

Los Angeles County Pharmaceutical Drugs and Sharps Collection and Disposal Stewardship Ordinance

Stakeholder Comments and EPR Working Group Responses

The following are key stakeholders' questions, comments, and/or concerns which were received during the Ordinance development process including written correspondence and comments received during stakeholder meetings, and the County's responses to these issues. The comments have been grouped together by type and divided into two major sections as shown below:

SECTION I: Summary of Comments Not Requiring a Response

SECTION II: Summary of All Other Comments and Questions (with Responses)

Topic 1: Purpose of and Need for Draft Ordinance

Topic 2: Other EPR Programs

Topic 3: State and Federal Regulations

Topic 4: Responsibility

Topic 5: Role of Pharmacies

Topic 6: Role for Law Enforcement

Topic 7: Environmental Related Concerns

Topic 8: Existing Disposal

Topic 9: Mail-back Programs

Topic 10: Alternative Options

Topic 11: Consumer Information

Topic 12: Sharps in the Draft Ordinance

Topic 13: Metrics

Topic 14: Cost to Industry

Topic 15: Service Area

Topic 16: Specific Draft Ordinance Language

Section I

Commenter Affiliation	Summary of Comments Not Requiring a Response
Water Quality	Development of the ordinance is an important step to protect waterways. There is a measurable and constant flow of pharmaceuticals in the water and there is evidence to show there are deleterious effects to aquatic life as a result. Ordinance will not solve entire problem, but take-back programs keep tons of products away from abuse and out of the environment.
Water Quality	If placing collection receptacles at pharmacies is not feasible, then the ordinance should supplement with other options such as take-back events and mail-back options.
Water Quality	The discussion should be about making a plan as effective as possible.
Consumer Advocate	This issue is a serious public safety threat in the County because of the drug abuse epidemic.
Consumer Advocate	San Francisco has been able to place collection receptacles for pharmaceuticals. They mandated that if pharmacies choose to not serve as a collection site, they would have to provide information to customers on where they can take their unwanted drugs, i.e. their competitors.
Water Quality	Pharmaceutical chemicals do indeed arrive at waste-water treatment facilities. TAG members opposing the ordinance keep saying "I can't and I won't" but the challenge and charge is to be problem solvers and look at what can be done. What does not work in other jurisdictions will need to be revised for this ordinance. This is not the only solution and this is just one aspect which is valuable so there will be more impactful effects.
Water Quality	The idea is to have an honest conversation during the stakeholder process on how to make the best program but many TAG members are stalling by stating they were not prepared to participate in constructive dialogue.
Consumer Advocate	Consumers want to do the right thing but people around the state are saying the problem is they do not know where to take things to dispose of them properly. Agree that part of the problem is that there are not enough options out there.

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Water Quality	The reason why bins are only in place at police stations in Alameda County is because that is who industry has reached out to thus far.
Solid Waste/Waste Water Management	In addition to the broader social goals to reduce drug abuse and diversion of unused drugs, reduction of the disposal of unwanted pharmaceuticals is important because when pharmaceuticals are flushed down toilets and drains, or placed in the trash, wastewater treatment facilities and solid waste facilities serve as pathways for pharmaceutical waste residuals to enter the aquatic environment.
Solid Waste/Waste Water Management Agencies	Source control is widely recognized as the most cost-effective approach to reduce levels of contaminants in wastewater, and a take-back program is an excellent example of a source control program.
Senior Advocates	There is appreciation for the Sheriff collection sites for medicines and/or for sharps in the county but they are not convenient, there are not enough of them and they are not easy enough to find and do not want law enforcement burdened with managing a health care industry product – the hospitals, doctors, pharmacies and drug companies should all share in the cost and responsibility to ensure safe management of these products. More public education is necessary to discourage flushing of unwanted pharmaceuticals in the sewer or throwing them in the trash. A collection system is needed for residents. It's time to ensure that all communities in our County have safe and convenient take-back locations for pharmaceuticals and sharps.
Sanitation Agencies	Pollution prevention efforts such as the development of stewardship plans, as called for in the Draft Ordinance, are among the most straightforward and achievable methods of keeping pharmaceuticals out of wastewater and the environment. Unused and expired medications are frequently (and improperly) flushed down the toilet and make their way into wastewater treatment streams and ultimately the environment.
Private Citizen	Drug abuse is a complex problem, and a secure system for collecting leftover and expired medicines from households is an important part of the solution.
Water Quality	The regular occurrence of used sharps on our beaches, which was highlighted during the recent unfortunate release of Materials of Sewage Origin from the Hyperion Water Treatment Plant in September, reinforces the need for proper post-use sharp collection and disposal in our community. We applaud that the Ordinance takes care to consider secure handling of returned materials and looks to dispose of these in an environmentally sound way.
Labor	When needles from syringes are not handled properly, they put families and sanitation workers at risk of dangerous needle sticks and infections.
Coalition of Supporters	Appreciate the County's transparent process for stakeholder input during the development of this ordinance. Manufacturers of medicines and sharps have the primary responsibility for secure collection and safe disposal of their products as a cost of doing business. Manufacturers must promote the stewardship program to residents and the health care community, and expressly discourage the stockpiling of unwanted pharmaceuticals/sharps and discourage disposal into the trash or by flushing into a sewer.

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Section II

Ref. #	Commenter Affiliation	Summary of All Other Comments and Questions	EPR Working Group Responses
Topic 1: Purpose of and Need for Draft Ordinance			
1A	Pharmaceutical Industry and Sharps Industry	What is the purpose of this draft Ordinance?	The purpose of this draft Ordinance as stated in Section 11.17.012 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 2) Protects, maintains, restores and/or enhances the environment and its natural resources.”
1B	Pharmaceutical Industry and Sharps Industry	<p>Why is a take-back program necessary for pharmaceuticals and sharps?</p> <p>A solution is being developed without a problem.</p>	The problem is there are limited options available to County residents for safe and environmentally sustainable disposal of unwanted pharmaceutical drugs and sharps waste. With 10 million residents and more than 3 million households in the County, take-back options are limited to County Household Hazardous Waste (HHW) events, drug collection bins at 21 Sheriff’s stations and 77 sharps collection locations. With safe, convenient, and sustainable take-back alternatives, County residents will have the option to safely dispose of unwanted drugs and sharps and avoid stockpiling or disposal through a plumbing or septic system or in the trash. Collection bins, mail-back services, and collection events will provide safe disposal and convenient options for residents that in turn will help protect public health and the environment.
1C	Pharmaceutical Industry	Industry understands that the Board of Supervisors (Board) directed the EPR Working Group through the stakeholder process to determine if a draft Ordinance is needed at all. Industry expressed concerns that the objective of the process was pre-determined and the County was not willing to look at other options.	The Board directed the EPR 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;” and to “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.” However, the EPR Working Group has consistently stated that if it received feedback from stakeholders that the EPR Working Group believed would be a better approach to adopting an ordinance, it would consider recommending such approach to the Board. To date, the EPR Working Group has not received any such feedback.
1D	Pharmaceutical	Why has the County ignored	Stakeholder feedback has not been ignored. The primary feedback received from

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	Industry and Sharps Industry	stakeholder feedback during the stakeholder process?	industry has been to recommend not proceeding with an ordinance at all, and instead to rely solely on an education and outreach plan. For the reasons discussed at the various stakeholder meetings and in the Board letter, the EPR Working Group does not believe these options to be sufficient to address the County's concerns about public health and safety and environmental sustainability. All comments received by the EPR Working Group have been reviewed and considered prior to completing the final draft Ordinance. Additionally, substantial revisions have been made to the early drafts of the Ordinance in response to comments and concerns received from a diverse group of stakeholders. A description of the stakeholder process is contained in the Board letter.
1E	Environmental Advocates	Increasing public awareness and communication is a good start to addressing water pollution, but a comprehensive take-back program is a much needed additional step towards pollution prevention.	The EPR Working Group agrees. There is a growing consensus regarding the need for take-back programs, which can include collection receptacles, take-back events and mail-back programs, as a mechanism to collect unwanted drugs and sharps. Consistent with the 2010 Federal Secure and Responsible Disposal Act, the U.S. Drug Enforcement Administration (DEA) adopted regulations to expand take-back programs. In addition, the U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA) both identify local take-back programs as the "first choice" or "best option" for safely and conveniently collecting these products in part to prevent environmental pollution caused by improper disposal of pharmaceuticals and sharps. We expect that this draft Ordinance will provide for the collection of thousands of pounds of drugs and sharps each year, managed through Stewardship Plans, and therefore decrease the potential for drug abuse and diversion and reduce the presence of potential contaminants in the environment.
1F	Pharmaceutical Industry	The County should replace the draft Ordinance with a program that educates consumers such as what the industry did in New York.	The EPR Working Group does not agree that an outreach and education program encouraging trash disposal of drugs meets the County's objective of identifying safe, convenient, and sustainably financed take-back options as specified in the August 11, 2015 Board Motion. The New York program, found online at myoldmeds.com, encourages disposal of pharmaceuticals into landfills, which increases the opportunities for diversion and abuse of drugs and contributes to pollution of the environment. It is also not a feasible option for sharps, which are banned from trash disposal in California. See also topic 1B.
1G	Pharmaceutical Industry and Sharps Industry	Los Angeles County should allow legislative debate at the State-level to conclude.	There have been several attempts to introduce legislation based on the concept of Extended Producer Responsibility (EPR) for pharmaceuticals and sharps, including AB 403 (Stone, 2013), SB 727 (Jackson, 2013), SB 1014 (Jackson 2014), and AB 1159

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			(Gordon, 2015). The County of Los Angeles and others have supported these bills, however to date the State has not been successful in passing any of them. This is partly why local jurisdictions throughout the State, including the County, have either enacted or are in the process of enacting local ordinances for EPR stewardship programs.
1H	Pharmaceutical Industry	Promotion of EPR principles in regards to pharmaceuticals and environmental/public safety concerns are mutually exclusive ideals.	The EPR Working Group is unclear of the meaning of this comment. EPR is a proactive approach to sound solid waste management, which is essential to helping protect the health and safety of the public and the environment.
1I	Pharmaceutical Industry	No research or data was ever provided by the County which showed a significant reduction in drug abuse as a result of drug take-back laws around the country or elsewhere or any other specific issue.	Many factors contribute to the problem of drug abuse, misuse and accidental overdose. Therefore, a take-back program cannot be the sole solution. However, it is nevertheless an important and much needed component to addressing the problem. In the Department of Public Health's 2013 Report <i>Prescription Drug Abuse in Los Angeles County</i> , the Health Officer recommended implementation of take-back programs to reduce the availability of unwanted drugs in the home. Reducing the amount of pharmaceutical drugs being readily available in the home will be a step in the right direction to solving this problem. Additionally, the Los Angeles County Prescription Drug Abuse Coalition has identified safe drug disposal as one of six priority areas included in its strategic plan to address prescription drug abuse.
1J	Pharmaceutical Industry	Inconclusive evidence of quantities of pharmaceuticals entering environment from flushing unwanted drugs versus natural human excretion.	Many factors influence the amount of drugs entering the environment. The draft Ordinance is intended to decrease the amount of unwanted and unused drugs and sharps that may be misused or improperly introduced into the environment by substantially increasing the collection and proper treatment and disposal of these items. The fact that there are other sources of pollution beyond the scope of this Ordinance does not mean the County should not attempt to reduce pollution and misuse from sources that can be affected by this Ordinance.
1K	Pharmaceutical Industry	Inconclusive evidence of quantities of pharmaceuticals impacting landfills/landfill leachate.	There have been various studies, including some submitted to the Working Group by the industry, which indicate measurable amounts of pharmaceuticals in landfill leachate. The EPA and the Los Angeles County Sanitation Districts, among others, recognize the presence of active pharmaceutical ingredients in landfill leachate, and support establishing pharmaceutical take-back collection programs.

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1L	Pharmaceutical Industry	A survey conducted by FM3 Public Opinion and Strategy indicates Los Angeles County residents do not have a great concern for disposal of expired or unwanted medications and one third of voters think implementing such a program would result in residents paying much higher prices.	<p>The EPR Working Group has requested a copy of the survey and the results and, to date, has not received either. Accordingly, we are unable to comment on the validity of this statement. However, the County has conducted its own survey and found that more than half (59%) of the 1062 respondents 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 these medicines. In addition, nearly three-quarters of participants (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 for the environment. Lastly, the vast majority of participants (87%) believe placing unwanted medicines and sharps in drop-off bins in pharmacies is a good approach, and the majority of people who provided comments expressed support for safe, accessible, and convenient options for disposal of medicines and sharps.</p> <p>This Ordinance is being introduced to address a need identified by the Department of Public Health to protect and promote public health and safety and environmental sustainability. Moreover, the draft Ordinance prohibits Responsible Stewards from charging consumers a point-of-sale or point-of-collection fee. See also topic 14A.</p>
Topic 2: Other EPR Programs			
2A	Pharmaceutical Industry	Other EPR programs, such as Alameda County's, do not/cannot work.	It is too early to determine the success of these ordinances, as implementation of EPR programs has not begun for most counties in California that adopted similar ordinances. This delay has been in part due to litigation that was initiated by the pharmaceutical industry, specifically "Pharmaceutical Research and Manufacturers of America v. County of Alameda." However, EPR programs for pharmaceuticals have been established and are currently operating in other countries such as Canada, Mexico, Belgium, France, Hungary, Portugal, Spain, Brazil, and Colombia which were developed and funded by the manufacturers and include pharmacies as collection sites. Alameda County and King County, Washington, have approved Stewardship Plans developed by industry, and King County's approved plan includes over 100 collection sites, primarily pharmacies. Accordingly, there is no basis for assuming that industry-developed plans for Los Angeles County will not be successful.
2B	Pharmaceutical Industry	Pharmaceuticals are different from other products in EPR programs since they cannot be	EPR is not limited to items which can be recycled; in fact, items that are difficult to recycle or properly dispose of are prime candidates for EPR. EPR is a concept where manufacturer and producer responsibility is extended to the post-consumer stage of

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		recycled.	a product's life. It is not simply about having manufacturers assume the costs; EPR can lead to better overall results for the end of life management for unwanted drugs and sharps, since manufacturers know their products and industry better than local governments. Accordingly, they are able to design and operate collection and disposal programs which are more efficient, environmentally sustainable, and effective than those designed or implemented by local governments.
2C	Pharmaceutical Industry	There is no evidence that long-term European take-back programs have reduced the amount of pharmaceuticals found in waterways, and the last four British Columbia reports question whether take-back programs have any real environmental and safety benefit.	See topic 1J. Also, the World Health Organization's 2012 report "Pharmaceuticals in Drinking Water" recommends take-back programs to support efforts for the proper disposal of unwanted and excess medicines and reduce the environmental impact of pharmaceuticals entering our environment, including water sources." (emphasis added) http://apps.who.int/iris/bitstream/10665/44630/1/9789241502085_eng.pdf?ua=1
Topic 3: State and Federal Regulations			
3A	Pharmaceutical Industry	Other laws in other Countries/States where EPR programs exist are different from Federal and California State Regulations.	Yes, they are different; however federal and state regulations were created specifically in order to allow for the collection of pharmaceuticals and sharps waste at locations such as retail pharmacies, hospitals/clinics with on-site pharmacies, law enforcement facilities, and collection events, as well as through mail-back services (See the Secure and Responsible Drug Disposal Act of 2010). The County's draft Ordinance encourages collection at such sites and mail-back services as well. The Draft Ordinance is in compliance with all federal and state regulations, including the DEA and the California Board of Pharmacy.
3B	Pharmaceutical Industry	DEA Rule for the disposal of controlled substances would require any location which hosts a take-back bin to register as a "collector" which would be difficult.	All pharmacies are already registered with the DEA if they sell controlled medications. If they chose to participate in the Stewardship Program, they would have to register as an authorized collector at no additional cost. The DEA rule was specifically designed to allow other authorized collectors such as pharmacies to host collection bins. Prior to this rule, only law enforcement entities could collect controlled medications.
3C	Pharmaceutical Industry and	Should companies need to modify the program(s) to	The draft Ordinance provides a mechanism for Responsible Stewards to make modifications to approved Stewardship Plans. This includes any required by law.

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	Sharps Industry	remain in compliance with applicable state and federal laws, they would have to petition the County for amendments to the plan or sue for injunctive relief. If the County designed the program, it would be easier to modify the program to be in compliance.	The Working Group believes that Responsible Stewards are in a much better position to develop the most effective and cost-efficient program for their own products than are local governments.
Topic 4: Responsibility			
4A	Pharmaceutical Industry and Sharps Industry	<p>It appears that all of the draft Ordinance responsibility falls on the pharmaceutical industry and sharps industry.</p> <p>As far as shared responsibility is concerned, the pharmaceutical manufacturers make medication and once shipped, it is the responsibility of the receiving institutions to ensure medication safety.</p>	EPR programs typically place the responsibility on producers to handle end-of-life product management issues, such as creating and funding a take-back program. Based upon our analysis, the costs of such a program to the pharmaceutical and sharps manufacturers would be minimal, as noted in topic 14A. Also, the entire responsibility would not fall on the pharmaceutical industry, as consumers, local governments, and pharmacies will all have parts to play.
4B	Sharps Industry	Mail order pharmacies should send a sharps container with each shipment of syringes or pen needles.	The draft Ordinance includes a requirement that Responsible Stewards of Sharps participating in the Stewardship Plan provide a mechanism for distribution of FDA-compliant Sharps containers to the consumer free of charge, preferably at the point of sale of the injectable drug, or at the time the consumer otherwise receives the Sharps for usage.
4C	Hospital Association	Hospitals are already managing their own pharmaceuticals and sharps.	The EPR Working Group recognizes that hospitals and others are already required to comply with State and Federal requirements for the pharmaceutical waste they generate. The draft Ordinance encourages, but does not mandate, hospitals with onsite pharmacies to participate as collection sites for home-generated unwanted medications and/or sharps waste.
4D	Pharmaceutical	This draft Ordinance ignores	The ordinance is founded on the concept of EPR. EPR programs typically place the

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	Industry	consumer accountability; it shields county residents, taxpayers, and even the federal government from the price tag of an unnecessary program.	responsibility on producers to handle end-of-life product management issues, such as creating and funding a take-back program. The costs of such a program to the pharmaceutical and sharps manufacturers would be minimal in comparison with the revenue that they generate in Los Angeles County, as noted in response to topic 14A. Moreover, consumer behavior is important, as evidenced by the requirement that Responsible Stewards engage in education, promotion and outreach. Finally, the program is necessary as explained in topic 1B.
Topic 5: Role of Pharmacies			
5A	Retail Pharmacy Industry	Raised concerns regarding mandating collection bins at all pharmacies, since some pharmacies are located inside stores that have different operating hours, have space constraints, and/or have other potential challenges.	From the very beginning of the stakeholder process, the Working Group has emphasized hosting collection bins would be voluntary and not mandatory, recognizing there may be constraints that prevent all retailers and pharmacies from being able to participate. The intent of the draft Ordinance is for the program to be designed and funded by the manufacturers and producers of pharmaceuticals and sharps.
5B	Pharmaceutical Industry and Sharps Industry	Raised concerns that they have had difficulties getting pharmacies to participate in other counties since pharmacy participation is voluntary.	According to the National Community Pharmacists Association Foundation, 1,600 independent pharmacies across the U.S. currently provide bins for the collection of unwanted drugs. Many of these are located in jurisdictions where participation is voluntary. Additionally, many clinics with pharmacies, hospitals with pharmacies (including Kaiser Permanente), and other entities throughout the country, do as well. Recently, Walgreen's pharmacies announced that it would be placing 500 collection bins in 39 states nationwide, including California, for this purpose. This would be in addition to its current sharps take-back program in San Francisco. See topic 2A regarding other programs that have been implemented.
5C	Retail Pharmacy Industry	There will be increased risk/liability to pharmacies that choose to host a collection bin.	Many pharmacies have been participating in take-back programs in other counties, states, and countries. It will be up to the Responsible Stewards to work with those entities who volunteer to host collection sites to resolve such concerns.
5D	Retail Pharmacy Industry	Grocery store pharmacies cannot have a collection bin because they have food and this may go against food safety regulations the stores need to comply with. However, they	The County understands there are constraints which may prevent some locations from hosting collection bins. Therefore, the Working Group believes that Responsible Stewards should work with pharmacies on the best solutions to gain their participation in hosting collection bins.

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		would be willing to provide mail-back envelopes financed by the pharmaceutical industry.	
5E	Retail Pharmacy Industry	If there are medications and/or sharps left by the bin when the pharmacy is closed, who assumes responsibility of monitoring?	The draft Ordinance requires that the Stewardship Plans provide a 24-hour hotline and website to report hazardous conditions. The draft Ordinance also requires Responsible Stewards to provide for the proper collection and handling of drugs and sharps collected under the program, which includes making sure that the collection bins are emptied with sufficient frequency, and that they do not become over-filled or otherwise create hazardous conditions. In addition, each Stewardship Plan must provide for the immediate abatement of any hazardous condition.
5F	Environmental Advocates	The Ordinance should require that any pharmacy or entity that notifies a producer that it is interested in hosting a bin and can do so under state and federal law be provided a bin within 90 days of notice to the producer.	The draft Ordinance requires Responsible Stewards to commence good faith negotiations with any Person expressing an interest to serve as a Collector within 30 days. For every Person not accepted as a Collector, the Responsible Stewards must provide a written explanation to the Director of the Department of Public Health of the reasons for the non-acceptance.
5G	Retail Pharmacy Industry	Pharmacists want to do the right thing, but workflow at pharmacies which would serve as collection points would be impacted by the DEA's rule for the collection of controlled substances, which requires a pharmacist to be present at all times.	The DEA rule requires that the collection kiosk is placed so that it can be seen from the pharmacy counter. Two employees, not pharmacists, would need to be present when a collector arrives to collect the full inner-liners. The County understands that these requirements may preclude some locations from serving as collection points, and as a result, participation by pharmacies and other entities for hosting collection bins is strictly voluntary.
5H	Pharmaceutical Industry	How can the program be successful if pharmacies choose not to host collection bins?	There are more than 1,800 pharmacies in Los Angeles County. Although pharmacies have already indicated an interest in participating, stewardship plans will have the flexibility in how they provide convenient options for collection, including hosting their own locations, hosting monthly collection events, and/or mail-back services. Recently adopted DEA regulations specify the types of entities that may register to collect pharmaceutical waste, namely, manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site

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			pharmacy, and retail pharmacies. These entities may voluntarily administer mail-back programs and maintain collection receptacles. The DEA regulations also allow law enforcement to continue to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. There are no regulations pertaining to hosting a sharps collection bin so these could potentially be placed anywhere, so long as the manufacturers are able to reach an agreement with the host. In addition, pharmacies will be required to participate in a robust outreach and education program developed by industry informing residents regarding where and how consumers may safely and lawfully dispose of unwanted drugs and sharps.
Topic 6: Role for Law Enforcement			
6A	Pharmaceutical Industry	It is important for law enforcement to weigh in on the stakeholder process.	The Los Angeles County Sheriff's Department has been an active participant in the overall Ordinance development process. The Sheriff's Department is supportive of the proposed draft Ordinance.
6B	Environmental Advocates and Consumer Advocates	No other country burdens their law enforcement with collecting pharmaceuticals and sharps waste.	The LA County Sheriff's Department initiated pharmaceutical and sharps collection as an added service for residents. However, the programs are overburdened, provide only a fraction of the collection sites needed to serve all residents in the County, and cannot provide the level of convenience residents need.
6C	Pharmaceutical Industry	Is there reason law enforcement participation is voluntary?	The draft Ordinance does not require any entity to serve as a collection site; thus law enforcement participation is also voluntary. Each potential collection facility should individually determine if they are suitable to participate in the take-back program. That being said, the Sheriff's Department has indicated that it intends to continue providing collection bins at Sheriff's stations.
Topic 7: Environmental Related Concerns			
7A	Pharmaceutical Industry and Sharps Industry	Take-back programs for pharmaceuticals and sharps do not improve water quality.	See topic 2C.
7B	Pharmaceutical Industry	Has the County considered looking at existing Household Hazardous Waste (HHW) program to include take-back?	The Countywide HHW program currently accepts non-controlled substances and sharps; however this program cannot provide the level of convenience, service needs, and financial support required to sustain an EPR program free of costs to consumers and taxpayers. Also, under DEA regulations, the Countywide HHW program cannot accept controlled substances.
7C	Pharmaceutical Industry	The County should look at upgrading waste-water	As stated in the July 2, 2015 Report to the Board of Supervisors, the complexity of pharmaceuticals and cost to retrofit treatment plants make it cost-prohibitive and

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		treatment plants to remove pharmaceuticals.	infeasible to treat pharmaceutical at wastewater treatment plants. Whereas providing a robust pharmaceutical take-back program will help decrease the amount of pharmaceuticals that are discharged from wastewater treatment plants at minimal cost to manufacturers and no cost to consumers, which will help improve the quality of the receiving waters and help reduce the level of pharmaceutical contamination that makes its way into the environment and drinking water.
7D	Pharmaceutical Industry	There may be negative environmental impacts of a take-back program due to increased transportation emissions	The additional transportation required under this draft Ordinance will be marginal, as these types of materials are already being collected by reverse distributors from pharmacies, hospitals, clinics, etc. In addition, the draft Ordinance establishes convenience standards that seeks to place collection sites in close proximity to residents' homes, thereby minimizing any negative environmental impact of additional trips.
Topic 8: Existing Disposal			
8A	Pharmaceutical Industry	Pharmaceutical industry already has outreach and education programs which include working with the DEA and FDA.	Although outreach and education are crucial, they are insufficient to solve the problem in and of themselves. In addition to educating the public of safe, lawful, and environmentally sustainable methods of disposal of unwanted drugs and sharps, as a practical matter, residents must be provided with convenient and adequate options for such disposal. In addition, see topic 1F.
8B	Environmental Advocates and Consumer Advocates	The draft Ordinance should include language to prohibit producers and the stewardship organization from promoting methods of disposal outside those in the stewardship plan.	The draft Ordinance requires that outreach and education materials expressly discourage the disposal of pharmaceuticals and sharps in the trash or through a plumbing or septic system. Note: that the revised Ordinance does not refer to producers, but instead defines "Responsible Stewards/Stewardship Organizations". Please see definition in topic 16B.
Topic 9: Mail-back Programs			
9A	Pharmaceutical Industry	Research has not identified a facility which is certified to destroy mail-back packages.	There are actually several companies that provide pre-paid mail-back envelopes and that are fully-authorized to collect and destroy pharmaceuticals received via their envelopes. As demand for these services grow, it is anticipated additional companies may begin offering these services.
9B	Pharmaceutical Industry	Mail-back programs may lead to increased diversion.	More and more drugs and sharps are being mailed directly to residents every day. Returning unwanted drugs and sharps in a mail back envelope poses no greater risk than shipping drugs and sharps to consumers by mail. The DEA's rules for collection of controlled substances, which include via mail-back services, include measures that

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			should be implemented to further reduce the risk of diversion. Pharmaceuticals left in medicine cabinets and disposed of in the trash pose a much greater diversion risk than a mail-back program.
9C	Pharmaceutical Industry	Mail-back envelopes are expensive. This service would substantially increase costs of many medications.	The proposed take-back program is based on three potential collection options: (1) having authorized collectors host collection bins throughout the defined service area; (2) offering free mail-back services, including prepaid envelopes/packages, upon request by a consumer; and (3) sponsoring periodic collection events, as needed, to allow residents to bring their unwanted drugs and sharps to specifically designated locations on a specified day and during a scheduled time period for collection. These options will help ensure that all residents have convenient access to properly dispose of unwanted drugs and/or sharps.
Topic 10: Alternative Options			
10A	Pharmaceutical Industry	There are envelopes that destroy unwanted drugs and can be thrown in the trash.	The draft Ordinance allows industry to make use of other disposal options, so long as they provide superior environmental and human health protections. These methods must also comply with the DEA's regulations, including rendering controlled substances non-retrievable.
10B	Pharmaceutical Industry	The FDA recommends in-home disposal of unwanted medications, either in the trash or in a few cases via flushing down the toilet.	The FDA recommends the use of community take back programs as the preferred option for disposal, and if take-back options are not available , then certain pharmaceuticals waste that may be especially harmful may be flushed down the sink or toilet as soon as no longer needed. The goal of the draft Ordinance is to provide residents with safe, convenient, and adequate take-back options in order to reduce the quantity of drugs and sharps being improperly discarded. In regards to pharmaceuticals, in-home disposal results in additional pharmaceuticals entering the environment and the potential for improper diversion of medications. Additionally, in-home disposal is illegal for sharps. (See also topic 1E.)
Topic 11: Consumer Information			
11A	Pharmaceutical Industry	Pharmaceutical industry does not want to confuse people about not taking their full course of medication.	<p>This draft Ordinance is not intended to interfere with doctors and/or pharmacists' recommendations for their patients.</p> <p>However, patients often do not finish all their medicines for various reasons, such as "side effects/intolerance, dosage changes, discontinuation of the medication (due to cessation of symptoms or conditions, because of non-compliance with or non-adherence to treatment instructions, or because of death of the patient) or</p>

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			expiration of the prescription. (Wilcox (2013); Seehusen and Edwards (2006); Ruhoy and Daughton (2008).” (County Sanitation Districts of Los Angeles County letter dated January 19, 2016 to the Pharmaceutical Working Group. Until such time as consumers no longer have any unwanted drugs or sharps requiring disposal, there continues to be a need to provide safe, convenient, and adequate options for disposal. The intent of the proposed Ordinance is to provide residents with such options.
11B	Pharmaceutical Industry	Take-back programs could create hoarding because people will keep their unused medications until they have the ability to drop them off.	While current take-back options are very limited, convenient take-back programs contemplated under the proposed Ordinance will give residents tremendous flexibility to drop-off unwanted medications and sharps at their convenience, and consequently avoid having to hoard in anticipation of periodic take-back events. Further, the mail-back option is yet another convenient and easy way for residents to dispose of their unwanted drugs and sharps without having to wait for a collection event.
Topic 12: Sharps in the Draft Ordinance			
12A	Sharps Industry	Sharps industry is disappointed with the inclusion of sharps in the proposed ordinance. They would like to see data that quantifies the problem.	The State of California estimates there are almost 400 million disposable needles used each year, with approximately a quarter of this amount used in Los Angeles County based on population. Waste haulers have indicated that they have experienced needle stick injuries at material recovery facilities, landfills, and other solid waste facilities. 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. Moreover, as the solid waste industry increases recycling rates, more solid waste needs to be processed and hand-sorted, increasing the likelihood of employees being stuck with sharps. A 2008 study suggested that "nationwide each year 25%...or roughly 150,000 to 200,000 needle sticks occurred outside the health services industry for a cost of \$38 million." http://www.ncbi.nlm.nih.gov/pubmed/18675147
12B	Sharps Industry	Sharps that are illegally disposed are the result of illegal drug use since sharps manufacturers place instructions for proper disposal.	Each year, the number of home-generated sharps is increasing, due to treatments for a variety of diseases such as diabetes. Although it is against the law in California for residents to dispose their sharps waste in the trash or recycling receptacles, many people still improperly dispose of their sharps waste due to the lack of convenient and affordable options for legal disposal, or lack of awareness of proper disposal options. Regardless of the reason, the Ordinance will provide safe, convenient, and environmentally sustainable options to residents free of charge to legally dispose of

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			their unwanted sharps, which will help reduce the incidence of improper disposal.
12C	Sharps Industry	The Department of Public Works has indicated that they are overwhelmed with the collection of sharps. This indicates that industry's education efforts are working.	The County is unaware of any public, County-wide efforts sponsored by the industry to educate residents on the proper disposal of unwanted pharmaceuticals and unwanted sharps, let alone directing them to use the County's collection events or sites. Further, the County being "overwhelmed with the collection of sharps" is evidence that a comprehensive system for the collection of pharmaceutical wastes should be implemented. Also, see topics 1B and 1F.
12D	Sharps Industry	The California Department of Resources Recycling and Recovery (CalRecycle) lists 616 sites on their website for the collection of sharps throughout the State and over 100 sharps collection sites within Los Angeles County.	CalRecycle's website may not be up to date. Our records indicate there are 77 collection sites within Los Angeles County, which are funded by local governments including the County. The draft Ordinance, if adopted, will be enforceable in the County's unincorporated communities with a population of over one million residents. Only six of the 77 collection sites are located in the unincorporated areas. This means that a great many unincorporated area residents still do not have adequately convenient access to dispose of sharps waste. The proposed Ordinance will ensure convenient locations, mail-back services or collection events will be available to all residents for proper disposal of their unwanted sharps.
12E	Retail Pharmacy Industry and Sharps Industry	Expressed concerns regarding disposal kiosks for used sharps, due to potentially hazardous materials and non-sharps waste being deposited in them.	<p>Participation by each pharmacy/retailer will be voluntary; however, the draft Ordinance will require all retailers selling drugs or sharps to the public, whether they serve as a collection site or not, to post approved display materials on how and where unwanted pharmaceuticals and sharps can be properly disposed.</p> <p>The County will be responsible for the oversight, administration, and monitoring of the Stewardship Plan activities, including collection site inspections. In addition, the Draft Ordinance requires that Collection Sites prominently display a 24-hour, toll-free phone number and a website for the Stewardship Plan through which anyone 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 must provide for immediate abatement of any hazardous condition arising from or related to operations performed under the Stewardship Plan.</p>
12D	Sharps Industry	If people do not follow instructions for proper disposal of sharps, why would they utilize the take-back program?	The Working Group believes if collection options were more readily available, there would be a significant reduction in improper disposal. A CalRecycle survey indicated that 31% identified not knowing where to take sharps as a barrier to disposal. http://www.calrecycle.ca.gov/homehazwaste/sharps/Survey/PersonalRslt.pdf

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			In addition, the outreach and education campaign that is required in the Ordinance will increase residents' knowledge of the take-back program. The Working Group believes that if provided access to safe, convenient, and free take-back options, residents will utilize the take-back program.
Topic 13: Metrics			
13A	Pharmaceutical Industry and Sharps Industry	The draft Ordinance should include measurable performance metrics, and a sunset date that discontinues the program if it is determined to be not working.	<p>Responsible Stewards are required to submit annual reports to the Director describing Stewardship Plan's activities. These reports will include, but not be limited to, a list of Responsible Stewards participating in the Plan, the total amount, by weight, of Unwanted Covered Drugs and Sharps collected, the total number of mailers provided to residents, the dates and locations of collection events held, the total number of sharps containers provided to residents, whether any safety or security problems occurred during the reporting period, and whether changes have been made or will be made to policies, procedures or tacking mechanisms to alleviate the problem and improve safety and security in the future.</p> <p>The Ordinance does not contain a sunset review date.</p>
13B	Pharmaceutical Industry and Sharps Industry	The amount of drugs and sharps collected are not adequate to measure the success of the program. Rather, the County should measure whether this Ordinance directly leads to a reduction in the concentration of pharmaceuticals in local water supplies and drug abuse rates.	<p>Section 11.17.80 of the draft Ordinance contains reporting requirements for the Stewardship Plans, among which is the requirement for a Responsible Steward to report the amount, by weight, of Covered Drugs and the amount, by weight, of Sharps collected, including the amount by weight from each collection event. The draft Ordinance under Section 11.17.160, <u>Stewardship Plans – Promotion, Outreach and Education</u>, also requires that each Responsible Steward, within six months of the effective date of the Ordinance, conduct a survey of residents, pharmacists, veterinarians, retailers, and health professionals who interact with patients on the use of the Drugs and Sharps. The surveys to residents is to gauge their awareness, use, and satisfaction with the program; assess to what extent the collection sites and other collection methods are safe, convenient, easy to use, and utilized by residents; and to assess residents' knowledge and attitudes about risks to the environment as well as risks of abuse, poisonings and overdoses from prescription and nonprescription drugs used in the home. While the program is anticipated to also reduce access to medications for diversion and keep pharmaceuticals out of the environment, many other factors affect these trends, and there may not be a way to precisely gauge the reduction in diversion and contamination attributable to the success of the program. Nevertheless, it will be an important measure towards</p>

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			helping to reduce the amount of unwanted drugs and sharps in the environment and in homes. See also topic 1I.
Topic 14: Cost to Industry			
14A	Pharmaceutical Industry	Non-prescription pharmaceuticals often serve as a primary form of healthcare for low-income residents, and any increases in costs will have a proportionate impact on these residents.	The draft Ordinance prohibits Responsible Stewards from charging consumers a point-of-sale or point-of-collection fee. In addition, the cost of the program is estimated to be minimal. The County estimates that the unincorporated area annual cost would be roughly \$3.2 million, and the County-wide annual cost would be roughly \$16.0 million. In contrast, the pharmaceutical industry sells over \$9 billion of prescription drug in LA County each year, and with an estimated profit margin of 11.76% based on industry data from Alameda County's court case, this sales figure translates into over \$1 billion in profit. Assuming countywide implementation, the cost of the program amounts to roughly 1.5 percent of estimated profits, and less than 0.2% of revenue (2 cents additional cost for every \$10 in sales). It is important to note that these revenue figures represent prescription drugs only, and do not account for revenues generated by the sale of generic drugs, over-the-counter drugs, and sharps, which would increase these sales and profit figures significantly, thereby further reducing the already de minimus impact of cost on overall profit margin. Therefore the Working Group anticipates that if there are increased costs as a result of the programs, they would be minimal. Furthermore, in existing EPR take-back programs in other jurisdictions, there have not been noticeable increases in the cost of medications.
14B	Pharmaceutical Industry	Generic drug sales make up a large percentage of total pharmaceutical sales, however, have very low cost margins in comparison to other pharmaceuticals.	It will be up to the Responsible Stewards or Stewardship Organizations to best determine how to equitably and proportionately allocate the costs for program implementation among industries and manufacturers and to consider such variables as profit margin and market share.
14C	Pharmaceutical Industry	Industry considers this as an unprecedented shifting of costs to industry.	This conclusion by the industry is fundamentally incorrect. There have been EPR programs for pharmaceuticals for many years around the world with many of the same multi-national pharmaceutical manufacturers and sharps manufacturers which would be required to comply with the proposed Ordinance. Additionally, there are other EPR programs currently being implemented in the State for materials such as paint, thermostats, and rechargeable batteries.
14D	Pharmaceutical	There are visible fees to	The Board of Supervisors directed the Working Group to draft an Ordinance based

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	Industry	consumers for other programs for products such as tires and oil. Why are fees prohibited in this draft Ordinance?	on the concept of EPR, which places responsibility for end-of-life management of a product on the product's manufacturer. Permitting a manufacturer to charge a point of sale or point of collection fee to cover the costs of the program is at odds with this principle. Additionally, the establishment of such a fee would create additional, unnecessary bureaucratic costs and hurdles.
14D	Pharmaceutical Industry	The pharmaceutical distribution network is a complex supply chain and everyone in this chain needs to be at the table in order for this draft Ordinance to be successful.	A comprehensive stakeholder engagement process was undertaken by the EPR Working Group in developing the draft Ordinance. A broad range of representatives that could potentially be most affected by the Draft Ordinance were participants on the Technical Advisory Group (TAG), including the pharmaceutical manufacturing industry, sharps manufacturing industry, pharmacies and retailers, including distributors/wholesalers, hospital associations, environmental advocacy organizations, public interest organizations, waste management businesses, and sanitation agencies including waste-water treatment facility operators. Such representatives were invited to fully participate in all four of the TAG meetings held by the County prior to completing the Draft Ordinance. The representatives were also asked identify anyone else who should be invited as well, and the TAG was adjusted based on recommendations received.
14E	Pharmaceutical Industry and Sharps Industry	Under Medicaid and Medicare, it is impossible for pharmaceutical companies to recuperate costs of programs.	See topic 14A.
Topic 15: Service Area			
15 A	Pharmaceutical Industry, Sharps Industry, and Environmental Advocates	Does this draft ordinance apply to the entire County or only to the County Unincorporated areas?	The Ordinance, if adopted by the Board of Supervisors, will only apply to the County unincorporated areas. Incorporated cities within the County that adopt the requirements of the Draft Ordinance into their respective municipal code will be able to participate in the program. Many cities have expressed support of the County adopting the draft Ordinance and have expressed an interest in joining the program.
15 B	Environmental Advocates	The ordinance should specifically address the process and timeline for cities to opt in to the program and the Stewardship plans to be made applicable to cities.	The draft Ordinance was revised to define "Service Area" which includes the unincorporated communities of the County as well as participating cities in the County that adopt the requirements of the Ordinance into their respective municipal codes. Each City would determine if and when they might adopt the requirements of the Ordinance into their municipal codes.

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Topic 16: Specific Draft Ordinance Language			
16A	Sharps Industry	11.17.020 Definitions “Covered Drugs”: Medical devices are exempted in definition. Sharps are considered a medical device.	The draft Ordinance contains separate definitions for Covered Drug and Sharp. “Sharp” is defined in the draft Ordinance as follows: “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, offered for sale, or otherwise distributed for use by or more consumers in the County and may include anything affixed to the instrument, such as a syringe. Responsible Stewards of pharmaceuticals and/or sharps are compelled to comply with the requirements of the draft Ordinance.
16B	Retail Pharmacy Industry and Healthcare Distributors	11.17.020 Definitions “Producer” (d): Retailers and distributors are inadvertently captured as “Producers.”	This section of the draft Ordinance has been revised. It now defines “Responsible Steward” as a Manufacturer engaged 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 unless said Wholesaler is also a Manufacturer.
16C	Healthcare Distributors	11.17.030 Stewardship Plans - Participation: Ordinance includes a reporting requirement for repackagers and private labelers, but does not indicate if these entities are not responsible.	As indicated under topic 16B above, this Section has been revised.
16D	Consumer Advocates	11.17.040 (E) Stewardship Plans - Components: Clarify what certification would be required that patient information on packaging will be destroyed.	The revised draft Ordinance addresses this by requiring responsible stewards to provide a certification that any patient information appearing on drug or sharps packaging be kept secure and promptly destroyed.
16E	Pharmaceutical Industry and Sharps Industry	11.17.050 Stewardship Plans – Collection of Unwanted Covered Drugs and Unwanted	The County rejects the notion that compliance with the proposed Ordinance requires violation of any laws. To the contrary, the Ordinance expressly requires Responsible Stewards to comply with all applicable federal, state, and local laws. It is up to the

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		Sharps: Incentives and “kick-backs” for participation are illegal.	Responsible Stewards to negotiate legal arrangements with potential hosts for the placement of their collection bins. To the extent a Responsible Steward is not able to fully meet these requirements, it may supplement the provision of bins with collection events and/or mail-back services.
16F	Environmental Advocates and Consumer Advocates	11.17.050 (B)(4) Stewardship Plans – Disposal of Covered Drugs and Sharps: Include a definition for safe container for sharps referencing FDA definition.	The draft Ordinance has been revised to require Responsible Stewards of Sharps participating in a Stewardship Plan to provide for distribution of FDA-compliant Sharps containers designed for the safe handling of Sharps to the consumer free of charge, preferably at the point of sale of the injectable Drug or at the time the consumer otherwise receives the Sharps for usage.
16G	Environmental Advocates, Consumer Advocates, and Sharps Industry	11.17.050 (B) (4) Stewardship Plans – Disposal of Covered Drugs and Sharps: Include provision that an FDA compliant sharps container must be provided at no charge with the purchase of sharps at the point of purchase.	The revised draft Ordinance addresses this concern. As indicated in topic 16F above, Responsible Stewards will be required to provide FDA-compliant Sharps containers free-of-charge to consumers.
16H	Pharmaceutical Industry and Sharps Industry	11.17.120 Stewardship Plans – Enforcement and Penalties (d): Provision identifies tax exempt organizations as capable of bringing a civil action against violators of the ordinance. This will entice frivolous lawsuits.	This provision has been removed from the draft Ordinance.