Report on Options for Managing Home Generated Medications in San Joaquin County

January 29, 2016

Photo: California State University Sacramento pharmacist demonstrating bin usage.

Prepared by the California Product Stewardship Council
Funded by and Prepared for the City of Stockton and San Joaquin County
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I. Purpose

Disposal of medications used in the home by residents has been addressed in federal, state, or local regulations and it varies by agency and state to state. Residents may dispose of unwanted medications not classified under Resource Conservation and Recovery Act (RCRA) in the trash or by flushing if it is not prohibited by local ordinances. RCRA medications that are generated by a regulated business entity may not be thrown in the trash and most cannot be flushed. There is a lack of consistent, harmonized disposal messaging to the public from local governments, environmental groups, pharmacists and pharmaceutical manufacturers to use. This report outlines the concerns about home-generated leftover and expired medications which can result in drug abuse and poisonings as well as be a source of water pollution. These issues are driving many jurisdictions to investigate options to increase the convenience of safe medication disposal. The City of Stockton and San Joaquin County co-funded the development of this report to ensure there is a comprehensive understanding of the current status of medication management in the region and beyond, as well as the challenges and recommended strategies for managing home-generated medication disposal.

II. Background

According to the U.S. Centers for Medicare & Medicaid Services, which publishes the National Health Expenditure Projections 2012-2022, approximately $275.9 billion in prescription drugs were predicted to be prescribed in the U.S. in 2014. However, 2014 expenditures were almost $100 billion more than predicted according to the IMS Institute for Healthcare Informatics. In an April 2015 study, IMS stated that “spending rose 13%, the biggest jump since 2001, to a total of $374 billion. After accounting for population growth and inflation, the increase equaled 10%. A record 4.3 billion prescriptions were filled in 2014.” These staggering numbers do not reflect the purchase of over-the-counter medications, commonly referred to as OTCs, which also contribute to preventable poisonings and water quality concerns. All prescribed and OTC medications are meant to be consumed, and if they were, there would be no leftover medicines to

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1 S. Centers for Medicare & Medicaid Services which publishes the National Health Expenditure Projections 2012-2022
2 Medicine Use and Spending Shifts April 2015 IMS Institute for Healthcare Informatics
dispose of or to pollute water. There are many reasons medications are not completely consumed including: adverse side effects, changes in medication dosages, patient non-compliance, over prescribing, over purchasing, and end-of-life care. Leftover medications are often stored in unlocked cabinets and are accessible by children or others in the household. According to the Centers for Disease Control (CDC), the abuse and misuse of prescription medications has become a national epidemic.³ Unused, expired, and leftover drugs that accumulate in homes increase the risk of preventable poisonings, drug abuse, and overdoses. Affected local government agencies including law enforcement, public health, public works and water treatment operators, are all interested in achieving a well-publicized, secure and environmentally sound medication disposal program. This report provides the background and makes recommendations for San Joaquin County and the City of Stockton to achieve their goals to protect public health and safety. This report can be beneficial to other local governments in the United States when considering their own medication disposal options.

A. Environmental Health and Water Quality Concerns

1. Flushing Medications

Many medicine collection programs were started in coastal and waterfront communities. Due to their proximity to water, these communities have a heightened awareness of water quality issues. Improper disposal of prescriptions by means of flushing medications in toilets or down the drain can directly pollute local water sources.

The public needs to be adequately educated on proper disposal. Medication waste is showing up at public hazardous waste collection events because the public lacks convenient locations to properly dispose of leftover medications. Although local household hazardous waste (HHW) facilities may accept unwanted medications; the facilities often have limited operating hours. Federal regulations do not allow HHWs to accept controlled medicines without law enforcement present.

According to San Joaquin County Solid Waste, over the counter and prescription medicine, drugs and medications can be harmful to humans if improperly disposed. They urge individuals to avoid flushing any unused pharmaceutical down any drains or toilets.\(^4\) The County’s website references a 2002 study by the United States Geological Survey (USGS) which stated that over 80% of our streams are contaminated with pharmaceuticals, including hormones and steroids. The USGS completed a report in 2005 identifying 24 pharmaceutical constituents for monitoring in groundwater samples collected at all wells in the Northern San Joaquin Basin Study Unit. Results of the pharmaceutical analysis are planned for publication in a future report.\(^5\) While research continues on that study, the data continues to grow on pharmaceuticals building up in the environment.

A 2010 study by the US EPA and Washington State of Ecology concluded that the “2008 screening study detected pharmaceuticals and personal care products in every influent, effluent, and biosolids sample analyzed from five Pacific Northwest wastewater treatment plants.”\(^6\)

Pharmaceutical pollution arises from multiple sources including human excretion, agricultural uses, and improper disposal of unused medications. Addressing each of these sources is challenging, involving complex system changes as well as development of new technologies. A significant amount of medications go unused and can be prevented from entering the environment if collected and safely disposed through medication management programs. Source reduction programs to prevent pollution are far more economical than wastewater treatment upgrades or environmental cleanup.

Until more pollution prevention approaches occur such as reducing overprescribing and overconsumption of medications or designing pharmaceuticals to be less eco-toxic, the most obvious option to prevent pollution is the collection of leftover medications to prevent disposal by flushing to sewers.\(^7\) Data collected on medication disposal from a study in Southern California (October 2014) states that:

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\(^5\) [http://www.waterboards.ca.gov/gama/docs/nsjv_dsr.pdf](http://www.waterboards.ca.gov/gama/docs/nsjv_dsr.pdf)

\(^6\) Control of Toxic Chemicals in Puget Sound Phase 3: Pharmaceuticals and Personal Care Products in Municipal Wastewater and Their Removal by Nutrient Treatment Technologies, USEPA 2010 Pub. Number 10-03-004

“Throwing medications in the trash” was the most common method for disposal (50%), followed by “flushing it down the toilet” (26%). Additionally the reported reasons for non-use included nearly two-thirds (66.2%) were expired, discontinued by the physician (25%), or became unused after the patient indicated feeling better (17.6%) and nearly two-thirds of these [collected medications] were tablets, capsules, and liquid preparations with more than half of the quantity remaining. Finally, the majority of the patrons (71%) preferred pharmacy as a convenient location for medication disposal compared to other choices such as police department/fire station, hazardous waste facility, or special collection events within the community.”

2. Disposing Medications in Trash

Disposing of medicines in the household trash has potential negative consequences at the home, and if the trash goes to landfills.

a. Medications disposed of in the trash are not secure. Most in-home and outside of the home bins are not locked and can be accessed by almost anyone, especially when placed at the curb. A common guidance for in-home trash disposal is to mix leftover medications with kitty litter or coffee grounds before placing in the trash as an attempt to disguise them to prevent theft or access.

b. Unwanted medications put in the trash are primarily taken to solid waste landfills, where they may end up in leachate. Leachate is water that infiltrates and percolates through the garbage placed in landfills. Landfill operators do not currently routinely screen landfill leachate for medications; however, they have been detected in landfill leachate in several studies including one completed in 2015 by USGS finding 65 different prescription and nonprescription medications in landfill leachate.

c. Some jurisdictions burn waste in combustors that meet the Maximum Achievable Control Technology (MACT) standards. There are different standards and permits for different sources of input materials, including hazardous waste, medical waste and general

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Municipal Solid Waste. The EPA Memorandum from September 26, 2012 states “The Agency believed that by recommending hazardous waste combustion as the preferred option for disposal and destruction of collected household pharmaceuticals, including controlled substances, and if not feasible, combustion by small or large municipal waste combustors as a minimum standard...”10

While we disagree with this statement the pharmaceutical manufacturers state that in-home disposal is the preferred option for leftover medication management, (Appendix X Item A) but there are concerns about it from a safety and environmental perspective. However, the EPA states that the best environmental option is using a medicine take-back program that send medicines to a hazardous waste combustion facility.

B. Epidemic of Abuse and Poisonings – Public Health Concerns

In January 2012, the Center for Disease Control and Prevention officially stated that prescription drug abuse is an epidemic in the United States.11 Prescription drug overdoses now kill more people than overdoses from heroin and cocaine combined.12 Since 2000 the rate of deaths from drug overdoses has increased 137% including a 200% increase in the deaths involving opioid overdoses with a significant increase of 14% in opioid overdose deaths over one year between 2013 and 2014.13 Large amounts of prescription and over-the-counter medicines – estimated at 30-40% of medicines sold to consumers – go unused for a variety of reasons. In a 2009 survey of Washington and Oregon residents, 93% of respondents had at least one container of prescriptions or over-the-counter medicine in their households, and more than half (52%) had six or more containers. Of those, 39% had at least one container of medicines that had expired or would not be used for some other reason.14

A July 2015 study found that approximately two out of three prescription medications were not used. The reasons for non-use ranged from disease/condition improvement, forgetting to take the

10 EPA Memorandum Subject: Recommendation on the Disposal of Household Pharmaceuticals Collected 9/26/12
11 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm
12 Ibid
13 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm
medication, or side effects. With so many medications in homes, there is a potential for misuse. In a Statewide survey of California students in 2009-10, 18.9% of 11th graders reported using prescription painkillers (Vicodin, OxyContin, Percodan, Lortab) recreationally. Of those polled, 12% of 9th graders and 19% of 11th graders had tried a prescription painkiller, making it the most popular class of abused drugs after marijuana. According to the Healthier San Joaquin County Community Assessment of 2011, youth drug use has continued to rise in San Joaquin County, particularly with 7th to 11th graders.

According to the 2013 San Joaquin County Coroner’s Report, 65% of accidental deaths were caused by drugs (Appendix X Figure 1.1). In addition to this, the coroner reported that 16% of suicides in 2013 were due to drug overdose (Appendix X Figure 1.2). The coroner made a special case report, noting that 22 of the deaths related to drugs were due to methadone overdose, and though this is a prescribed legal pharmaceutical, many of the individuals who overdosed from this pharmaceutical had not been prescribed this medicine and had procured it through other means.

In 2013, over 11% of the population in San Joaquin County were persons 65 years and older. Seniors are more likely to take multiple medications. Medication Use Safety Training (MUST) is an online educational campaign and workshop designed to promote safe and appropriate medication use for seniors. According to MUST, older adults account for 34% of all prescription medicine use, 30% of over-the-counter (OTC) use, and almost 40% of seniors are unable to read prescription labels. This can lead to confusion if leftover medications are stored in the home. In some areas, seniors are targeted by criminals searching for medications that are being stored.

Unused, expired, and leftover medications accumulated in homes increase risks of preventable poisonings, drug abuse, and overdoses by children, seniors, abusers, and pets. In San Joaquin

16 http://www.wested.org/online_pubs/hhdp/css_13th_highlights.pdf
19 http://quickfacts.census.gov/qfd/states/06/06077.html
20 http://www.mustforseniors.org/index.jsp
21 http://www.mustforseniors.org/facts.jsp
County and many locations across California and the U.S., there are no convenient methods of disposal, therefore consumers hold on to leftover medications. This provides the opportunity for individuals gaining access to medications that are not prescribed for them.

**III. The Safest Way to Manage Medications**

Some agencies and communities have developed collection programs to safely manage expired and unwanted medicine. These programs provide secure collection and environmentally sound destruction of unwanted medications to protect public health and the environment. The White House Office of National Drug Control Policy, Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), and the Environmental Protection Administration (EPA) all recommend medication collection programs as a more secure and environmentally safe method than throwing medicines in the trash.

Drug Disposal Guidance from Federal Agencies:

1. The 2015 National Drug Control Policy from the White House Office of National Drug Control Policy encourages increasing prescription return/take-back and disposal programs for the public use,
   See:[https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/2015_national_drug_control_strategy_0.pdf](https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/2015_national_drug_control_strategy_0.pdf)

2. The Drug Enforcement Administration states “Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold…Take-back programs are the best way to dispose of old drugs.” – materials for DEA National Prescription Drug Take-back Day, April 30, 2011;

3. The Food and Drug Administration encourages consumers and caregivers to remove unused medicines from homes and promote use of medicine take-back programs currently advises that specific medicines are especially harmful that they should be flushed down the sink or toilet when they cannot be disposed of through a drug take-back program.”
4. The Environmental Protection Agency encourages the public to take advantage of pharmaceutical take-back programs.


Disposing of medications from households in the trash is legal in many areas but some communities have banned sewering and trash disposal, but, as these citations demonstrate, there is support at the federal level for medicine take-back. All four of the federal agencies agree that take-back programs are the safest way to manage medications but the FDA also recommends sewering of some medications which concerns a broad group of stakeholders who have asked the FDA to end its “flush list” (Appendix X Item B Letter to FDA).

The 2015 National Drug Control Strategy calls for increased use of prescription medication return/take-back programs as one of four “pillars” in combating prescription medication misuse.

A. Secure Medication Collection Receptacles (Kiosks or Bins)

One of the most crucial aspects of any take-back program is having secure collection receptacles which meet the DEA requirements for any program collecting controlled substances. The DEA’s Final Rule (21 C.F.R. part 1317) effective October 9, 2014, titled The Final Rule for the Disposal of Controlled Substances implementing 2010’s Secure and Responsible Drug Disposal Act (DEA Final Rule) provides requirements for placement and security of receptacles.

Commercially available receptacles vary in size, cost, and complexity. Diversion is a concern when creating a medication disposal program, therefore security of the bins is important. “Diversion” in the medicine collection vernacular means the diversion of licit drugs for illicit purposes and it involves the diversion of drugs from legal and medically necessary uses towards

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uses that are illegal and typically not medically authorized or necessary. To ensure security, each bin should be constructed of steel and securely fastened to the floor or a countertop, have a tamper-proof drop chute, and be equipped with a dual-key locking system as outlined by the guidelines developed by CalRecycle and the Board of Pharmacy in 2007.

**B. Special Collection Events**

Special collection events are typically one-day events that accept household generated medications. To collect controlled medicines, partnership with law enforcement agencies is necessary. As awareness has grown from problems associated with leftover medicines in the home, a variety of ad hoc and more regularly scheduled collection events have occurred across the country. Beginning in 2010, the U.S. Drug Enforcement Administration (DEA) initiated the National Prescription Drug Take-Back Day program in response to growing concern about prescription drug abuse and diversion. Through this program, the DEA collaborated with local law enforcement agencies, public health organizations, and other stakeholders to hold twice-a-year one-day collection events where the public could bring their medicine for disposal free of charge. The first Take-Back Day held on September 27, 2010, was a tremendous success, with over 4,000 take-back sites in all 50 states collecting over 242,000 pounds (121 tons) of unwanted medicine. Ultimately, nine DEA events took place between September 2010, and (what was billed as the final event) September 20, 2014, collecting over 4,823,251 pounds, or 2,411 tons. Many local law enforcement agencies came to rely on the twice-a-year DEA events as a way to dispose of all the medicines they had collected in their ongoing drop-off programs, saving them expense and staff time.

When the DEA released the updated regulations in September 2014, it indicated it would no longer host and organize special collection events. Many local government solid waste, sanitation and water treatment agencies, law enforcement and drug prevention groups, concerned that the new regulations would take time to implement, requested the DEA to continue to host the twice-a-year collection events. The DEA hosted the tenth event on September 26, 2015 collecting over 702,365 pounds of medications at 5,000 collection sites. The DEA now plans to continue to host these

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events twice a year, in spring and fall; however the DEA also hopes to end its involvement in drug
take-back and is encouraging state and local governments to develop sustainable, ongoing drop-off programs.

C. Mail Back Programs

Pharmaceutical mail-back programs are an option used by some pharmacies, drug manufacturers
and environmental service organizations. These programs were not authorized by the DEA to
accept controlled substances until the release of the new regulation in October 2014. Most mail-back programs have customers pay for a postage-paid envelope to mail their unused medications to a secure incineration facility. The City of San Francisco piloted a mail-back program using pre-paid mailing envelopes, which they have since discontinued because it contributed to a high disposal cost of $5.65 per pound for their medication collection program. The return rate of the mailers was only forty percent, and the mailers size limited it to an average of eight ounces of medicines per envelope.25 A statewide mail-back program operated by the State of Maine for a limited time under grant funding had even higher costs of $7.50 per each mailer designed to hold roughly 6-8 ounces of medicines (actual costs per pound were not calculated).26

Sharps Compliance Inc. (Sharps Inc.), a private company based in Texas, has had medication mail-back services for consumers in various forms for many years. Sharps Inc. has partnered with pharmacies, including large retail chains, for distribution of mailers that have been either purchased by consumers or provided by the pharmacy as a customer service. For many years, consumers were advised that Sharps Inc. mailers could not be used to return controlled substances, however, Sharps Inc. is now authorized27 under the new DEA regulations to accept controlled drugs.

Mail-back programs clearly have some advantages, including convenience for seniors, disabled, and home-bound residents. However, mail-back programs are typically significantly more expensive than drop-off programs. Generally, the mailers are small, limiting the number of pills

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27 http://www.sharpsinc.com/pharmaceutical-waste
they can contain. They are not convenient for consumers who have large amounts of medicines to return such as after an illness or, the death of a family member.

The general consensus of California local governments, who have studied and used mail-back systems, is that they are too costly and are not enough for large amounts of medications but are important to use for home-bound residents.

D. Costs of a Safe Medication Management System

Costs of a county-wide secure medicine return system vary depending on the program’s design. The variable costs depend on the amount of medicines collected, number of collection sites, where they are located, and how effectively they are promoted to the public.

Start-up expenses include development of the program’s protocols, promotional materials, and a website. There’s also the start-up expense of purchasing secure boxes for drop-off sites. Ongoing variable expenses include collection supplies for drop-off sites, transportation and disposal of collected medicines. These costs are dependent on the number of drop-off sites, amount of medicines collected, and other collection methods used. If a mail-back option is provided, there are also costs for pre-paid mailers. Ongoing fixed expenses include program promotion, evaluation, and administration. Fixed expenses may also include warehouse rental for consolidation and secure storage of collected medicines prior to transport to final disposal.

1. Examples of Cost Categories for a Medicine Take-Back System:

   a. Collection
      i. Secure Metal Bin/Receptacles
      ii. Collection Supplies-Including Boxes and Liners
      iii. Staff Time at Collection Site
      iv. Pre-paid Mailers and Distribution (if utilized)

   b. Transportation to Interim Storage at Central Warehouse (if needed based on program design & operation)
      i. Transportation to Central Warehouse
      ii. Law Enforcement Escort for Consolidation (if needed)
      iii. Warehousing of Medicines

   c. Transportation & Final Disposal
i. Transportation to Final Disposal Facility  
ii. Law Enforcement Escort to Final Disposal Facility (if needed)  
iii. Disposal at Properly Permitted Incineration Facility 

d. Programmatic  
i. Administration  
ii. Promotion  
iii. Evaluation  

Receptacles are often one of the largest startup costs for medication collection programs. They come in a variety of different sizes and from different vendors. CPSC uses Securr Bins with a 38 gallon capacity to have maximum capacity and decrease the number of times it has to be emptied. The pictures to the right and left show different models. The cost of the bin is dependent on its size and the number of bins purchased at one time, with an average cost for a 38 gallon bin of $1,000 per bin including shipping and labeling. There are other companies that supply bins and some are less expensive, however CPSC is happy with the security and quality of the Securr bins.

**IV. How Medications are Managed in Other Jurisdictions**

The number of communities with some type of secure medicine take-back program has steadily increased in recent years. The nature of these programs vary greatly depending on community resources and engagement. Some communities are only served when the DEA hosts a twice-a-year National Prescription Drug Take-Back Day, and others organized more frequent collection events through their local law enforcement. Other communities have ongoing medicine drop boxes at their local sheriffs’ offices or police stations. Some cities or counties have medicine drop boxes at retail pharmacies and/or hospitals. Resources for public education and program promotion also vary greatly depending on community resources.
This section describes the relatively new passage of producer responsibility ordinances for pharmaceutical stewardship. Six California counties and one Washington county have enacted ordinances, which mandate creation of comprehensive county-wide medicine take-back systems that are financed and provided by pharmaceutical producers.

A. Programs

1. Voluntary Programs

Below are examples of voluntary programs.

a. The Nebraska Medication Education for Disposal Strategies (MEDS) implements educational efforts and supports a pharmacy-based disposal program utilizing the Sharps Compliance, Inc. TakeAway Environmental Return System. The program promotes safe and proper medication disposal by allowing patients to turn in expired or unused controlled and non-controlled medications at participating pharmacies. It is funded by a grant from the Nebraska Environmental Trust, which is funded through the Nebraska State Lottery.28 According to an article in December 2015, more than half of Nebraska’s 500 pharmacies are participating in take-back programs. The state funded program spends about $10.00 per pound to ship and destroy medications. The program began as a pilot in Lincoln and Lancaster County in 2012 and went statewide in early 2015.29 The list of participating pharmacies includes three major chains CVS, Walmart and Walgreens that are present in California.30

b. The California Product Stewardship Council’s (CPSC) Don’t Rush to Flush, Meds in the Bin, We All Win (DRTF) program operates in Sacramento and Yolo counties. The program launched in July of 2013 and currently has six locations. Between July 2013 and December 31, 2015 these six locations have collected 5,355.5 pounds of medications that would have otherwise ended up in water supplies via the toilet, and through leachate via the trash. The bins for the program were provided at no cost to the pharmacies and law

28 http://www.nebraskameds.org/
30 http://www.nebraskameds.org/Files/PharmacyDrugDisposalLocations.pdf
enforcement through grant funding CPSC received from the Rose Foundation for Communities and the Environment. Under the DRTF program, the host pharmacies agree to host the bin and pay for ongoing disposal costs. CPSC and the local government partners promote the host locations and recognize the hosts as strong community partners. The program is expanding to Madera, Contra Costa, and Santa Clara Counties. Through the program, CPSC has developed cost calculations for placing and promoting bins, signage and list of potential waste haulers to service the bins. Most of the collection bins are located at local law enforcement agencies which utilize Covanta’s Prescription for Safety Program (Rx4Safety)-For Disposal from Community Programs. Rx4Safety is a Covanta Energy program that provides for the safe disposal and ultimate destruction of medications. The program provides free of charge disposal for community medicine take-back programs utilizing Covanta’s Energy-from-Waste facilities. Currently there are 19 municipalities that are approved to bring in RX 4 Safety to the Stanislaus facility. The DRTF program has won two awards, one for best public service announcement and the other for environmental stewardship.

c. The Michigan-based Yellow Jug Old Drugs program was created by the Great Lakes Clean Water Organization and began operating in April of 2009. The non-profit 501(c3) has since expanded their program to roughly 300 locations in three different states and plans to expand into four more states. As a service to their customers, the program is funded mostly by pharmacies, but also receives funding from both private and public sector entities. “Yellow Jugs” receptacles were located behind the pharmacy counter at the participating locations prior to implementation of the DEA’s regulation; the program has now shifted to using secure collection receptacles as mandated by the DEA. Customers bring back their unused medications (not in pill bottles) and return them to the pharmacist. The program employs part-time staff who haul the medicines themselves to one of two incinerators in the Great Lakes area. Michigan laws do not consider unused pharmaceuticals to be “hazardous” which would require higher fees for both hauling and incinerating purposes. As an organization not approved to handle controlled substances, the program collects uncontrolled medications only. As of January 2014, the program has collected and properly disposed of 45.75 tons of drug waste. Future plans for the “Yellow Jug, Old Drugs”
program include an outer shell to contain the yellow jugs which will be considered an inner liner for regulatory purposes. As of March 2015, in response to the changing DEA regulations, Great Lakes Clean Water has become a registered reverse distributor authorized to handle controlled substances in order to continue their program. The Yellow Jug Old Drugs program is now available in Michigan, Illinois, Wisconsin, Ohio, Indiana, and Minnesota and has just received a $30,000 grant from Eli Lilly to expand the program in Indiana to an additional 100 locations. The organization is not currently licensed to operate in California.

d. The Snohomish County (WA) Partnership for Secure Medicine Disposal (Partnership) was launched in December 2009 to provide residents with an easy, responsible way to safely dispose of unwanted and expired medicines, including prescribed controlled substances. The program is a multi-agency effort between the Snohomish Health District, the Snohomish County Sheriff’s Office, the Snohomish Regional Drug & Gang Task Force, and the Snohomish County Solid Waste Division. Residents can deposit unwanted medicines in secure collection boxes at 28 law enforcement locations. All medicines used in the home are accepted including: all prescription drugs including controlled substances, all over-the-counter medicines, and vitamins. In addition, 12 stores in the local Bartell drugs pharmacy chain provide secure collection boxes, but do not currently accept prescription drugs that are controlled substances. Satisfaction with the program is widely reported by residents and law enforcement staff interacting with the public. Collection continues to gain momentum, with amounts of collected medicines increasing every year since the program’s inception. In 2014, a total of 8,036 pounds of medicines were collected (county population ~ 760,000). Funding for the law enforcement collection program has been pieced together from the budgets of the partner agencies, as well as some grant funds from a state toxics reduction program administered by the Washington State Department of Ecology. The program has often utilized the twice-a-year DEA take-back events for disposal of accumulated collected medicines. Available funding for the program is declining, creating concerns about sustainability, and there are no resources to expand collection to more convenient pharmacy sites or to adequately promote the program. As of January 2012, many of the Bartell’s locations in the county began using a new protocol
that allows the safe disposal of the unwanted medications without the containers that has environmental and cost benefits (Appendix X Item C).\textsuperscript{31} The Partnership is part of \textit{Take Back Your Meds} coalition which is a diverse network of health organizations, law enforcement agencies, local governments, drug stores, environmental groups and others in Washington State who support medicine take-back programs.

2. Mandatory Programs

\textit{Retail Take-Back Ordinances}

On March 11, 2015 an ordinance mandating pharmacy take-back of waste medications was passed by the \textit{San Luis Obispo County Integrated Waste Authority} (IWMA) Board of Directors by an 11-0 vote with two Directors absent. The ordinance is a “Transitional to EPR” policy since the retailers pay for the program, not the producers. The ordinance requires that:

\begin{quote}
“By September 1, 2015, every retail pharmacy in the IWMA Region shall provide consumers with a mail back program and/or collection receptacle program to dispose of unwanted prescription drugs consistent with state and federal laws. The retail pharmacy shall not charge the consumer to use either the mail back program or collection receptacle program. The retail pharmacy shall have appropriate signage [. . .] indicating that the retail pharmacy has a program for the management of unwanted prescription drugs.”
\end{quote}

\textit{Extended Producer Responsibility Ordinances}

“Extended Producer Responsibility” or EPR policies place primary responsibility on product manufacturers for managing end-of-life disposal or recycling of toxic or hard-to-handle products, and also have some shared responsibility components on other stakeholders. Pharmaceutical companies manage and pay for drop box disposal systems for unwanted household medicines in several other countries, including three Canadian provinces, France, Spain, and Mexico. In the U.S., producer responsibility legislation for pharmaceutical take-back has been proposed in a number of states but has not yet passed and more information can be found in Exhibit I. Recently, some counties have adopted pharmaceutical stewardship ordinances requiring drug companies to operate safe drug disposal programs for local residents, first in Alameda County, CA in 2012 and

\footnotesize{\textsuperscript{31} \url{http://www.takebackyourmeds.org/what-you-can-do/dispose-of-pills-without-a-container}}
then by the King County Board of Health (WA) in 2013. A legal challenge to these laws from pharmaceutical trade associations has been rejected by the U.S. Ninth Circuit Court of Appeals in a decision that was upheld by the U.S. Supreme Court in May 2015. Thus far in 2015, six more California counties - San Francisco, San Mateo, Santa Clara, Marin, and Santa Cruz - have adopted ordinances similar to King County’s law. Pharmaceutical companies are complying with the county laws in the states of California and Washington, with King County projecting a program start in spring of 2016.

**Alameda County**

In 2008 the Alameda County Alcohol and Other Drugs Task Force (AOD) working with County Board of Supervisor Nate Miley’s office had attempted one-day collection events and established multiple drop off locations in the county mainly using volunteers and the Sheriff’s Department. Alameda County. They determined that the one-day events were too expensive and inconvenient and the permanent collection locations were not convenient enough as they were primarily at law enforcement and small pharmacies. The most successful location was at Eden Hospital. Because this was primarily operated by volunteers, the data collection was sporadic and incomplete. They needed a more sustainably funded and convenient program to meet the public’s needs.

In July 2012, the Alameda County Board of Supervisors approved the [Alameda County Safe Drug Disposal Ordinance](http://www.co.alameda.ca.us/aceh/safedisposal/index.htm) after almost two years of stakeholder discussion. This ordinance created the first manufacturer funded pharmaceutical take-back program in the United States. More specifically, the ordinance would require manufacturers that “sell, offer to sell, or distribute certain prescription drugs in Alameda County to participate in a Product Stewardship Program.”[^32]

[^32]: http://www.co.alameda.ca.us/aceh/safedisposal/index.htm

The County currently has 31 collection sites operated by ten different participating agencies. The ordinance received broad community support, but was strongly opposed by pharmaceutical companies and their trade associations. Three trade associations, PhRMA, Generic Pharmaceutical Association, and Biotechnology Industry Organization, sued the County over the ordinance in December 2012, claiming it violated the dormant Commerce Clause. A U.S. District Judge rejected these arguments and ruled in favor of Alameda County in August 2013. Meanwhile, the Board of
Health in King County, Washington passed a similar pharmaceutical producer responsibility ordinance in June 2013.

**The City and County of San Francisco**
The City and County of San Francisco’s medicine take-back program is managed by the San Francisco Department of the Environment with diverse participating organizations including local municipalities, law enforcement, pharmacies, and other non-governmental organizations. The evolution of their effort to provide a program for residents is typical of what happens when counties try to provide pharmaceutical disposal without industry support. Law enforcement agencies will set up take-back bins in response to prescription drug abuse, overdose deaths, and illegal sale of these medications. Sanitation Districts, Recycling Centers, and Household Hazardous Waste Facilities will do their part to provide take-back locations in response to pharmaceuticals in the waterways. Finally, select, family-owned pharmacies will provide take-back as a logical and convenient service to their customers. Efforts like these are admirable because cities and counties like San Francisco realize the need for proper disposal of unused pharmaceuticals, however the lion’s share of the associated costs fall on the taxpayer.

In 2010, San Francisco introduced a Safe Drug Disposal Ordinance, which moved forward in the legislative process but did not reach final adoption. In 2012, the City chose to try a voluntary public-private partnership and accepted $110,000 from Pharmaceutical Research and Manufacturers Association (PhRMA) and Genentech to fund a pilot project to collect data used to inform future policy making. In August 2013, they accepted $125,000 to extend the pilot project for an additional year to collect even more data. The pilot launched in April 2012 was successful and by March 2015 had collected 26 tons or 52,000 pounds of medication, proving that a pharmacy-based collection program works. The program also resulted in only local pharmacies voluntarily hosting the bins and large chains saying no, which led to the City adopting a Safe Drug Disposal Information Ordinance that passed in May 2011 to supplement the PhRMA-funded pilot program by requiring pharmacies that are **not hosting** a bin to advertise those that do (Appendix X Item D). After collecting the data, San Francisco’s reasoning for the ordinance included their goal of zero-waste to landfill by 2020. Therefore, all trash would be sorted by recycling workers to
remove recoverable materials. Trashed medicines would expose recycling workers to potentially dangerous chemicals.33

Following the U.S. 9th Circuit Court of Appeals ruling upholding Alameda’s ordinance, San Francisco Board President David Chiu reintroduced a revised ordinance on October 21, 2014. San Francisco Mayor Edwin Lee signed the legislation on March 26, 2015.

**King County**

The rule and regulation which created a convenient, county-wide medication take-back program for King County is similar to Alameda’s ordinance, which requires all manufacturers of pharmaceuticals sold to residents of the county to finance and provide the program. In contrast to Alameda’s law, King County’s regulation included all prescription and non-prescription medicines used in the home, including controlled substances, and more specifically defined required program components, such as drop-off locations at pharmacies and law enforcement agencies. A federal lawsuit, from the same pharmaceutical associations that sued Alameda County along with the association representing over-the-counter medicine makers, was also filed against King County for their ordinance in November 2013. On November 25, 2013, the pharmaceutical associations appealed the ruling in the Northern California Federal Court of Appeals. The Ninth Circuit Court of Appeals ruled in favor of Alameda County in July of 2014, after which the plaintiff filed a Petition For Writ of Certiorari, asking the U.S. Supreme Court to consider the case. In May 2015 the U.S. Supreme Court denied the petitioners’ request, setting a precedent for the entire United States.

With the U.S. Supreme Court’s action, implementation of the King County, Washington ordinance is moving forward. In October 2015, King County approved one stewardship plan submitted by ReturnMeds, LLC group from Call2Recycle, as meeting all the requirements of County law. That stewardship program must start collecting medicines by April 13, 2016. Another group of producers, working together in the King County MED-Project LLC, is submitting stewardship plans to King County. Approval as meeting all requirements of the county ordinance is pending.

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33 San Francisco Environment Safe Drug Disposal Ordinance Fact Sheet
http://sfenvironment.org/sites/default/files/fliers/files/sfe_th_factsheet_safemedsord_0.pdf
Following the U.S. Supreme Court’s action in May 2015, other California counties passed similar ordinances including: **San Francisco, San Mateo, Marin, Santa Clara and Santa Cruz Counties.** The counties of San Francisco, San Mateo, Marin, and Santa Clara are collaborating on implementation of their pharmaceutical stewardship ordinances as they all have similar implementation timeframes. **Santa Cruz County’s ordinance is the only one that includes mandatory participation by retailers.** At the time of the publication of this report, several more jurisdictions have begun the stakeholder process. More information can be found at [http://calpsc.org/products/pharmaceuticals/](http://calpsc.org/products/pharmaceuticals/).

**B. International Pharmaceutical EPR**

1. **Examples of Producer Responsibility International Programs**

[Canada’s Health Product Stewardship Association](http://calpsc.org/products/pharmaceuticals/) (HPSA) runs the pharmaceutical take-back program in Canada, the British Columbia (BC) Medications Return Program. This program was created over 15 years ago and has been entirely funded by the pharmaceutical industry since its inception under the provincial recycling regulation. The program’s budget for 2012 was $583,000 and with close to 2,000 participating pharmacies, the program’s operating cost is roughly $550 per pharmacy. In 2012, the BC Medications Return Program collected 87 tons of unused medications. Most of the pharmaceutical companies that fund this program are the same ones that filed unsuccessful lawsuits against similar laws in Alameda and King Counties.

Pharmaceutical EPR take-back programs are also being operated in Mexico, and outside of North America as well. This includes Brazil, Columbia, France, Hungary, Portugal, and Spain. CPSC has developed fourteen fact sheets on international programs.34

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34 [http://calpsc.org/products/pharmaceuticals/](http://calpsc.org/products/pharmaceuticals/)
V. How Medications are Managed in San Joaquin County

A. Medication Dispensing

Prescription medications are dispensed at pharmacies. Based on California Board of Pharmacy data obtained from the Board’s Verify a License Tool, as of June 3, 2015 there are 105 pharmacies with active pharmacy registrations in San Joaquin County. The majority of pharmacy locations in the County are concentrated in the urban centers of Lodi, Stockton, Manteca, Lathrop, and Tracy, with a few pharmacies in the smaller communities of Escalon and Ripon. (See Figure 1). Additional maps depicting pharmacies located in the urban communities of Lodi, Stockton, Manteca, and Tracy can be found in section XI Figures 1.3 through 1.6.

B. Collection

The majority of the County’s more than 700,000 residents have very limited access to ongoing medication disposal opportunities. Currently, there are only three permanent collection sites for expired and unwanted medications in San Joaquin County: San Joaquin County Household Hazardous Waste (HHW) Facility located in Stockton, Tracy Police Department, and BJRX Pharmacy in Stockton. The San Joaquin County HHW facility cannot accept medicines that are controlled substances. Neither the HHW facility nor the Tracy Police Department charge a fee to
the public. **BJRX Pharmacy collects both controlled and non-controlled medications from the public, charging $1.50 per pound.** They began the program in fall of 2015.

Law enforcement agencies in San Joaquin County do participate in DEA National Prescription Drug Take-Back events twice-a-year and hosted nine locations for the last event held on September 26, 2015.35

### C. Disposal

There are three open landfills that serve the San Joaquin County. The leachate from all landfills in the County is handled on-site. The County maintains and operates two landfills, Foothill Sanitary Landfill and North County Landfill & Recycling Center. At both facilities the leachate is collected and recirculated to the landfill in the lined areas according to regulations. Forward Landfill is privately owned by Republic Services and the leachate is kept on-site in evaporation ponds. The evaporation ponds are lined and do not percolate into the ground. At the closed landfills, Corral Hollow and Harney Lane, the leachate is collected and sent to the flare station where it is metered into the flare after it has been atomized.

### VI. Options for Managing Medications in San Joaquin County

Three secure medication collection programs have been successfully operated throughout the County one each at law enforcement, a pharmacy and the HHW facility and protocols are well established. The core question is how to sustainably fund it. Most programs are exclusively funded by government or temporary grants which are not sustainable funding mechanisms. Therefore, the programs that exist have often shared costs and responsibilities to fully fund a program. Partnering with entities such as pharmacies, volunteer groups, and water districts are used but are not sustainable long-term. The need for ongoing funding has led municipalities to look at models that tie the costs of disposal into the product’s price and the manufacturer’s business model through producer responsibility legislation at the federal, state or local level. This section describes the voluntary options first and the mandated options second.

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A. Program Options

1. Voluntary

Voluntary programs are those that most often are initiated by government representatives to obtain support from the healthcare community and others to develop partnerships where costs and education activities are shared in some fashion to “cobble” a whole program together. There are several voluntary programs that currently exist in San Joaquin County. The County can continue to expand on those. One option is to do strictly voluntary programs and place efforts through partnerships and collaborations. Examples of voluntary programs that were covered in section IV include: Nebraska’s Medication Education for Disposal Strategies, California Product Stewardship Council’s Don’t’ Rush to Flush Program, and Michigan’s Yellow Jug Old Drugs Program.

2. Mandatory

Mandatory programs are often difficult to enact politically as the business community does not generally support mandates. There are many ways to mandate all or parts of a medicine collection program to ensure it is sustainable. One example described in section IV is San Luis Obispo’s ordinance mandating the retailers to take back waste medications.

3. Extended Producer Responsibility

A third option is to have EPR policies created for products such as medication. EPR is a policy where a manufacturer of a product, such as medications that require special management and disposal, has the primary share of responsibility for the product’s end-of-life management, but others who have benefited from the product also have a share of responsibility. Other countries have developed, implemented and refined EPR policies for a variety of products that have the potential for public or environmental harm upon their disposal. These products include but are not limited to: batteries, carpet, fluorescent lights, mattresses, paint, packaging, automobiles, mercury thermostats and sharps.

EPR policy is implemented through a legislative directive(s) requiring manufacturers and/or other members of the product chain to share responsibility for the management of hazardous or problematic products at end-of-life. Industries subject to EPR laws commonly manage their
products through the formation of a “product stewardship organization,” which is most frequently a non-profit corporation funded by industry to comply with the requirements of the EPR legislative directive. Participating manufacturers collaborate with fellow producers and other stakeholders to design and submit a plan for meeting their responsibilities under the law. These stewardship plans are then sent to a governmental agency charged with approving the plan and overseeing program implementation. In this sense, EPR policies are free-market based because the product manufacturers, through their stewardship organizations, have latitude to design a cost-effective private sector system that meet the laws standards for proper management of the product.

As our waste stream contents continue to grow in volume and complexity of materials and our natural resources are constrained, more people understand the importance of the saying: “reduce, reuse, recycle.” The United States has a strong infrastructure in place to handle commonly discarded materials and items. However, when items that are more difficult to handle or have negative environmental consequences start to appear in the waste stream, processing costs go up. Extended Producer Responsibility does not seek to shift the entire burden of proper disposal costs to the manufacturer of a potentially environmentally hazardous product, it requires that they have primary responsibility shared with other stakeholders. Once this is the case, producers, driven by real economic incentives, will strive to replace hazardous materials in the products with materials that are more easily recycled and may not require special end-of-life management. Some industries in the United States such as manufacturers of paint and batteries are moving toward embracing their role in EPR. However, most industries are opposed to being held responsible for the full lifecycle of their products. Jurisdictions that passed EPR Ordinances in California include Alameda, San Francisco, San Mateo, Marin, Santa Clara and Santa Cruz Counties. King County in Washington has also passed an EPR ordinance. Their program details are described in section IV.

**VII. Recommendations**

Options for San Joaquin County to improve residential medicine disposal practices range from voluntary projects to legislated EPR Ordinances and include the following:
1. Establish a voluntary public education and collection program with local stakeholders where the county pays the program costs. San Joaquin County and each of their cities have their own website. Some of these sites lack sufficient information about proper methods of medication disposal. It is recommended that the County and cities coordinate to harmonize the messaging by reducing duplicate and conflicting information. One example of this is that some websites list medicines under hazardous waste, some in recycling, and others under medical waste. Table 1 in the Appendix lists the websites. Local pharmacies and police stations may volunteer to host secure drop bins, to expand beyond the three take-back locations currently available. A list of stakeholders to engage in this effort is provided in section XII.

2. Work to establish a transitional program where other stakeholders share in some or all of the costs for education, collection, transportation, disposal, and other program costs. This could involve county staff work to identify:
   - Any potential state or federal grant opportunities;
   - Private sector support from pharmaceutical manufacturers, drug distributors, pharmacies, hospitals, pharmaceutical waste disposal companies, etc.; and,
   - Financial contributions and/or fundraising by community organizations and individuals.

3. Engage in a stakeholder outreach and policy development process to pass a local ordinance. Examples of two ordinances are in the Appendix (Items E and F).
   - Pharmacy Take-Back - San Luis Obispo County March 11, 2015 (final)
   - Producer Responsibility – Los Angeles County January 5, 2016 (draft)

The next steps for San Joaquin County and its cities is to review this report and listed options to determine which option to pursue.
VIII. Exhibit 1: Existing State and Federal Regulations and Guidelines

A. DEA Regulations

Title 21, chapter 13 of the United States Control Substance Act is entitled Drug Abuse and Prevention. This chapter states that handling controlled substances falls under the DEA’s purview. Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are listed below.36

**Schedule I Controlled Substances:** Examples of Schedule 1 substances heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

**Schedule II/IIN Controlled Substances (2/2N):** Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone. Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

**Schedule III/IIN Controlled Substances (3/3N):** Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®). Examples of Schedule IIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

36 [http://www.deadiversion.usdoj.gov/schedules/]
Schedule IV Controlled Substances: Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances: Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

It is important to note that this report does not address collection programs for Schedule 1 substances which are primarily illegal drugs.

The DEA licenses a network of registrants who are authorized to handle controlled substances in the manufacturing and dispensing realm where law enforcement is exempt allowing them to collect controlled drugs. Controlled substances from the home environment are regulated by the general Act. This creates problems for programs that are not run by, or located at, police stations. It seems logical that the take-back bins should be located at pharmacies where people are receiving their drugs so they can drop off their unused medicines when going to a pharmacy.

In October of 2010 President Obama signed into law the Secure and Responsible Drug Disposal Act which authorized the Attorney General of the United States to restructure the framework within the Controlled Substances Act regarding who can handle these controlled drugs for purposes of secure disposal. The law did not mandate the creation of medicine take-back programs or provide any funding.

Taking effect October 9, 2014, the Drug Enforcement Administration’s new regulation, the Final Rule for the Disposal of Controlled Substances implemented 2010’s Secure and Responsible Drug Disposal Act. The Final Rule (21 C.F.R. part 1317) outlines new options for residents transfer unused or unwanted controlled substances to authorized collectors for disposal. It also allows authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with on-site pharmacies, and retail pharmacies who administer mail-back programs to maintain collection receptacles voluntarily. The DEA’s Regulation requires that controlled substances collected by take-back programs must be rendered “non-retrievable” so that they are unavailable and unusable. The DEA does not stipulate a specific disposal method, but
lists incineration and chemical digestion as examples of technologies that meet the non-retrievable standard.

At the time of publication of this white paper, the California Board of Pharmacy is in the process of drafting regulations for California pharmacists if they would choose to be part of a medicine collection program. Until those regulations are finalized likely in late 2016, it is extremely difficult to recruit new pharmacies to host collection bins in California. In fact, bins located in Kaiser Hospitals for non-controlled medications only were removed in the fall of 2015 awaiting the final BOP rulemaking.

**B. EPA Pharmaceutical Disposal Guidance**

Approximately 15 percent of medicines currently on the market are categorized as federal RCRA Hazardous Waste\(^37\), however, the U.S. EPA does not consider these chemicals hazardous waste when they are generated by residents under the household exemption of RCRA.\(^38\) EPA does recommend that medicines collected by take-back programs are handled properly through high temperature incineration. EPA recommends the use of hazardous waste incinerators, or at a minimum specific solid waste combustors.\(^39\)

**C. Regulatory Considerations in California**

According to California Department of Resources Recycling and Recovery (CalRecycle) *medication waste* is defined as items intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals and is synonymous with drug waste, pharmaceutical waste, unused or expired medication, unused or expired drugs, prescription and over-the-counter human drugs, veterinary drugs, diagnostic agents, and nutritional supplements.\(^40\)

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\(^37\) Smith, C. (2009). Personal correspondence to the Local Hazardous Waste Management Program in King County, WA from Charlotte Smith founder of PharmEcology, a company that assists the health care and pharmaceutical industry with managing pharmaceutical waste. PharmEcology is now owned by Waste Management.  
\(^38\) U.S. EPA Memo “Household Hazardous Waste Exemption for Pharmaceuticals Collected Via DEA Approved Take-Back or Collection Programs” 10/02 2015. RCRA Online Number 14853.  
\(^40\) http://www.calrecycle.ca.gov/HomeHazWaste/Medications/
There are no federal laws that forbid households from putting medication into the trash because household waste is exempt from classification as hazardous waste (RCRA 40 CFR 261.4(b)) and as medical waste (California Health and Safety code Section 117700) although California banned several household wastes from the trash (excluding pharmaceuticals).\textsuperscript{41}

\textsuperscript{41} http://www.calrecycle.ca.gov/HomeHazWaste/Medications/household.htm
IX. Exhibit 2: Attempted Legislation

Since 2009, more than 20 states have considered or adopted legislation relating to medicine take-back programs. These legislative proposals can be broadly grouped into several categories:

- Bills that address regulatory barriers to operation of take-back programs,
- Bills that authorize or regulate drug take-back programs by specific entities without providing dedicated funding,
- Bills establishing some type of statewide take-back programs through state funds or grant opportunities, and,
- Bills in 10 states (CA, FL, ME, MD, MN, NY, OR, PA, VT, WA) that would require pharmaceutical manufacturers to finance and operate a statewide medicine take-back system; none of these have yet passed.

A. California

Recently in California, there were bills two years in a row to establish EPR statewide, SB 717 in 2013 and SB1014 in 2014 attempting to address the issue of improper pharmaceutical disposal. Authored by Senator Hannah-Beth Jackson, this bill originally sought to create an EPR style, statewide, take-back program similar to Alameda County’s local ordinance. The bill gained support from a wide array of organizations. Law enforcement agencies, sanitation districts, drug abuse prevention coalitions, senior citizens’ rights alliances, environmental groups and various local governments all wrote letters of support for the state legislation. However, pharmaceutical industry opposition, questions over implementation and debates on associated cost responsibilities stalled the legislation in the Business, Professions and Economic Development Committee. 

*Senator Jackson then sent a letter to every county supervisor in California asking them to consider adopting a local EPR ordinance like Alameda’s (Appendix X Attachment G). Since then, San Francisco, San Mateo, Santa Clara, and Marin have all adopted EPR pharmaceutical ordinances with unanimous votes by the Board of Supervisors in Los Angeles, Santa Barbara and Santa Cruz all in the process of creating similar ordinances.*
In 2015 California Assembly Bill 45, authored by Assembly Member Kevin Mullin proposed collection of household hazardous waste including pharmaceuticals through curbside collection programs. The bill will be taken up again in January 2016.

B. Colorado

In Colorado HB 14-1207, the state has moved to provide safe disposal. The bill requires the Director of the Public Health Department to establish a medicine take-back program to collect unused pharmaceuticals. The program creates the take-back medication cash fund for program implementation. This fund is created and appropriated in the State Treasury by funds from the general assembly, and any gift or grants from the public or private sectors. This bill did not set up a manufacturer funded program.\(^{42}\)

C. Indiana

In 2011 Indiana House Enrolled Act 1121 became law, which revised statutory and regulatory requirements so pharmacies would be able to accept unused prescription drugs from consumers and dispose of them without the need for a monitoring police presence.

D. Federal

In 2015 Federal Legislation HR 2463 by Congressman Ami Bera, known as the Dispose Responsibly of Your Pills (DROP) Act, was introduced to establish a federally funded grant program to expand or make available disposal sites for unwanted prescription medications. It has been referred to the House Committee on Energy and Commerce: Subcommittee on Health and two other committees which will consider it before sending it to the House floor for consideration.\(^{43}\)

The Comprehensive Addiction and Recovery Act (CARA) was first introduced in the United States Senate during the 113\(^{th}\) Congress as S. 2839 on September 17, 2014. In 2015 Federal Legislation HR 953 by Congressman James Sensenbrenner Jr., known as the Comprehensive Addiction and Recovery Act (CARA) Act, was introduced to authorize the Attorney General to

\(^{42}\)HB 14-1207 was passed and signed by the Governor May 21\(^{st}\), 2014, https://legiscan.com/CO/bill/HB1207/2014
\(^{43}\)https://www.govtrack.us/congress/bills/114/hr2463/text
award grants to address the national epidemics of prescription opioid abuse and heroin use. Grants will be available to implement and expand medicine waste collection programs. The bill currently has 66 Democratic and Republican co-sponsors, including four California representatives. It has been referred to the House Committee on the Judiciary and two other committees which will consider it before sending it to the House floor for consideration. A bill must be passed by both the House and Senate in identical form and then be signed by the President to become law.

44 https://www.govtrack.us/congress/bills/114/hr953
X. Appendix

Item A: Letter from California Life Sciences Association—Opposition to Ordinance
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Item B: Letter to FDA
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Item C: 2012 Notice for Washington State Medicine Collection Program
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Item D: San Francisco Safe Drug Disposal Information Ordinance
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Item E: San Luis Obispo Retail Pharmacy Medication Take-Back Ordinance
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Item F: County of Los Angeles Draft Safe Drug and Sharps Disposal Ordinance
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Item G: Letter from Senator Hannah Beth Jackson to County Board of Supervisors
Page 97-98
November 30, 2015

Santa Cruz County Board of Supervisors
701 Ocean Street
Santa Cruz, California 95060

RE: Opposition to the Santa Cruz County Safe Drug and Sharps Disposal Ordinance

Dear Members of the Board:

On behalf of the California Life Sciences Association (CLSA), I am writing to oppose the Santa Cruz County Safe Drug and Sharps Disposal Ordinance. CLSA is the leading voice for California’s life sciences sector and serves over 750 biotechnology, pharmaceutical, medical device, and diagnostics companies, research universities and institutes, investors and service providers. Overall, California’s life sciences sector directly employs more than 281,000 people and indirectly employs another 581,000—totaling nearly one million California-based jobs.

The stated goals of preventing the abuse of prescription medicine and diversion of pharmaceutical waste from the environment are laudable, but there is no science that suggests drug takeback is a better option for disposal versus household trash. Additionally, the ordinance as drafted will be difficult to administer, and places an unprecedented burden on a single industry. Lastly, the program contemplated in the ordinance will not achieve your stated goals.

Pharmaceutical takeback programs do not improve water quality

One of the stated desired outcomes of the ordinance is to reduce the amount of active pharmaceutical ingredients found in waterways. However, there is no evidence that takeback programs achieve that goal, and there is significant evidence that the current practice of household trash disposal is a safe and preferable alternative. Consider the following:

- According to an editorial in the San Francisco Chronicle on January 4, 2011 by former Greenpeace leader Patrick Moore, the trace amounts of active pharmaceutical ingredients (“APIs”) are at such low levels that they are measured in parts per trillion, equal to one drop of water in 20 Olympic swimming pools.
- Europe has long had takeback programs for unused medicines, but it has not resulted in any measurable reductions of API in European waterways. These programs were established by article 127b of the European Union Directive 2004/27/EC which requires that, “Member states shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.” Studies in European countries with mandatory
take-back programs show that there are no discernible changes in the concentration of pharmaceuticals in surface waters after enactment of pharmaceutical take-back programs (Ternes 1998; Wick et al. 2009; Coetsier et al. 2009).

- Proponents of the measure claim that disposal of unused medicines by flushing them down a sink or toilet contribute to the amount of pharmaceuticals in the water, but it is a minor source of pharmaceuticals in the environment compared to patient excretion of medicines. Indeed, the past four annual reports from the British Columbia takeback program state, "The bulk of human pharmaceuticals found in waterways most likely got there by way of sewage. It is questioned whether take-backs have any real environmental and safety benefit."

- The pharmaceutical industry among others has studied the environmental fate of unused medications disposed in household trash and sent to landfills. In 2006, Tischler and Kocurek studied the potential for release of 23 APIs to surface waters through disposal in Subtitle D municipal solid waste (MSW) landfills. The potential landfill releases were compared to the releases occurring from patient use and excretion to wastewater treatment systems. Despite several conservative estimates designed to over-predict the occurrence and release of APIs in landfill leachate, the authors found that the average contribution of landfill leachate to the total load of APIs in surface water ranged from 0.21% to 0.78%. In other words, only a fraction of one percent of all APIs discharged to surface waters was estimated to originate from drugs disposed in landfills.

- The proponents have additionally not considered the costs to the environment that this approach would itself entail. Since all collected waste would have to be transported across state lines to one of only two approved incineration facilities for medical waste in the United States (one is in Utah, the other in Louisiana), it is quite likely that the ordinance will negatively impact air quality in a more substantial way than it positively impacts water quality.

**Sharps takeback programs pose significant risk and cannot replace consumer education**

The ordinance is the first of its kind to add a mandatory sharps take-back program. There is a significant risk in having disposal kiosks for used sharps due to potential hazardous material and non-sharps waste being deposited in them. The Board of Pharmacy has also expressed concern about retailers taking back used sharps. There are currently both effective public and private sector solutions available to consumers. Consider the following:

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• Patients can already access a list of 616 sites on www.calrecycle.ca.gov to dispose of their used sharps. Many jurisdictions also offer ‘at your door’ or curbside pickup for sharps as well.

• Patients using self-injectable therapies at home are educated by their health care providers on how to properly dispose of their used sharps. Materials on safe disposal are also available in packaging inserts that come with their medicines. Some manufacturers currently offer support and training on using and disposing of sharps on their product websites.

• An enhanced consumer education platform would result in a significantly increased understanding of proper sharps disposal for legally obtained prescription medicines. An infrastructure for a program is available through www.calrecycle.ca.gov.

• Education should also provide information on the advances in needle technology that have been developed to help prevent needle sticks. The use of pre-filled pens, needles with a safety sheath and existing manufacturer mail back programs should be recognized as a proactive step in patient safety.

• The ordinance being proposed does not address syringes found on beaches and other collateral damage resulting from illegal drug and needle use. Current needle exchange programs encourage safe disposal within this segment of the population.

**Stewardship programs are cumbersome for private entities to implement and manage**

The stewardship program proposed in the ordinance bestows the responsibilities of county government upon a private industry, yet withholds granting the industry any authority to compel other parties to participate in the implementation of the program. We are also extremely concerned that the ordinance also mandates or proposes several scenarios that would force industry to violate local, state, and federal law due to conflicting regulations among the laws at those various levels of government and this ordinance. Specifically:

• Unlike the County of Santa Cruz, we do not have the authority to mandate the necessary participation of other private entities in the implementation of the law, such as pharmacies, healthcare providers, law enforcement, patients, and practitioners.

• The ordinance states that private industry could provide incentives to encourage participation in the program by retail pharmacies. This concept of incentivizing pharmacies to encourage their participation ignores prohibitions in federal anti-trust law forbidding companies from collaborating in ways that would affect their respective competitive positions within the marketplace. It additionally ignores anti-kickback statutes that
govern what monetary incentives pharmaceutical companies can and cannot provide to pharmacists and retailers.

- As industry has no legislative authority in the County of Santa Cruz, should companies need to modify the program contemplated in this ordinance to remain in compliance with applicable state and federal laws, they would have no choice but to petition Santa Cruz County for successive amendments to the stewardship plan, or to sue for injunctive relief. Should the County design and implement a stewardship program itself, it should be able to easily modify the program to comply with state and federal law.

**Shared responsibility among all parties in the supply chain is conspicuously absent here**

While proponents have stated that shared responsibility should be a guiding principle in the design of a takeback program, ultimately the proposed approach institutes the exact opposite of shared responsibility. I.e., it requires that the responsibility should fall solely on biopharmaceutical and sharps manufacturers. Even the surveying of citizens to gauge awareness of the program is left to industry, and the County has no responsibility to show that the program is actually accomplishing the goal of reducing waste and preventing diversion. This is inequitable and, more importantly, unworkable.

The sale of pharmaceuticals and sharps products in the United States is extremely complicated. It entails manufacturers, wholesalers, doctors, hospitals, nursing facilities, insurance companies, government programs like Medicare and Medicaid, as well as thousands of retail outlets from pharmacies to corner stores and ultimately the patient. Placing the entire burden of waste on the manufacturers ignores this complex supply chain and will ultimately fail.

**Unlike other disposal programs, this ordinance ignores consumer accountability**

The proponents of the ordinance claim that there is broad public support for drug takeback programs, and that even without their extensive lobbying and media campaigns for this policy, the public would still demand takeback programs. Yet, this ordinance is a radical departure from other recycling paradigms in place already and imposes unrecoverable costs on a single industry for its implementation. This is all in an attempt to shield county residents, taxpayers, and even the federal government—which solely oversees the Medicare program and incurs the bulk of Medicaid costs—from the price tag of an unnecessary program.

- California has several recycling programs in place to manage disposal for particularly challenging products. The state has mandatory fees to cover the cost of end-of-life management for cell phones, computers, mattresses, tires,
and televisions. Those fees are paid by the consumer and disclosed up front at the point of sale.

- Proponents often point to the paint industry, which recently volunteered to manage their own stewardship program at no cost to consumers. Paint manufacturers, unlike pharmaceutical companies, can adjust the cost of their product to recover the costs of taking back unused paint. As the majority of pharmaceutical products are sold to public payers under the Medicare and Medicaid programs, it is impossible for our companies to recoup the costs of the program mandated here, as those federal programs do not allow for reimbursement of costs related to takeback programs. Paint manufacturers also enjoy direct relationships with the retailers that sell their products, while pharmacies purchase their inventory not from the manufacturers, but companies that specialize in the wholesale trade of pharmaceuticals.

- This ordinance sets a very dangerous precedent since there is zero accountability downstream should the program not produce the results promised by the proponents, as the costs will be hidden from consumers and constituents alike. Santa Cruz County is abdicating its public duty to consider the benefits and the costs of its policy proposals. Instead, the proposed approach requires that all of the costs be paid by private entities while providing neither demonstration of benefit nor a mechanism to gauge the efficacy of the program once in place.

**Sound solutions already exist to educate patients about proper drug disposal**

Our member companies recognize that illicit diversion of prescription drugs is a real problem in the United States, and we are happy to work with the proponents to provide education and outreach where appropriate to prevent prescription drugs from falling into the wrong hands. To that end, we have endeavored via several public awareness campaigns to provide education on safeguarding all drugs in the home—not just those that are expired or unwanted—from getting into the wrong hands. We also provide information regarding the appropriate and affordable household disposal options currently available to consumers.

- In response to a growing concern about the improper disposal of unused or expired medications, our industry has funded various outreach and education programs, including Mind Your Meds™, My Old Meds™, and SMART DISPOSAL™.
- Mind Your Meds™ and My Old Meds™ both utilize various forms of traditional and new/social media to provide information to consumers and parents about the risks of prescription drug abuse, as well as responsible in-home disposal options when drugs are no longer needed or expired.
- SMART DISPOSAL™ is a consumer-focused outreach program designed to educate American consumers about the proper disposal of unused medicines through the current household trash disposal infrastructure. The program
recommends that consumers put unwanted medications into a sealable plastic bag, add kitty litter, sawdust, or coffee grounds to the bag (crush any pills in the bag, or add water to dissolve) before placing the sealed bag into the household trash (www.smarxtdisposal.net).

In conclusion, the stated rationale for this ordinance is to protect the water system and the environment, to prevent drugs from being used or sold illegally, and to provide guidance to patients on how to properly dispose of drugs and sharps. Yet, no evidence is available to suggest this program will do anything to prevent abuse or reduce the levels of API in the environment. Additionally, given that drugs and sharps are regulated at the state and federal level, any solutions for end-of-life disposal should be forged at the state and federal levels to ensure uniformity in the guidance that is given to patients regarding handling of drugs and sharps when they are expired or no longer needed. The implementation of various local ordinances will do little more than create a patchwork of inconsistent regulations that will only confuse consumers and forestall conversations at the state and federal level around truly effective and equitable solutions.

For all the reasons stated above, we strongly oppose the Santa Cruz County Safe Drug and Sharps Disposal Ordinance. Please feel free to contact me with any questions or concerns.

Sincerely,

Sara Radcliffe
President & CEO
California Life Sciences Association
Figures

Figure 1.1

[Diagram: Pie chart showing miscellaneous deaths by cause.]

Comparison of miscellaneous deaths by cause as cited in:
http://www.co.san-joaquin.ca.us/SHERIFF/annual2013.pdf

Figure 1.2

[Diagram: Pie chart showing suicides by mode of death in 2013.]

Comparison of suicides by mode of death in 2013 as cited in:
http://www.co.san-joaquin.ca.us/SHERIFF/annual2013.pdf
January 22, 2016

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal

Dear Commissioner Ostroff:

To protect public health and environmental quality, the signatories to this letter urge the FDA to work with the EPA, the DEA, and the White House Office of National Drug Control Policy to develop clear and consistent guidance to consumers on safe disposal of leftover household medications. We call on the FDA 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.

We appreciate the FDA’s efforts to protect people from leftover medications that can be particularly harmful, even fatal, if abused or mistakenly consumed. However, the time has come for FDA to align its medicine disposal guidance with that of federal, state and local agencies who seek to protect both the public’s health and our water quality.

Disposal of leftover medications by flushing contributes to pharmaceutical pollution that is harming aquatic ecosystems and entering our food web. Wastewater treatment plants are designed to remove human waste and easily degraded organics, and cannot effectively remove pharmaceuticals and other complex, synthetic chemicals. Because of this, some wastewater agencies have established laws, regulations, or guidance prohibiting flushing as a disposal method for pharmaceuticals. In these areas, FDA’s recommendations infringe on wastewater districts’ jurisdictional authority to protect public health.

While pharmaceuticals also enter wastewater through excretion, flushing of unwanted medication is a source that we have the ability and technology to control. The amount of leftover and expired medications in American homes is significant – estimated at 30-40% of all medications sold. It is critical to keep these pharmaceuticals from polluting our waterways by recommending secure and environmentally sound disposal through medicine take-back programs. Preventing pollution is always the most effective and least expensive option to protect public health and environmental health.

Many communities across the country now have medicine collection programs and the DEA’s regulation to implement the Secure & Responsible Drug Disposal Act allows new options for take-back of prescription drugs that are controlled substances. We need clear and harmonized direction to the public and health practitioners on using medicine take-back programs, as well as ongoing efforts to increase access to secure medicine take-back programs in all communities.

Messages on medicine disposal are inconsistent between federal agencies and often in conflict with state and local regulations or guidance against flushing or trash disposal of leftover medications. This is confusing and frustrating for the public. Furthermore, some in the pharmaceutical industry take advantage of inconsistencies in federal agency messaging to undermine efforts to establish local medicine take-back programs and regulations.
We therefore urge the FDA to end its “flush list” recommendation, and work to create a single disposal guidance that is endorsed by all federal agencies and consistently used on all federal websites and materials. The public should be directed to store medications securely in locked containers or cupboards, to use secure medicine take-back programs where available, never to flush medications, and to dispose of medications in the trash only as a last resort where allowed by local ordinances. We encourage adoption of the following, clear messages on safe medicine disposal:

1. To protect water quality, never flush unwanted medicine down any drain.
2. Use a community medicine take-back program for secure and safe medicine disposal. Check with local household hazardous waste, wastewater, or police departments for locations. Use the medicine manufacturer's mail-back program if available.
4. As a last resort, if there are no medicine take-back options in your community: put medicines in a sealed container in the trash after mixing the medicines with an undesirable substance, such as cat litter or used coffee grounds. Make sure the trash cannot be accessed by children, pets, or others who might be looking in garbage. Check with your local government or garbage service first, because local laws may not allow disposing of any pharmaceuticals in the trash.

We look forward to your response to our letter and to your actions to address our concerns.

Sincerely,

Individual signers, affiliation stated for purposes of identification only.

Robert F. Kennedy, Jr., Los Angeles, CA and Waterkeeper Alliance
Barbara J. Bickford, Madison, Wisconsin
Nancy Busen, Bentonville, Arkansas
Jennifer Caldwell, CalRecycle
Audrey L. Comeaux, Director - West County Wastewater District
Gary Goldbaum, Health Officer, Snohomish County, Washington
Sarah Hellekson, Solid Waste Manager, City of Plymouth, Minnesota
Heidi Mayer, Marin, California
Chris McFaul, Spokane, Washington
Nate Miley, Oakland, California
Karim North, City of Palo Alto, Watershed Protection Manager,
Carol Scianna, City of Winters, Environmental Services Manager
Ruth W. Shearer, Ph.D., Retired Toxicologist
Margaret Shield, Ph.D., Seattle, Washington
Mary Anne Sullivan, Aging in Place Facilitator, Sibert & Sullivan, LLC
Susan Strand, Environmental Specialist, City of West Sacramento
Mark Nystrom, Energy, Environment and Land Use Policy Manager, the Association of Oregon Counties
Angela Goldberg, Member of the San Diego Drug Abuse Task Force
Carol Bailey, Concerned Consumer and Member of California Alliance for Retired Americans
Veora M. Little, Certified Registered Nurse Anesthetist, Naples, Florida
Food & Drug Administration
RE: FDA Recommendations toFlush Certain Medications and
Harmonize Federal Agency Messaging on Safe Medicine Disposal

Cc:
Administrator Gina McCarthy, U.S. Environmental Protection Agency
Director Dan Ashe, U.S. Fish & Wildlife Service
Acting Administrator Chuck Rosenberg, Drug Enforcement Administration
Director Michael Botticelli, White House Office of National Drug Control Policy
Jacqueline T. Zipkin, Manager of Environmental Services
East Bay Municipal Utility District

Stuart Moody, Board President
Green Sangha

Colin Bailey, Executive Director
The Environmental Justice Coalition for Water

Rachel Gibson, Director, Safer Chemicals
Health Care Without Harm

Violette Brown, President
FillAbox Corporation

John Mohoff, General Manager
Healthwise Services

David Stitzhal, MRP, President
Full Circle Environmental, Inc.

Sherrie Rubin, Founder/Director
Hope2gether Foundation

Daniel Parshley, Project Manager
Glynn Environmental Coalition

Rodney Larson, Founding Dean
Husson University School of Pharmacy

CPSC Report on Options for Managing Home Generated Medications in San Joaquin County

January 29, 2016
Cynthia Stark-Wickman, Executive Coordinator
San Juan Island Prevention Coalition

Doug Duttawalker, Environmental Outreach Representative
Union Sanitary District

Stiv J. Wilson, Campaigns Director
The Story of Stuff Project

Dan Tafolla, Director of Environmental Services
Vallejo Sanitation & Flood Control District

Angela T. Howe, Esq., Legal Director
Surfrider Foundation, Representing 84 domestic chapters

Melissa Meeker, Executive Director
WateReuse

Tina Segura, Chair
Surfrider Foundation West L.A./Malibu Chapter

Angie Rosser, Executive Director
West Virginia Rivers Coalition

Debbie Branch, Chair
Texas Product Stewardship Council

Nancy A. Eggleston, R.S.
Environmental Health and Communicable Disease Supervisor
Wood County Health Department
Food & Drug Administration
RE: Opposition to FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal
Page 19

Steve Devine, Program Manager
Zero Waste Marin

ZERO WASTE MARIN
Update: Drug Take-Back Programs Can Collect Pills without Containers

Good news! There are now 10 Bartell Drugs medicine take back locations, and some law enforcement offices in Washington State, that allow safe disposal of your unwanted pills without the pill container. This new protocol development has environmental and cost benefits. For a list of locations that are participating in this new protocol, go to http://www.takeyourmeds.org/what-you-can-do/dispose-of-pills-without-a-container

Background: When these medicine take-back programs were first set up, U.S. Department of Transportation (DOT) regulations did not easily allow for loose pills to be shipped for disposal in a full 5-gallon bucket or box. In 2009, DOT regulations changed, and it is our understanding that it is now okay to collect and ship loose pills in a larger container.

Residents are directed to bring their unwanted medicines to the pharmacy in the original containers, so the pharmacist can ensure that the medicines are not controlled substances (medicines that are subject to abuse or addiction). Under current federal regulations, which DEA is in process of revising, only law enforcement offices can take-back controlled substances.

Environmental and cost savings benefits to collecting pills without containers:

Environmental benefits:
- Consumers can take their packaging home and recycle some containers. Over-the-counter medicines are often in No. 1 and No. 2 bottles, and some recycling programs accept these. However, many prescriptions are in the amber bottles labeled #4; unfortunately, most programs do not recycle these types of bottles at this time. Check with your local recycling program or waste hauler to see what bottles you can recycle.
- The plastic bottles are not sent to the high-temperature incinerator with the waste medicines.

Cost savings benefits:
- Without the packaging, the collected medicines take up less volume and weigh less (about 28% less) – which leads to significantly lower disposal costs.
- Lower volumes mean that the staff providing the take-back program don’t have to change out the inside collection container as often, saving valuable staff time.

Take Back Your Meds would like to thank the law enforcement offices and pharmacies who are able to provide drug take-back programs for their communities, protecting our families and our environment.

January 2012. For more information about collection of loose pills by secure medicine take-back programs, contact Cheri Grasso, Local Hazardous Waste Management Program in King County, at 206-263-3089.

Ordinance amending the San Francisco Environment Code by adding Sections 2250 through 2254, to require any business selling prescription drugs to the public to post display materials explaining how to safely and lawfully dispose of unused prescription drugs; and making environmental findings.

NOTE: Additions are single-underlined in italics Times New Roman; deletions are strike-through italics Times New Roman. Board amendment additions are double-underlined. Board amendment deletions are strikethrough normal.

Be it ordained by the People of the City and County of San Francisco:

Section 1. The San Francisco Environment Code is hereby amended by adding Sections 2250 through 2254, to read as follows:

SEC. 2250. SHORT TITLE.

This Ordinance shall be entitled the "Safe Drug Disposal Information Ordinance."

SEC. 2251. DEFINITIONS.

For the purposes of this Ordinance, the following words shall have the following meanings:

(a) "Business" means a fixed location within the City and County of San Francisco, whether indoors or outdoors, at which Prescription Drugs are offered for sale at retail and that is required to obtain a valid San Francisco business registration certificate from the San Francisco Tax Collector’s office.

(b) "Department" means the Department of the Environment.

(c) "Director" means the Director of the Department of the Environment.

(d) "Display materials" means signs, posters or other similar informational materials.
(e) "Prescription drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.

SEC. 2252. INFORMATION REQUIRED AT POINT OF SALE.

(a) Beginning December 1, 2011, any business selling prescription drugs to the public shall post display materials approved by the Director explaining how members of the public may safely and lawfully dispose of unused prescription drugs. The materials shall be in English, Spanish, and Chinese, and legible and easily readable by the average person. The materials shall be posted on the premises of the business in a location visible to the public and adjacent to the area where the prescription drugs are dispensed.

(b) The Director may, in his or her discretion, authorize a business to use alternate means to comply with the requirements of subsection (a). The Director shall authorize such alternate means through the adoption of a regulation after a noticed hearing, and no business may sell prescription drugs to the public or offer to sell prescription drugs 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.

(c) The City urges all persons and entities providing prescription drugs to the public for free to also participate in this program.

SEC. 2253. IMPLEMENTATION.

(a) The Director, after a public hearing, may adopt and may amend guidelines, rules, regulations, and forms to implement this Ordinance.

(b) By October 1, 2011, the Department shall issue regulations specifying the contents and format for the display materials required by Section 2252.
SEC. 2254. ENFORCEMENT.

(a) During the period between the effective date of this Chapter and September 1, 2011, the operative date for compliance, the Department shall develop and conduct an education and assistance program for businesses subject to the Chapter, and shall contact the businesses and assist them with meeting the requirements of the Chapter.

(b) Beginning September 1, 2011, the City Administrator shall issue a written warning to any person he or she determines is violating provisions of this Chapter or any regulation issued under this Chapter. If 30 days after issuance of the written warning the City Administrator finds that the person receiving the warning has continued to violate the provisions of the Chapter or any regulation issued under this Chapter, the City Administrator may impose administrative fines as provided below in subsections (c), (d), and (e).

(c) Violation of this Chapter or any regulation issued under this Chapter shall be punishable by administrative fines in the amount of:

1. Up to $100.00 for the first violation;
2. Up to $250.00 for the second violation within a twelve-month period; and,
3. Up to $500 for the third and subsequent violations within a twelve-month period.

(d) Except as provided in subsection (c), setting forth the amount of administrative fines.

Administrative Code Chapter 100, “Procedures Governing the Imposition of Administrative Fines,” as may be amended from time to time, is hereby incorporated in its entirety and shall govern the imposition, enforcement, collection, and review of administrative citations issued by the City Administrator to enforce this Chapter or any regulation issued under this Chapter. Violation of this Chapter is not a misdemeanor, and the Board of Supervisors intends that the requirements of this Chapter be enforced only through administrative fines as provided in this Section.
(e) For purposes of this Chapter, each week that a business sells or offers to sell prescription
drugs to the public contrary to the provisions of this Chapter or any regulation issued under this
Chapter shall constitute a separate violation.

Section 2. General Provisions.

(a) Severability. If any section, subsection, sentence, clause, or phrase of this
Ordinance is for any reason held to be invalid or unconstitutional by a decision of any court of
competent jurisdiction, such decision shall not affect the validity of the remaining portions of
the Ordinance. The Board of Supervisors hereby declares that it would have passed this
Ordinance and each and every section, subsection, sentence, clause, or phrase not declared
invalid or unconstitutional without regard to whether any portion of this Ordinance would be
subsequently declared invalid or unconstitutional.

(b) No Conflict with State or Federal Law. Nothing in this ordinance shall be
interpreted or applied so as to create any requirement, power, or duty in conflict with any
federal or state law.

(c) Undertaking for the General Welfare. In adopting and implementing this
Ordinance, the City and County of San Francisco is assuming an undertaking only to promote
the general welfare. It is not assuming, nor is it imposing in its officers and employees, an
obligation for breach of which it is liable in money damages to any person who claims that
such breach proximately caused injury.

Supervisors Mirkarimi, Campos
BOARD OF SUPERVISORS
(d) **Environmental Findings.** The Planning Department has determined that the actions contemplated in this ordinance are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.). Said determination is on file with the Clerk of the Board of Supervisors in File No. 110025 and is incorporated herein by reference.

APPROVED AS TO FORM:
DENNIS J. HERRERA, City Attorney

By: THOMAS J. OWEN
Deputy City Attorney
Ordinance amending the San Francisco Environment Code by adding Sections 2250 through 2254, to require any business selling prescription drugs to the public to post display materials explaining how to safely and lawfully dispose of unused prescription drugs; and making environmental findings.

May 05, 2011 Public Safety Committee - AMENDED

May 05, 2011 Public Safety Committee - RECOMMENDED AS AMENDED

May 17, 2011 Board of Supervisors - PASSED ON FIRST READING
Ayes: 10 - Avalos, Chiu, Chu, Cohen, Elbernd, Farrell, Kim, Mar, Mirkarimi and Wiener
Excused: 1 - Campos

May 24, 2011 Board of Supervisors - FINALLY PASSED
Ayes: 11 - Avalos, Campos, Chiu, Chu, Cohen, Elbernd, Farrell, Kim, Mar, Mirkarimi and Wiener

I hereby certify that the foregoing Ordinance was FINALLY PASSED on 5/24/2011 by the Board of Supervisors of the City and County of San Francisco.

Angela Calvillo
Clerk of the Board

Mayor Edwin Lee
Date Approved
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San Luis Obispo County
Integrated Waste Management Authority
ORDINANCE NO. 2015-1

AN ORDINANCE ESTABLISHING A HOME-GENERATED UNWANTED PRESCRIPTION MEDICINE DISPOSAL PROGRAM

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

Section 1. General Provisions

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

(a) The purpose of this Ordinance is to have the IWMA, a joint powers agency established pursuant to California Government Code Section 6500 and empowered by its member jurisdictions to exercise the members' common powers to achieve the mandates imposed by the Integrated Waste Management Act of 1989 (AB 939) on a regional basis, enact a comprehensive and innovative system for the proper and legal management of prescription drug waste in San Luis Obispo County in accordance with applicable federal and state laws including the Secure and Responsible Drug Disposal Act of 2010 and the Disposal of Controlled Substances Final Rule issued on September 9, 2014.

(b) The purpose of this Ordinance is to enact a law that establishes a program that is convenient for consumers to return and ensure the safe and environmentally sound disposal of unwanted prescription medication.

(c) The purpose of this Ordinance is to enact a law that reduces the likelihood of abuse of prescription drugs by providing a free and convenient program for disposal of unwanted prescription drugs.

(d) The purpose of this Ordinance is to assure that the costs associated with the handling and disposal of prescription drugs are the responsibility of the producers and retailers of prescription drugs and not local governments or their service providers, state government, or taxpayers.

(e) The purpose of this Ordinance is to assure that manufacturers and retailers of prescription drugs, while working to achieve the goals and objectives of this Ordinance, should have the flexibility to partner with those private and nonprofit business enterprises that provide collection and processing services to develop and promote a safe and effective prescription drug waste management system.

(f) The purpose of this Ordinance is to provide for the safe and convenient collection and disposal of 100 percent of the unwanted prescription drugs in the IWMA Region.
Section 2. Definitions

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

(a) "Consumer" means a person who has lawfully obtained, and who possesses, a prescription drug for his own use or the use of a member of his household or for an animal owned by him or by a member of his household and who resides in the IWMA region.

(b) "Controlled Substance" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

(c) "Drugs" means: (i) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (ii) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) substances, other than food, intended to affect the structure or any function of the body of humans or other animals.

(d) "IWMA Region" means the geographic area that includes the unincorporated area of San Luis Obispo County, California and the seven incorporated cities within San Luis Obispo County.

(e) "Nonprescription drugs" means any drug that may be lawfully sold without a prescription.

(f) "Prescription drugs" means any drug that by federal or state law may be dispensed lawfully only by prescription, including controlled substances, scheduled II, III, IV and V.

(g) "Retail pharmacy" means any retail store which sells prescription drugs to a consumer.

Section 3. Prescription drug management

(a) By September 1, 2015, every retail pharmacy in the IWMA Region shall provide consumers with a mail back program and/or collection receptacle program to dispose of unwanted prescription drugs consistent with state and federal laws. The retail pharmacy shall not charge the consumer to use either the mail back program or collection receptacle program. The retail pharmacy shall have appropriate signage, prominently displayed within 5 feet of any entrance to the retail establishment and easily visible to the consumer, indicating that the retail pharmacy has a program for the management of unwanted prescription drugs.

(b) Mail back program. A retail pharmacy is required to provide prepaid and preaddressed mailing envelopes in which the consumer can place unwanted prescription drugs for shipment to a company that will dispose of them safely and legally.

(1) The retail pharmacy is required to offer a mail back envelope at the time of purchase of any prescription drug by a consumer. If the consumer wants a mail back envelope, one will be provided at that time at no cost to the consumer.

(2) The retail pharmacy is required to provide a mail back envelope to a consumer who had previously obtained prescription drugs from the retail pharmacy. The mail back envelope will be provided at no cost to the consumer.

(3) The retail pharmacy is required to only provide one envelope per month to a retail
customer.

(c) Collection receptacle program. The retail pharmacy is required to install a collection receptacle for use by consumers during the retail pharmacy’s normal hours of operation. Consumers shall be allowed to dispose of unwanted prescription drugs in the collection receptacle at no cost to the consumer. Consumers shall also be allowed to dispose of nonprescription drugs in the collection receptacle. Retail pharmacies shall routinely empty the collection receptacle so that it is not full.

Section 4. Enforcement

(a) The IWMA may enforce the provisions of this Ordinance through a civil action for civil penalties in the amounts established herein, and any other civil remedy, including prohibitory and mandatory injunctive relief, filed in the Superior Court for the County of San Luis Obispo to compel and enforce the provisions herein against any retailer within San Luis Obispo County who sells prescription drugs in violation of this Ordinance. In addition to any relief available to IWMA to enforce this Ordinance, the IWMA shall also be entitled to recover its reasonable attorneys’ fees and costs incurred in enforcing this Ordinance.

(b) For any violation of this Ordinance, the IWMA may sue to recover civil penalties in the amount of $1,000.00 per day for every day on which a violation exists. For purposes of calculating the civil penalties to be established hereunder, each day on which the retailer fails to comply with the requirements of this Ordinance, after having received a written notice of violation issued by the IWMA, shall constitute a separate offense.

(c) In addition to the civil relief available to the IWMA set forth above, any violation of this Ordinance shall also constitute a misdemeanor punishable under the laws of the State of California. The District Attorney, the County Counsel, or any City Attorney shall be authorized to enforce the provisions of this Ordinance within their respective jurisdictions. In the event of such criminal enforcement, the following criminal penalties apply to violations of this Ordinance:

1. Violation as Misdemeanor. Violations of the provisions of this Ordinance or failure to comply with any of its requirements shall constitute a misdemeanor.

2. The San Luis Obispo County Sheriff’s Department and/or any other police department or law enforcement agencies located within the IWMA’s jurisdiction may issue a Notice to Appear Citation for any misdemeanor pursuant to California Penal Code Section 853.6 for any violation of this Ordinance.

3. Penalty for Misdemeanor. Any retailer found to be in violation of any provision of this Ordinance, or who fails to comply with any of its requirements, shall upon conviction thereof be punished by imprisonment in the county jail for not more than six months, or be fined not more than one thousand dollars ($1,000.00), or by both. Each day such violation continues shall be considered a separate offense.

4. To the extent that the County of San Luis Obispo, the incorporated cities, and the districts within said County have adopted code enforcement ordinances applicable to their jurisdictions, this Ordinance shall be enforceable by said governmental entities under said ordinances as land-use or code-enforcement violations consistent with said ordinances.
Section 5. Conflict with State or Federal Law

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

Section 6. CEQA Findings

The IWMA has determined that the actions contemplated in this Ordinance are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.)

Section 7. Severance Clause

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

Section 8. Effect of Headings in Ordinance.

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

This Ordinance was introduced and the title thereof read at the regular meeting of the IWMA Board of Directors on November 12, 2014 and further reading was waived by a majority vote of those Directors present.

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

On a motion by Director Ashbaugh, seconded by Director Gibson, the foregoing Ordinance was passed and adopted by the Board of Directors of the San Luis Obispo County Integrated Waste Authority, this 11th day of March 2015, by the following vote:
AYES:  Ashbaugh, Blake, Brown, Compton, Gibson, Hamon, Headding, Hill, Lee, Lloyd, O’Malley

NOES: None

ABSENT: Arnold, Mecham

Original signed by

Tom O’Malley, President
San Luis Obispo County
Integrated Waste Management Authority

ATTEST:

Original signed by

Carolyn Goodrich, IWMA Board Secretary

ORDINANCE CODE PROVISION APPROVED
AS TO FORM AND CODIFICATION:

Original signed by

Raymond A. Biering, IWMA Counsel

Date: March 11, 2015
LOS ANGELES COUNTY PHARMACEUTICALS AND SHARPS

COLLECTION AND DISPOSAL STEWARDSHIP ORDINANCE

An ordinance amending Title 11 – Health and Safety of the Los Angeles County Code, relating to requirements for the collection and disposal of unwanted drugs and sharps.

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

Chapter 11._._ is hereby added as follows:

Chapter 11._._ – Stewardship Program for Collection and Disposal of Unwanted Covered Drugs and Unwanted Sharps.

11._._010 Title.

11._._015 Purpose

11._._020 Definitions.

11._._030 Stewardship Plans – Participation.

11._._040 Stewardship Plans – Components.

11._._050 Stewardship Plans – Collection of Covered Drugs and Sharps.

11._._060 Stewardship Plans – Disposal of Covered Drugs and Sharps.

11._._070 Stewardship Plans – Administrative and Operational Costs.

11._._080 Stewardship Plans – Reporting Requirements.

11._._090 Stewardship Plans – Identification of Responsible Stewards of Covered Drugs and Sharps.


11._._110 Stewardship Plans – Prior Approval for Change.

11._._120 Stewardship Plans – Enforcement and Penalties.

11._._130 Stewardship Plans – Regulations, Guidelines, and Reports.

11._._140 Plan Review and Annual Operation Fees.
11.010 TITLE.

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

11.015 PURPOSE.

The purpose of this Chapter is to establish a Pharmaceutical and Sharps Stewardship Program that: (1) allows for the safe, convenient and sustainable collection and disposal of unwanted Drugs and Sharps by County residents, 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 federal and state law by prescribing higher standards of sanitation, health and safety where not preempted by federal or state law. Whenever any technical words or phrases are not defined herein, but are defined under federal or state law, such definitions are incorporated into this Chapter and shall be deemed to apply as though set forth herein in full.

11.020 DEFINITIONS.
For purposes of this Chapter, the following definitions shall apply:

“Collection Site” shall mean a location where one or more receptacles are provided pursuant to a Stewardship Plan for County residents to safely and securely deposit Unwanted Covered Drugs and/or Unwanted Sharps.

“Collector” shall mean a Person who hosts one or more receptacles for the collection of Unwanted Covered Drugs and/or Unwanted Sharps pursuant to this Chapter.

“Contact Information” shall mean a business phone number, facsimile phone number, mailing address, and electronic mail address.

“Controlled Substances” for purposes of this Section shall mean any substance listed under the California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code Sections 812 and 813 or any successor legislation.

“County” shall mean the County of Los Angeles.

“Covered Drug” shall mean a Drug in any form, including a controlled substance, that is sold, offered for sale to, or otherwise distributed for use by, one or more consumers in the Service Area, including prescription, nonprescription, brand name, and generic. “Covered Drug” shall include controlled substances and, notwithstanding the previous sentence, 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 (Title 21 U.S.C. Sec. 355-1); and (5) Drugs that are biological products as defined by 21 C.F.R. 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.

“Department” shall mean the Department of Public Health.

“Director” shall mean the Director of the Department of Public Health or his or her
designee.

“Drug” shall mean: (1) any article recognized in the official United States
Pharmacopeia - National Formulary, the official homeopathic pharmacopoeia of the United
States or any supplement of the formulary or those pharmacopoeias as published by the U.S.
Pharmaceutical Convention and the Homeopathic Pharmacopoeia Convention of the United
States; (2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or
prevention of disease in humans or other animals; (3) any substance, other than food,
intended to affect the structure or any function of the body of humans or other animals; or (4)
any substance 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.

“FDA” shall mean the United States Food and Drug Administration.

“Hazardous Waste Disposal Facility” shall have the meaning set forth by the United
States Environmental Protection Agency under Title 40 Code of Federal Regulations, Parts
264 and 265, or any successor legislation.

“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.
"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.

"Mailer" shall mean a prepaid, preaddressed, tamper-resistant envelope or container used for mailing Unwanted Covered Drugs and/or Unwanted Sharps. Any Mailed used for Unwanted Sharps must be FDA-compliant.

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

"Participating City" shall mean an incorporated city within the County that adopts the requirements of this Chapter into its respective municipal code.

"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.

"Pharmaceutical" shall have the same meaning as Drug.

"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 prescriptions are dispensed.

"Potential Authorized Collector" shall mean any entity that is registered, or that may apply to register, with the U.S. Drug Enforcement Administration (DEA) for the collection of Drugs, such as a manufacturer, distributor, reverse distributor, narcotic treatment program, retail Pharmacy, or a hospital/clinic with an on-site Pharmacy.

"Repackager" shall mean a Person who owns or operates an establishment that repacks and/or relabels a product or package for further sale or distribution.

"Responsible Steward" shall mean:
(a) The Person who Manufactures or causes to be Manufactured a Covered Drug or Sharps; or

(b) If the Person described in (a) is beyond the County’s jurisdiction, the first Person who repackages or distributes the Covered Drug or Sharps in or into the County, including but not limited to a Wholesaler or Repackager; or

(c) If the Persons described in (a) and (b) are beyond the County’s jurisdiction, the first Person who sells or offers for sale the Covered Drug or Sharps in or into the County.

“Service Area” shall mean the unincorporated County and all Participating Cities.

“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 one or more consumers in the County and may include anything affixed to the instrument, such as a syringe.

“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.

“Stewardship Plan” or “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.

“Stewardship Program” or “Program” shall mean the County program described in this Chapter.
“Unincorporated Community” shall mean a community located within the
unincorporated area of the County, as identified by the County’s Chief Executive Officer on its
official website.

“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.

“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.

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

11. __.030 STEWARDSHIP PLANS – PARTICIPATION.

(a) Each Responsible Steward shall notify the Director in writing of the Responsible
Steward’s intent to operate or participate in a Stewardship Plan for the collection,
transportation, and disposal of the Covered Drug or Sharps, respectively, within six months of
the effective date of this Chapter or six months after the Covered Drug or Sharps are first sold
into or offered for sale in the County, whichever is later.

(b) Each Responsible Steward shall participate in such 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, on the
Responsible Steward’s behalf.

(c) Each Stewardship Plan must be approved by the Director before any collection of
Unwanted Covered Drugs and/or Unwanted Sharps may commence thereunder. Proposed
changes to an approved Plan shall be subject to the requirements set forth in Section 11.110.

(d) Each Responsible Steward operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization shall:

(1) Within six months of the effective date of this Chapter or six months after the Covered Drug or Sharps are first sold or offered for sale in or into 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 Contact Information. Said Contact Information shall be kept current at all times. Director shall be notified of any change in such Contact Information within ten (10) business days;

(2) Within six months of the effective date of this Chapter or six months after the Covered Drug or Sharps are 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 Collectors, and provide the Director with copies of all such notifications:

(A) All retail Pharmacies, hospitals/clinics with on-site Pharmacies, and other Potential Authorized Collectors;

(B) Persons other than Potential Authorized Collectors, such as retail establishments, that could potentially host Collection Sites for Sharps; and

(C) All law enforcement agencies in the County.

(3) Within nine months of the effective date of this Chapter or nine months after the Covered Drug or Sharps are first sold or offered for sale in or into the County, whichever is later, submit a proposed Stewardship Plan as described in Section 11.040 to the Director for review;
(4) Within three months of the Director’s approval of the Stewardship Plan, the
Stewardship Plan shall be implemented in accordance with this Chapter;

(5) At least every three 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 plan review fee in accordance with Section 11.__.140 of this Chapter. The Director shall
review updated Stewardship Plans using the process described in Section 11.__.100.

(e) 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.

(f) Should the Responsible Steward undergo any change in ownership or control, it
must notify the Director within 30 days of such change, and should ownership or control be
transferred to a company not conducting business in the County, the Responsible Steward
shall provide the name and Contact Information of the first Person who causes the Covered
Drug or Sharps to be brought in or into the County for repackaging, distribution, or sale.

(g) Each Responsible Steward, operating individually, jointly with other Responsible
Stewards, or through a Stewardship Organization, shall commence within thirty (30) calendar
days good faith negotiations with any Responsible Steward expressing an interest to
participate in its Stewardship Plan. For every Responsible Steward not accepted as a
participant in the 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.
(h) 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.

(i) 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 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 11.0.040 to the Director for review. The new Stewardship Plan shall be accompanied by the plan review fee in accordance with Section 11.0.140 of this Chapter. The Director shall review new Stewardship Plans using the process described in Section 11.0.100.

(j) Should a Responsible Steward, operating individually, jointly with other Responsible Stewards, or through a Stewardship Organization, become aware of any Covered Drug or Sharps being sold or offered for sale in or into 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.

(k) 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.__.030.

(l) The Director may audit the records of a Responsible Steward, group of Responsible
Stewards, or Stewardship Organization 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.__.040 STEWARDSHIP PLANS – COMPONENTS.

Each Stewardship Plan, which must be submitted and reviewed according to Section
11.__.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 either Manufactures
or purchases for repackaging, distribution, sale or offer of sale; and the name and Contact
Information of an individual authorized to be the official point of contact for each Responsible
Steward and 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.__.050. The description shall include but not be limited to a list of all
collection methods and participating Collectors; 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. __.030, and a list of all who expressed an interest in serving as Collectors in the Stewardship Plan;

(c) A description of the proposed handling and disposal system, including the name and Contact Information for each Collector, 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. __.050 and 11. __.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 Collector, each Person retained to transport the collected items, Hazardous Waste Disposal Facilities, and any other Person retained to implement any portion of the 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 United States Drug Enforcement Administration and the State of California Board of Pharmacy;

(e) A certification that any patient information appearing on Drug and Sharp packaging will be kept secure and promptly destroyed;
(f) A description of the public education and promotion strategy required in Section 11.030, including but not limited to a copy of instructions, signage, and promotional materials for residents, as well as instructions and signage, as may be needed, for Collectors, Persons retained to transport collected items, Hazardous Waste Disposal Facilities, and all other Persons implementing any portion of the Plan;

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

11.050 STEWARDSHIP PLANS – COLLECTION OF COVERED DRUGS AND SHARPS.

(a) This Chapter does not require any Person to serve as a Collector in a Stewardship Plan. A Person may offer to serve as a Collector 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 County 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 shall 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 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.

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

C. Sites per Supervisorial District: In no event shall there be fewer than 10 Collection Sites for Unwanted Covered Drugs or fewer than 10 Collection Sites for Unwanted Sharps in each County Supervisorial District;

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

(3) Be safe and secure, including requiring the prompt destruction of patient information on any and all packaging;

(4) Include a mechanism whereby Responsible Stewards of Sharps participating in the Plan 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;
(5) Provide FDA-compliant Sharps collection receptacles to any hosts of Collection Sites for Sharps. A Sharp may be refused for collection if it is not placed within a FDA-compliant Sharps container designed for the safe handling of Sharps;

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

(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 phone number and website. Assistance through the toll-free phone 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 Collector 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 24-hour, toll-free phone number and website for the Stewardship Plan.
Said toll-free phone 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 24 hours of notice of same.

11.060 STEWARDSHIP PLANS – DISPOSAL OF COVERED DRUGS AND SHARPS.

(a) Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted Hazardous Waste Disposal Facility.

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

(c) The Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under Title 40 Code of Federal Regulations, Parts 60 and 62, or any successor legislation if the Director deems the use of a Hazardous Waste Disposal Facility described under subsection (a) to be infeasible for the Stewardship Plan based on cost, logistics, or other considerations.

(d) 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) through (c), 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,
bioaccumulative, and toxic pollution; and (4) overall impact on the environment and human
health.

11.__070 STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS.
   (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 the
       costs of any Stewardship Plan, nor may they charge a specific point-of-sale collection fee at
       the time that Covered Drugs and/or Sharps are collected.
   (c) Responsible Stewards are not required to pay for costs of staff time at Collection
       Sites provided by Collectors volunteering to participate in a Stewardship Plan.

11.__080 STEWARDSHIP PLANS – REPORTING REQUIREMENTS.
   (a) Within six 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 their plan’s activities during the previous reporting period.
       The report must include:
       (1) A list of Responsible Stewards participating in the Stewardship Plan;
       (2) The amount, by weight, of Covered Drugs and the amount, by weight, of
           Sharps collected, 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 Sharps containers provided to County residents and the method and location of distribution;

(6) The dates and locations of collection events held;

(7) The transporters used and the disposal facility or facilities used for all Covered Drugs and Sharps;

(8) Whether any safety or security problems occurred during collection, transportation or disposal of Unwanted Covered Drugs and Unwanted Sharps during the reporting period and, if so, what changes have 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 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; and

(12) The total expenditures of the Stewardship Plan during the reporting period.

(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 Plan must be
provided to the Department within 30 days of the change.

(c) The Director shall make reports submitted under this Chapter available to the
public.

(d) For the purposes of this Section 11.__.080, “reporting period” means the period
from January 1 through December 31 of the same calendar year, unless otherwise specified
by the Responsible Steward, group of Responsible Stewards, and Stewardship Organization
to the Director.

11.__.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 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, 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.__.100 STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS.

(a) By nine 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 plan review fee in
accordance with Section 11.__.140 of this Chapter. The Director may upon request provide

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information, suggestions, and technical assistance about the requirements of this Chapter to
assist with the development of a proposed Stewardship Plan.

(b) The Director shall review the proposed Stewardship Plan and determine whether it
meets the requirements of this Chapter.

(c) After the review under subsection (b) and within 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 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
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.

(f) The Department, at the sole discretion of the Director, may establish a technical
advisory committee to assist the Department in reviewing Stewardship Plans or otherwise
assisting in the implementation of this ordinance.

(g) The Director shall make all proposed and approved Stewardship Plans submitted
under this Chapter available to the public for review and comment.

11. __.110 STEWARDSHIP PLANS – PRIOR APPROVAL FOR CHANGE.
(a) Proposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to, changes to participating Responsible Stewards, Collectors, collection methods, Hazardous Waste Disposal Facilities, how to achieve the service convenience goal, policies and procedures for handling Unwanted Covered Drugs and Unwanted Sharps, or education and promotion methods, must be approved in writing by the Director before the changes are implemented.

(b) A Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall submit to the Director any proposed change to a Stewardship Plan in writing at least 30 days before the change is scheduled to take effect. Any such submittal shall be accompanied by the review fee in accordance with Section 11.140 of this Chapter.

(c) A Responsible Steward, group of Responsible Stewards, or Stewardship Organization shall notify the Director at least 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 11.050 of this Chapter, or other changes that do not substantively alter 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 plan operations.

11.120 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 send a written
warning, as well as a copy of this Chapter and any regulations adopted pursuant to this
Chapter, to the Person or Persons who violated it. The Person or Persons shall have 45 days
after the date of mailing of the warning to come into compliance and correct all violations.

(c) If the Person or Persons fail to come into compliance or correct all violations, the
Director may impose administrative fines for violations of this Chapter or of any regulation
adopted pursuant to this Chapter, Los Angeles County Code, Title 1, Chapter 1.25, as
amended, is hereby incorporated in its entirety and shall govern the imposition, enforcement,
collection, and review of administrative citations issued to enforce this Chapter or any rule or
regulation adopted pursuant to this Chapter. Each day 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. The court shall award reasonable attorney’s
fees and costs to County Counsel, the District Attorney, and any applicable City Attorney.

(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) for each 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. Each day in which the violation continues
shall constitute a separate violation. Civil penalties shall not be assessed pursuant to this
subsection (f) for the same violations for which the Director assessed an administrative penalty pursuant to subsection (c).

(g) In determining the appropriate penalties, the court or the Director shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

(h) The Director may exercise reasonable discretion to waive strict compliance with the requirements of this Chapter that apply to Responsible Stewards in order to achieve the objectives of this Chapter.

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

(c) The Director shall report biennially to the Board of Supervisors concerning the status of all Stewardship Plans and recommendations for changes to this Chapter. The biennial report may also include a summary of available data on indicators and trends of pharmaceutical pollution, abuse, poisonings and overdoses from prescription and nonprescription drugs and a review of comprehensive prevention strategies to reduce risks of drug abuse, overdoses, and preventable poisonings. The first report shall be due two years from the effective date of this Chapter.
11.140 PLAN REVIEW AND ANNUAL OPERATION FEES.

(a) Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization participating in a Stewardship Plan shall pay to the Director plan review fees to be established under subsection (d) for the performance of certain functions as applicable, including but not limited to:

(1) Review of a proposed Stewardship Plan;
(2) Review of a revised, proposed Stewardship Plan;
(3) Review of changes to an approved Stewardship Plan;
(4) Review of an updated Stewardship Plan at least every three years as required under Section 11.030 of this Chapter;
(5) Review of any petition for approval to use alternative final disposal technologies under Section 11.060 of this Chapter; and
(6) Environmental review of a Stewardship Plan.

(b) In addition to plan review fees, each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall pay to the Director annual operating fees to be established under subsection (d) of this Section 11.140.

(c) A Stewardship Organization may remit the plan review fee on behalf of its participating Responsible Stewards.

(d) As soon as practicable, the Director shall propose to the Board of Supervisors a schedule of fees charged to each Responsible Steward, group of Responsible Stewards, and Stewardship Organization to cover costs of administering and enforcing this Chapter. The Director shall set the fees to recover but not exceed actual and reasonable costs to the County. The Board of Supervisors must approve the schedule of fees after a public hearing.

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for it to become effective. The Auditor-Controller shall confirm that the fees set by the Director
do not exceed the actual and reasonable costs to the County.

11. __.150 INFORMATION REQUIRED AT POINT OF SALE.

(a) Any Person selling or offering for sale Covered Drugs or Sharps to the public 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 the Person’s place of business in a
location visible to the public, if applicable, and adjacent to the area where prescription drugs
are dispensed. Mail-order Pharmacies and on-line Pharmacies selling Covered Drugs or
Sharps to County residents shall provide such materials with the order.

(b) The Director may, in his or her discretion, authorize a business 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. __.160 STEWARDSHIP PLANS – PROMOTION, OUTREACH AND EDUCATION.

(a) Each Responsible Steward, group of Responsible Stewards, or Stewardship
Organization shall develop a system of promotion, outreach, and public education to be
included in the Stewardship Plan. Specifically, each Responsible Steward, group of
Responsible Stewards, or Stewardship Organization shall:
(1) Promote the collection options offered under its Stewardship Plan to residents and the health care community. Promotion shall include outreach and educational materials:

   A. Promoting safe storage of Drugs and Sharps by residents during the treatment period;
   B. Describing where and how to return Unwanted Covered Drugs and Unwanted Sharps under the Stewardship Plan;
   C. Expressly discouraging stockpiling of Unwanted Covered Drugs and Unwanted Sharps; and
   D. Expressly discouraging disposal of said items in the trash or through a plumbing or septic system.

   These materials must be provided to Pharmacies, retailers of Covered Drugs and Sharps, health care practitioners, health care facilities, veterinary facilities, and other prescribers for their own education as well as for dissemination to residents;

(2) Use Plain language and explanatory images so as to be readily understandable by all residents, including individuals with limited English proficiency;

(3) Work with Collectors participating in Stewardship Plans to develop clear, standardized instructions, signage and promotional materials for residents on the use of collection receptacles and a readily-recognizable, consistent design of collection receptacles;

(4) Establish a 24-hour, toll-free phone number and single website where information can be obtained regarding collection options and current locations of Collection Sites;

(5) Within six 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 plans. Survey questions shall include but not be limited to questions designed to: (1) assess the awareness of the County's Stewardship Program, the Stewardship Plans in operation, and the location of all available Collection Sites; (2) assess to what extent Collection Sites and other collection methods are safe, convenient, easy to use, and utilized by residents; and (3) assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription Drugs used in the home. Draft survey questions shall be submitted to the Director for review and comment at least 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 11.160 within 90 days following the end of the survey period. Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall ensure the privacy of all survey respondents.

(b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this Section 11.160 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.

11.170 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, an obligation for breach of which it is liable in money damages to any Person who
claims that such breach proximately caused injury.

11. __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 Collector, each 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 any agency or department
to impose any duties or obligations in conflict with limitations on municipal authority
established by State or federal law at the time such agency or department 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. __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.
October 14, 2014

Dear __________________:

Over the last two years, I have worked with numerous stakeholders to develop legislation that would create a convenient and environmentally responsible home-generated prescription drug disposal program. These efforts included my hosting several large stakeholder meetings, working with legislative consultants, and meeting with hundreds of individuals with an interest in the safe handling and disposal of unused medications. During that time, I introduced two bills, SB 727 (2013) and SB 1014 (2014) in response to the feedback I received to help decrease the supply of unused prescription drugs in homes across California. Due to the current legislative climate, moving forward with these programs was unsuccessful.

I am now respectfully requesting your participation and help to move this critical issue forward in our state. Adopting a county ordinance similar to Alameda County’s Safe Drug Disposal ordinance will help California residents prevent prescription drug abuse, address their disposal needs now, and increase support for a statewide solution.

The Alameda County Board of Supervisors unanimously adopted the first Safe Medication Disposal Ordinance in the country in July 2012. Pharmaceutical manufacturers with medications being sold or distributed in Alameda County must participate in and fund a program to collect and dispose of unwanted drugs. The ordinance was challenged by Pharmaceutical Research and Manufacturers of America, Generic Pharmaceutical Association, and Biotechnology Industry Organization on the basis that the ordinance violates the dormant Commerce Clause for interstate commerce and discriminates against out-of-county producers. In August 2013, the U.S. District Court upheld the ordinance, as did the Ninth U.S. Circuit Court of Appeals in September 2014.

Alameda County’s ordinance may be found here:

I encourage you to consider introducing a similar ordinance in your county to demonstrate your support for, and commitment to, addressing this problem. A preponderance of evidence points to the need for action:
October 14, 2014
Page 2

- The National Drug Control Strategy of 2014 lists providing safe medicine take-back as one of four key interventions to prevent prescription drug abuse.
- In October 2013, the DEA’s seventh National Take-Back Day collected 324 tons of expired and unwanted medications across the nation. Since the inception of National Take-Back Day in 2010, it has resulted in the disposal of more than 3.4 million pounds of unused medications.
- In 2010, CalRecycle identified 297 take-back programs in California including one-time take-back events, continuous take-back programs, and mail-back programs. The majority of these programs are funded and run by local governments.
- 70% of Americans are taking at least one prescription medication.
- Studies estimate between 10 – 33% of medications go unused.
- Poisoning is one of the fastest rising causes of accidental death among older adults, particularly from overdoses of prescription drugs and over-the-counter medications.
- A 2013 study by The Partnership at Drugfree.org found that one in four teens had intentionally misused a prescription drug in their lifetime — a 33% increase from five years ago.
- According to the National Institute on Drug Abuse, accidental overdose deaths from prescription opiates have quadrupled since 1999 and now outnumber those from heroin and cocaine combined.
- Flushing expired or unused medications down the toilet can add to the pharmaceuticals in our streams and drinking water and is extremely costly, if not impossible, to eradicate.

Until a cohesive statewide strategy is established, the most effective way to help prevent the risk of accidental poisoning and abuse of unused medications in your county is to increase disposal options through the adoption of an ordinance. I hope you will give this important public safety and environmental issue your most serious consideration.

Sincerely,

HANNAH-BETH JACKSON
State Senator, 19th District
XI. Maps of San Joaquin County Pharmacies with Active Board of Pharmacy Registrations

Figure 1.3 Pictured: City of Stockton BoP Registered Pharmacies
Figure 1.4 Pictured: City of Lodi BoP Registered Pharmacies, 12-15-2015
Figure 1.5 Pictured: Cities of Manteca BoP Registered Pharmacies, 12-15-2015
Figure 1.6 Pictured: City of Tracy BoP Registered Pharmacies, 12-15-2015
XII. Stakeholders List

Below is a list of organizations in the City of Stockton and San Joaquin County that are potential stakeholders the City and County could coordinate with to provide education and outreach for proper disposal of medications:

- University of the Pacific School of Pharmacy & Health Sciences
- Greater Stockton Chamber of Commerce, and Statewide Asian Chamber of Commerce
- San Joaquin County and City of Stockton governments, City and County utilities, public health and law enforcement agencies
- San Joaquin County General Hospital and St. Joseph’s Medical Center
- SWOOCH (“Serving With Other Organizations to Change Humanity”), a local community-service based organization that encourages youth to become involved in their communities.
- Waste haulers and disposal companies, including Republic Services, Waste Management and Barnett Medical Services (medical waste transporter).
- The San Joaquin County Government’s Substance Abuse Services’ Prevention Services offers three programs designed for county’s youth. These are Friday Night Live, Communities Taking Charge, and Students in Prevention. The website additionally lists the following Prevention Intervention Programs: Building Awareness Through Support (BATS), Environmental Prevention Project, Live Youth Programs (Friday Night Live/Club Live/Friday Night Live Kids) and Students In Prevention. Our early intervention and treatment programs include: Adolescent Intervention Program, CROSSROADS Adolescent Program, Family Assistance Teams, Juvenile Justice Center CAMP and Kids Alcohol/Drug Alternative Program (KADAP).

Below is the list of medical practitioners’ professional organizations and their main contacts that are potential stakeholders the City and County could coordinate with to provide education and outreach for proper disposal of medications:

- San Joaquin Pharmacists Association: http://www.sjpharx.com/ - part of California Pharmacists Association
  - President: Edward Sherman sjpharx@gmail.com
- Central Valley Pharmacists Association: http://www.sjpharx.com/ - part of California Pharmacists Association
  - President: Anna Vu cvpha@yahoo.com
- San Joaquin Medical Society: Part of California Medical Association
  - Lisa Richmond, Executive Director - Lisa@sjcms.org
  - Phone (209) 952-5299
- California Emergency Nurses Association- Mid-Valley Chapter: http://www.californiaena.org/mid-valley-chapter/
  - Janet Williams, Chapter President jrae00@sbcglobal.net
  - 559-908-7533
- Preventative Cardiovascular Nurses Association- California Central Valley Chapter

45 http://www.co.san-joaquin.ca.us/OSA/Programs/Prevention_Services/default.htm
46 http://www.co.san-joaquin.ca.us/OSA/Programs/prevention/default.htm
http://pcna.net/member-center/chapters/pcna-chapters/california-central-valley-chapter
  o President: Kim Newlin, RN, CNS, NP-C, FPCNA knewlinpcna@surewest.net
  o Phone: (916) 797-2309

• National Association of Hispanic Nurses - San Joaquin Valley Chapter
  https://www.nahnnet.org/NAHNCalifornia.html#SanJoaquin
    o Chapter President: Pilar De La Cruz-Reyes, MSN, RN
• American Nephrology Nurse’s Association- San Joaquin Valley Chapter 532
    o President/ President elect : Marycela Tamaz marycela@bak_rr.com
• Association of Perioperative Registered Nurses- Chapter 0502 Central San Joaquin Valley
  http://www.csjvaorn.com/links.html#local
    o President: Kris Scaffidi, RN
• San Joaquin Valley Chapter (SJV) of the National Association of Pediatric Nurse Practitioners
  (NAPNAP)
    o http://community.napnap.org/casanjoaquin/home
• American Association of Critical Care Nurses (AACN), Central San Joaquin Valley Chapter
    o President: Carole Cooper https://aacncvc.nursingnetwork.com/contact
• American Academy of Pediatrics, California – Chapter 1, Northern California AAPCA1.ORG
    o Executive Director: Beverly Busher cc1aapoffice@gmail.com
      o 415-479-9200
• California Society of Health-System Pharmacists- Central Valley http://www.cvshp.cshp.org/
    o President: Jennifer Cashman jennifer.m.cashman@kp.org
• Additional Resource: http://www.valleychildrens.org/PressRoom/Publications/NursingExcellence8/Pages/LeadershipInProfessionalNursingOrg.aspx