 22, 2016) available at http://casaweb.org/documents/fda_sign-on_letter_dec11_final_12-14-15.pdf.

Kodesova, Radka, et al., An analysis of the dissipation of pharmaceuticals under thirteen different soil conditions, SCIENCE OF THE TOTAL ENVIRONMENT VOL. 544 (2016).

Dana Kolpin et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance, USGS STAFF -- PUBLISHED RESEARCH 68 (2002).

Kostich, Mitchell S., Angela L. Batt and James M. Lazorchak, U.S. Environmental Protection Agency, Concentrations of Prioritized Pharmaceuticals in Effluents from 50 Large Wastewater Treatment Plants in the US and Implications for Risk Estimation,"

(2014), found at http://www.epa.gov/sites/production/files/2014-09/documents/50 large wwtp effluent.pdf

Kostich, Mitchell S. et. al. U.S. Environmental Protection Agency, *Risks to aquatic organisms posed by human pharmaceutical use*, SCIENCE OF THE TOTAL ENVIRONMENT VOL. 389 (2-3), 329-339 (2008), available at http://www.epa.gov/sites/production/files/2014-09/documents/risks_to_aquatic_organisms_posed_by_human_pharma_use.pdf.

Maruya, K.A., D. Vidal-Dorsch, S.M. Bay, J.W. Kwon, K. Xia, and K.L. Armbrust. (2012). Organic contaminants of emerging concern in sediments and flatfish collected near outfalls discharging treated wastewater effluent to the Southern California Bight. *Environmental Toxicology and Chemistry* 31:2683-2688.

Masoner, Jason R. et al., Contaminants of emerging concern in fresh leachate from landfills in the conterminous United States, Environmental Science Processes & IMPACTS (2014).

Murdoch, Kirstie, *Pharmaceutical Pollution in the Environment: Issues for Australia, New Zealand and Pacific Island countries*, NATIONAL TOXICS NETWORK (2015) *available at* http://www.ntn.org.au/wp/wp-content/uploads/2015/05/NTN-Pharmaceutical-Pollution-in-the-Environment-2015-05.pdf.

Nair, Abhilash T., *Pharmaceuticals in Environment: A review on its effect, RESEARCH JOURNAL OF CHEMICAL SCIENCE Vol.* 2(1), 103-105 (2012).

Onesios, K.M. et al., Biodegradation and removal of pharmaceuticals and personal care products in treatment systems: a review, BIODEGRADATION 20, 441–466 (2009).

Phillips, P.J., et al., Concentrations of hormones, pharmaceuticals and other micropollutants in groundwater affected by septic systems in New England and New York, SCIENCE OF THE TOTAL ENVIRONMENT VOL. 512-513 (2015).

Ruhi, Albert, et al., Bioaccumulation and trophic magnification of pharmaceuticals and endocrine disruptors in a Mediterranean river food web, SCIENCE OF THE TOTAL ENVIRONMENT VOL. 540 (2016).

Schoenfuss, Heiko, et al., Complex Mixtures, Complex Responses: Assessing Pharmaceutical Mixtures Using Field and Laboratory Approaches, ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY, Vol. 9999 (first published online November 12, 2015).

Seattle Times, Drugs found in Puget Sound salmon from tainted wastewater, (February 23, 2016), found at www.seattletimes.com/seattle-news/environment/drugs-flooding-into-puget-sound-and-its-salmon.

Sengupta, Ashmita et al., The Occurrence and Fate of Chemicals of Emerging Concern in Coastal Urban Rivers Receiving Discharge of Treated Municipal Wastewater Effluent, ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY, Vol. . 33(2), 350-358 (2014).

Stancova, Valasta, Effects of Mixture of Pharmaceuticals on Early Life Stages of Tench (Tinca tinca), BIOMED RESEARCH INTERNATIONAL VOL. 2014 (2014).

Sui, Qian et al., Occurrence, sources and fate of pharmaceuticals and personal care products in the groundwater: A review, EMERGING CONTAMINANTS Vol. 1(1) (2015).

Tischler, Lial, et al., Landfill Disposal of Unused Medicines Reduces Surface Water Releases, Integrated Environmental Assessment and Management Vol. 9 (1), 142–154 (2013).

Tong, Alfred Y., et al., *Disposal practices for unused medications around the world*, ENVIRONMENT INTERNATIONAL 37, 292-298 (2011).

United States. Cong. House. Committee on House Energy and Commerce Subcommittee on Health, *Hearing on Pending Public Health Legislation, July 22, 2010* (statement of Joseph T. Rannazzisi Deputy Assistant Administrator, Office of Diversion Control Drug Enforcement Administration), available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/22/10/07-22-10-rannazzisi-pending-public-health-legislation.pdf.

- U.S. Food and Drug Administration, *Disposal of Unused Medicines: What you Should Know,* FDA (January 13, 2016) *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm
- U.S. Geological Survey- Environmental Health, National Water Quality Laboratory, *Land Application of Municipal Biosolids*, available at http://toxics.usgs.gov/regional/emc/municipal biosolids.html.
- U.S. Geological Survey- Environmental Health, Toxic Substances, *Complex Mixtures, Complex Responses—Using Comprehensive Approaches to Assess Pharmaceutical Effects on Fish*, available at http://toxics.usgs.gov/highlights/2015-11-13-pharmacuticals_and_minnows.html.
- U.S. Government Accountability Office, *Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water* (August 2011), found at http://www.gao.gov/new.items/d11346.pdf.
- Verlicchi, P. & Zambello, E., *Pharmaceuticals and personal care products in untreated and treated sewage sludge: Occurrence and environmental risk in the case of application on soil*—*A critical review*, SCIENCE AND THE TOTAL ENVIRONMENT VOL. 538 (2015).

Vidal-Dorsch, D., K.A. Maruya, S.M. Bay, B. Vanderford, and S.A. Snyder. 2012. Contaminants of emerging concern in municipal wastewater effluents and marine receiving water. *Environmental Toxicology and Chemistry* 31:2674-2682.

Villain, Jonathan et al., Acute toxicities of pharmaceuticals toward green algae, mode of action, biopharmaceutical drug disposition classification system and quantile regression models. Ecotoxicology and Environmental Safety Vol.124 (2016).

World Health Organization, *Pharmaceuticals in Drinking Water* (2012); available at http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085 eng.pdf?ua= 1.

Writer, Jeffrey H., *Widespread occurrence of neuro-active pharmaceuticals and metabolites in 24 Minnesota rivers and wastewaters*, SCIENCE OF THE TOTAL ENVIRONMENT, Vol. 461-62 (2013).

Wu, Chenxi et al., *Uptake of Pharmaceutical and Personal Care Products by Soybean Plants from Soils Applied with Biosolids and Irrigated with Contaminated Water*, SLUDGENEWS.ORG (2010) *available at* http://www.sludgenews.org/resources/documents/wu_ppcps.pdf.

Yager, Tracy J.B., et al., Dissipation of Contaminants of Emerging Concern in Biosolids Applied to Nonirrigated Farmland in Eastern Colorado, JAWRA VOL. 50(2), 343-357 (2014).