



Alameda County Safe Medication Disposal Initiative Assessment

2007-2014

SUBMITTED TO:

Alameda County Health Care Services Agency

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Teleosis Institute completed this study under contract with the
Alameda County Health Care Services Agency (HCSA)
with services that conform to the Measure A Ordinance.

Teleosis Institute maintained full editorial control
and the conclusions expressed here are those of the author.

TABLE OF CONTENTS

Executive Summary	5
Introduction	7
Initiative Outline	9
History.....	9
• Bringing Diverse Stakeholders Together – Linda Pratt.....	9
• Take-Back Events Or Take-Back Sites – Bill Pollock.....	11
The Alameda County Safe Drug Disposal Ordinance And Regulations	12
• We Will Continue Working To Make This Successful – Supervisor Nat Miley.....	14
Agency Oversight	14
Location Of Take-back Sites.....	15
Take-Back Collection System and Waste Collections.....	17
Waste Disposal Services.....	18
• What Happens To The Medicines That Are Returned – Larry McCarty.....	18
Results	19
Total Collected Waste	19
• I Thought It Was A Good Fit For Our Hospital – Christine Graham.....	21
Costs Of Disposal	22
Educational Outreach	22
• Getting It Out There Is The Next Step – Mike Auer	24
Who Uses The Program	24
Characteristics Of Users	25
Number Of Persons Represented By The Returned Medicine	27
Characteristics Of The Collection Data	28
Assessment and Recommendations	30
Agency Oversight	30
Location And Access.....	31
Costs of Disposal.....	32
Educational Outreach.....	32
Program Users: Socio-Demographics.....	33
• I Consider It A Success – Liz Jimenez.....	34
Next Steps	34
• Nobody Would Have Taken This On At The State Level – Heidi Sanborn	35
Conclusion	36
Appendices	
1. Agencies Operating Take-Back Sites	37
2. Take-Back Sites With Contact Information	39
3. Waste Disposal Services Companies.....	42
4. Websites and Promotion.....	42
5. Alameda County Safe Drug Disposal Ordinance	43
6. Alameda County Safe Drug Disposal Regulations	60
7. Alameda County Safe Drug Disposal Fee Schedule And Cost Recovery.....	80
8. Survey Questions	81

LIST OF TABLES

TABLE 1.	Take-Back Sites in Operation.....	12
TABLE 2.	Types Of Agencies With Fiscal Oversight	14
TABLE 3.	Take-Back Site Locations By Type	16
TABLE 4.	Total Medication Collected: 2009-2013.....	19
TABLE 5.	Total Medication Collected: 2013	20
TABLE 6.	Sites With Largest Collection By Weight	20
TABLE 7.	Sites With Smallest Collection By Weight	20
TABLE 8.	Costs Of Disposal.....	22
TABLE 9.	Age Of Respondent	26
TABLE 10.	Gender Of Respondents	26
TABLE 11.	Annual Household Income Of Respondents	26
TABLE 12.	Health Insurance Status Of Respondents	26
TABLE 13.	Number Of Persons Represented By Medicine Returned.....	27
TABLE 14.	Number Of Persons in Household Of Respondents	27
TABLE 15.	Percentage Returning Medication For A Deceased Person	28
TABLE 16.	Respondents By Site.....	28
TABLE 17.	Zip Codes Represented By Respondents.....	29

EXECUTIVE SUMMARY

The Alameda County Safe Medication Disposal Initiative was founded in response to a growing need for preventative strategies that address substance abuse in seniors citizens in 2007. Focus groups, organized by Community Prevention of Alcohol & Drug Related Program (COMMPRE), revealed that a leading issue is the challenge of the mix of prescription drugs and alcohol. A workgroup was established devoted to preventative public health solutions. These entailed access to safe medication disposal sites and a sustainable funding mechanism. The Safe MEDS Workgroup brought together over 30 diverse stakeholders to establish and implement program goals. This report summarizes the work from 2007-2014 on this initiative. Also included are an assessment of the results and recommendations for ongoing improvement.

In 2009, once the Alameda County Safe Medication Workgroup (Safe MEDS Workgroup) clarified the emergence of safe medicine disposal as the primary issue, the workgroup then turned to the task of identifying locations for take-back sites and coordinating a countywide effort. At that time, only 10 sites were operating within the Safe MEDS Workgroup jurisdiction. As of 2014, 31 take-back sites are currently in operation in the county, fiscally overseen by 11 local agencies. These take-back sites include pharmacies, household hazardous waste centers, medical clinics, hospitals, senior centers, recycling centers, fire stations, police stations, office buildings, and a public works center. Six medical waste disposal companies are responsible for collecting the medicines accumulated in the take-back bins and safely transporting this waste for disposal in approved incinerators.

In terms of total volume of medicines collected and disposed, in 2009 just 473 pounds were reported from one site. By 2013, the most recent year accounted for, 12,564 pounds were collected and disposed, with an average of 449 pounds per site. Since not all sites report total pounds collected, this average weight per site was used to extrapolate the total collection weight, 13,919 pounds for the program in 2013. The largest collection sites are the Alameda County Sheriff's Station (1100 pounds), Eden Medical Center (1036 pounds), Washington Hospital (960 pounds) and Ted's Pharmacy (936 pounds). The sites reporting the smallest weight collected were the City of San Leandro Public Works (56 lbs) and Medical Arts Pharmacy (169 lbs). Total costs of disposal grew annually as larger accumulations of medicine were collected. In 2013, the extrapolated costs of disposal are \$27,838, with an average costs per pound of \$2.00, down from \$2.51 per pound in 2009.

Educational outreach was assessed through a survey and follow-up phone calls. As more sites opened, program operators provided consumers with announcements and direct mailing outreach. On-going promotion relies heavily on website listings with occasional annual notification in newsletters inserted in monthly bills mailed to local residents.

In an effort to assess who is using the program, a voluntary survey was completed by site users. With 62 responses to the survey received from nine sites, the take-back participants identified by age as this: 20% aged 26 and 40, 40% aged 41 to 65, and 40% over 65. 65% of respondents were women, 22% male and 13% declined to identify their gender. Household annual income was reported as 28% earned under \$30,000; 21% earned income between \$31,000 and \$50,000; 4% reported earning an annual household income between \$51,000 and \$70,000; 28% earned between \$71,000 and \$105,000; and 19% of users earned an annual income above \$105,000. 98% of respondents currently have health insurance.

Another survey result indicated how many persons are represented in relations to the medicine delivered in a single return. 56% of the respondents were returning medicine for only one person; 27% were returning medicine for two people; 15% were returning for three persons; and 7% were returning for four or more than four persons. The number of persons in the household returning medicine was as follows: 24% with a single person household; 29% for two persons household; 8% have three persons in the household; and 10% have four members in their household. The percentage of respondents returning for a deceased person was 23%.

Other program deliverables included two educational conference events, one in 2011 and another in 2013. In 2012, the Alameda County Safe Medicine Disposal Ordinance was adopted by the Alameda County Board of Supervisors, which became law in May 2014. While a legal challenge is pending in the United States Court of Appeals 9th Circuit, currently approximately 180 pharmaceutical manufacturers have adopted the newly formed Pharmaceutical Product Stewardship Work Group (PPSWG) as the agency responsible for working with the Alameda County Environmental Health Department to create and implement a stewardship plan that complies with the regulatory framework developed for the Alameda County Safe Medicine Disposal Ordinance.

The overall assessment offers the following of the key insights and recommendations:

- Establishing one centralized agency to oversee a countywide program would minimize operational overlap and thus improve collection efficiency.
- With roughly 51% of the county citizens within close proximity to a take-back site, new sites are necessary for residents that lack easy access to take-back sites.
- Establishing new sites in larger medical institutions, such as hospitals, would likely provide the most efficient and effective results.
- Educating pharmacists would likely improve collection rates in pharmacies and educating health executives, health professionals in primary care and end-of-life caregivers will likely improve program outcomes.
- Centralizing management would simplify the waste collection system and drive cost of disposal down.

In keeping with on-going transition in national regulatory agencies, including the United States Drug Enforcement Agency and the United States Environmental Protection Agency, there will likely be modifications to the current design and implementation of the Alameda County Safe Medicine Disposal Program. Whether the Alameda County Safe Medicine Disposal Ordinance is upheld or overturned, it is likely that the results of total medicine collected and safely disposed will continue to climb. While great progress now shows in the fact that roughly 50% of citizens of the county live in close proximity to a take-back location, continued development of new take-back locations is necessary, to continue this welcome trend toward increased collection quantities of unused and unwanted household pharmaceutical waste. Costs of disposal too will likely continue to trend downward.

In summary, overall, the Alameda County Safe Medication Disposal Initiative and the Safe MEDS Workgroup together have successfully brought about an innovative public health service that continues to remove unwanted medicine waste from households with the benefit of reducing accumulations of unused medicines in homes throughout the county. This initiative, program, and ordinance serves as a model for grass-root efforts to further develop public health policy in other municipalities.

INTRODUCTION

The Alameda County Safe Medication Disposal Initiative involves a diverse group of individuals committed to reducing prescription drug misuse in seniors and youth by assuring that all citizens have access to a safe disposal system for unused medicines. Over a period of seven years, the Alameda County Safe Medicine Disposal Workgroup (Safe MEDS Workgroup) focused on providing a sustainable solution to the challenges of creating safe medication disposal systems for unused household medicine.

Previously the Bay Area Pollution Prevention Group, a consortium of environmental professionals devoted to keeping the water of the San Francisco Bay Area free from contamination, had been working to reduce household pharmaceutical waste from entering surface and ground water. As the Safe MEDS Workgroup emerged, it became clear that public health professionals and policy professionals would need to work together with environmental professionals to develop a program for educating the public on the need for and the value of creating a functional waste disposal system for managing household pharmaceutical waste. These different stakeholders came together in this workgroup.

While often considered a single identifiable program in conventional terms, the Alameda County Safe Medication Disposal Initiative is in reality a loosely knit collection of public, civic and private stakeholders who worked towards providing a comprehensive service or program. The Safe MEDS Workgroup provided space for agencies and organizations to meet, discuss and coordinate collection efforts. Under the leadership of Supervisor Nat Miley, the Safe MEDS Workgroup also coordinated the ground activities and advocacy for legislative and public policy that forwarded the goal of safe medicine disposal. The team has seen over fifty participants, representing over thirty organizations, come and go over roughly six years of strategic planning, mapping and growing the initiative into a program.

As of May 1st 2014, the Alameda County Safe Drug Disposal Ordinance and the associated Alameda County Environmental Health Department's regulations have officially come into effect. What this means for the Alameda County Program is uncertain, but in terms of the initiative, the workgroup's goals are in place to be continued.

The assumption is that the current program will evolve into a 2nd iteration, in which an independent product stewardship organization working with the Alameda County Environmental Health Department, will manage a more comprehensive program throughout the county. This new, non-governmental organization will provide fiscal leadership and the oversight to operate the program effectively. This should translate into refined program goals, improved growth rates and target outcomes, as well as the fiscal commitment that supports growing and maintaining the infrastructure necessary for operations well into the future. Educational outreach will likely also be clarified and updated for greater effectiveness.

It is within this backdrop that this report is presented. To date there has been little if any *assessment* of the initiative's effectiveness or effect. This was unfortunately not a priority for the Safe MEDS Workgroup and there has not been a single identifiable person or organization to perform this task. Given the transition, the new organization taking over this initiative will find this report poignant and helpful in defining how to proceed. Yet there are many other stakeholders who might also find this assessment useful. Alameda County will be the first county in the United States to have a safe medicine disposal program using a product stewardship model. As a model program, others are paying attention

to this initiative. Policy advocates in other counties and states throughout the United States will find this report of value as a measure of change, an assessment of scale (how small the numbers really are compared to how big the situation really is), and as an evaluation of what could be improved.

Another consideration taken by this report is the reality that without an assessment, there will be little if any way of knowing how the initiative evolved into policy. To citizens of Alameda, new guidelines for safe medicine disposal simply turn up as a notice in a utility bill, a link on a website that says “bring back your meds” to the local hospital or pharmacy nearby, or a sign on a green mailbox that appears in a pharmacy letting one know how to place pills inside. Should it matter how we got here? Given the continuous challenges in our ability to care for one another and our environment, this story is just a small episode for the larger changes in public and environmental health policy, but one that is the beginning of what may turn out to be a change in how we do business in the future. A look at the history of soda and beer bottle returns, smokefree restaurants and airplanes, and most recently plastic bag bans come to mind. These changes in human social behavior started in a very small way. This report captures some of this evolution for future use.

What follows in the initiative outline of this report is a brief history of the initiative, a survey of which agencies in fact operate the programs, an assessment and discussion of the take-back locations, the systems used for collecting wastes, and finally a discussion of waste disposal services, the regulated system that takes care of the collected waste once picked up from the take-back bin.

The next section is the research section, which reviews the overall results of waste collection over the five years this data has been collected, including pounds collected and costs of disposal. A brief review of educational outreach is followed by the results of a survey of users of the program completed this past February through April of 2014 at nine take-back sites.

The report continues with an assessment of program results with recommendations about lessons learned. A section on next steps offers a very current update on what is emerging. While this document is in no way comprehensive, it is the author’s intention to provide relevant data for a variety of stakeholders that have worked tirelessly to support and see the project through its entirety.

This report does not contain the evidence for the need and reason for drug disposal systems pertaining to unwanted household drugs. Over the seven years of the Safe Medication Disposal Initiative, countless hours have been devoted to revealing the evidence for the public health and environmental challenges of unwanted medicine. Briefly, the evidence suggests that a) the elderly and the very young are at risk for accidental poisoning due to significant accumulations of medications in home and improper or careless disposal of prescription drugs; b) groundwater and drinking water are currently contaminated with very low concentrations of pharmaceuticals; c) teenagers are at increased risk of prescription drug abuse. With these in mind, providing a safe, reliable, cost-effective means for reducing the accumulation of unused and unwanted medications became the focus of the work reviewed in this report.

INITIATIVE OUTLINE

History

Beginning in 2007 with funding from the Alameda County Behavioral Health Care, the Community Prevention of Alcohol & Drug Related Program (COMMPRE) operated by Horizon Services, Inc. initiated focus groups in an effort to identify essential substance abuse issues for older adults. These focus groups identified alcohol and prescription drugs as the most pressing issue, and the challenges of mixing the two were surprisingly significant for seniors. Emerging from these focus groups was the initiation of a workgroup devoted to appraising and implementing policy in response to the growing need for public health programs addressing prescription drug issues for seniors. Under the direction of Linda Pratt of COMMPRE, workgroup meetings began with the goal of bringing together a diverse group of stakeholders to tackle this problem.

BRINGING DIVERSE STAKEHOLDERS TOGETHER

Linda Pratt

Alameda County Safe Medicine Disposal Workgroup Facilitator

"I've been really heavily involved in coalition work over the last 10 years and established two drug-free community coalitions, the only ones in Alameda County. Both of them are based on the methodology of having a minimum of 12 diverse sectors in the coalition. So that's what is so exciting about this coalition, because, as a preventionist, I've never worked next to waste collection, water people, and waste management. They have really different perspectives — and they're not used to partnering with us. So I think it's a really effective way of moving community change efforts.

"You just never know what is going to resonate or be important to emphasize when you're working with legislators. I think for a while we got away from drug prevention and got more into the environmental effects. But now we've come back more to the science around the drug and alcohol connection. That's why it's so important to support each other. We're much more powerful together than on our own. When we started doing the Safe Medication Disposal Initiative, we had to bring in Alameda County Household Hazardous Waste, Teleosis Institute, the sanitary districts, and all these other new partners, in order to fulfill that implementation strategy. I see this as an implementation strategy leading to policy."

Over the course of five years, at least 30 different organizations and agencies participated in the Safe Meds Workgroup. They include: Castro Valley Community Action Network, United Seniors of Alameda County & Oakland, Alameda County Hazardous Waste, Cherryland Community Association, Davis Street Family Resources Center, County Counsel, Senior Injury Prevention Partnership, Lifelong Medical Care, Teleosis Institute, Alameda County Public Health, County Hepatitis B Free Campaign, Union Sanitary District, Eden Hospital, East Bay Municipal Utility District, California Product Stewardship Council, Alameda County Environmental Health, Supervisor Nat Miley's office, and Supervisor Alice Bitker's Office. This group, which eventually took the title *Alameda County Safe Medication Disposal Workgroup*, continues to meet monthly, hosted by Supervisor Nat Miley. He first became aware of the problem by participating in one of the initial focus groups in 2007.

With health promotion and policy as the emphasis of the group, assembling interested parties around prescription drug removal became center stage. Professionals working with seniors in the public health sector felt that the misuse and abuse of prescription drugs was a significant problem and that seniors were becoming 'accidental addicts.' The workgroup found that drug disposal, or rather the lack of the ability to dispose of medicine, posed a significant barrier to the reduction of the accumulation for these potentially harmful substances. Seniors in the United States are typically taking over seven different medications daily. The average 75-year-old will receive 15 prescriptions annually, assuring that it is common for seniors to have prescription and over-the-counter (OTC) drugs piling up in their homes. The workgroup felt that securing a method for safe and accessible disposal was a necessary and achievable first step towards mitigating the problem.

Safe medication disposal was not new to the San Francisco Bay Area. The Bay Area Pollution Prevention Group had identified the issue as early as 2003, hosting take-back events successfully in 2006¹. These initial programs were event-based, a cadre of staff, including a pharmacist, a police officer, and other staffers would set up a booth for a day to make collections. From these events it became clearer that ongoing take-back sites would be more efficient and more effective. Such permanent take-back sites were already in operation throughout the San Francisco Bay Area in Palo Alto and San Mateo County. On-going take-back programs are far more cost-effective to operate. Household Hazardous Waste facilities typically have been taking back unused or unwanted medications for years at a very low cost. In 2007, the Teleosis Institute initiated the Green Pharmacy Program², which set up 12 ongoing take-back sites in pharmacies in San Francisco, Berkeley and other locations in the Bay Area. The Green Pharmacy Program collected over 4,500 pounds of unwanted medicines over a period of 18 months. In 2009, the Alameda County Safe Medicine Disposal Workgroup contracted Teleosis Institute to identify and initiate five new permanent take-back sites in unincorporated Alameda County. As part of this work agreement, Teleosis was to develop a plan for sustained funding for such endeavors. Throughout the region, all take-back programs were essentially funded by local municipal agencies, with the exception of sites operated in hospital pharmacies and the occasional independent sites funded by non-profit philanthropic donations.

¹ Report on the San Francisco Bay Area's Safe Medicine Disposal Days, Bay Area Pollution Prevention Group, (2006)
http://c.ymcdn.com/sites/www.productstewardship.us/resource/resmgr/imported/SFBAYSafeMeds_Report_August2006.pdf

² Green Pharmacy Preliminary Data Report, Teleosis Institute (2009) www.Teleosis.org

TAKE-BACK EVENTS OR TAKE-BACK SITES

Bill Pollock

*Program Manager of the Alameda County Household Hazardous Waste Program,
a program run by Alameda County Environmental Health.*

"One of the emerging developments in household hazardous waste is classes of wastes like batteries and fluorescents which everybody has. But having three or four household hazardous waste facilities isn't a very convenient way of getting rid of it; having to get in your car and travel a couple of miles to drop this stuff off isn't very convenient. So for all those types of waste streams that are universal in nature, and distributed at places like drugstores or hardware stores, we're looking for ways of distributing the collection mechanism. We have a number of sites for batteries and lamps around Alameda County in hardware stores, and we are looking at the same idea in some ways for pharmaceuticals.

"I first got involved in setting up sites when Supervisor Alice Lai-Bitker in 2008 asked us for help in doing a pharmaceutical take-back at a local community clean-up in San Lorenzo. It was a one-day event. And after that, word got around. I was invited to start attending the medication disposal initiative meetings about that time. So we did a couple of events for Supervisor Lai-Bitker, and we did about 12 or 13 more for others, often with Supervisor Miley on the Medication Disposal Initiative. We tried different kinds of events. Some occurred on DEA co-sponsored national medication collection days. Linda Pratt and I did an experiment of a rolling take-back, where we went to several senior citizen developments, not nursing homes but just residences that were overwhelming inhabited by senior citizens. We scheduled an hour at each facility. We pulled up with a policemen in tow. We'd collect some drugs. We'd sort them out. The cops would recover the controlled substances, and we would gather the other stuff.

"We were experimenting with those events. The one-day events were pretty labor-intensive, and for some we didn't get many drugs or people coming by. Supervisor Miley actually staffed some of these too and suggested that this was silly. The best way was permanent sites. So that's when we at the Medication Disposal Initiative started identifying sources of funding, recruiting potential sites, and potential long-term financial sponsors, for those sites in the Central County area."

As of 2009, when the workgroup began to collect data on take-back sites, there were 10 take-back sites operating in the county. Due to the diversity of program sponsors as well as take-back locations, data on the number of sites in the county at that time was inconsistent. It is more accurate to say that in 2009, when the Safe MEDS Workgroup began collecting data on the 10 sites, remaining independent sites were not reported. Figure 1 shows the number of sites operating in the county by year since 2009.

TABLE 1

Take-Back Sites In Operation	Total
2009	10*
2010	18
2011	27
2012	29 (30)**
2013	31 (32)**

* Other sites in operation at that time were not part of this program.

By 2010, all sites within the county were reporting to the Safe Meds Workgroup.

** One site operated by East Bay Municipal Utility district is in Contra Costa County.

The Alameda County Safe Medicine Disposal Ordinance and Regulations

As the number of sites increased rapidly between 2009 and 2011, the workgroup began the necessary steps to initiate public policy that would provide improved program outcomes and for a sustainable funding mechanism.

One method for funding programs for non-hazardous or emerging contaminants is *product stewardship* or *extended producer responsibility* (EPR). EPR considers the manufacturer of a product responsible for the entire life-cycle of the product, including take-back and final disposal. EPR is used in many programs worldwide. In particular, it is the method used for safe medication disposal programs operating in much of Canada.

With the help of Heidi Sanborn of the California Product Stewardship Council, Joel Kreisberg (author) of Teleosis Institute, Bill Pollock of Alameda County Household Hazardous Waste, Ariu Levi of Alameda County Environmental Health and Robert Reiter, Deputy County Council for Alameda County, a proposed ordinance was drafted which became titled the *Alameda County Safe Medicine Disposal Ordinance*. The model used to develop this legislation was introduced in San Francisco in 2010 by Supervisor Ross Mirkarimi. This model, *The Safe Drug Disposal Ordinance*, was not approved by the San Francisco Board of Supervisors. Instead, a pilot program was funded by pharmaceutical manufacturers with a contribution of \$110,000. The initial results of this program were published in 2013.³

The Alameda County ordinance was first introduced for approval to the Alameda County Board of Supervisors in February 2012. The Board of Supervisors, while supportive of the bill, was concerned that the ordinance appeared to have been developed without enough participation of the pharmaceutical producers and several other related stakeholders. They requested a series of four stakeholder meetings. These meeting would serve as a means of informing and engaging all stakeholders as to the nature of the legislation and provide a forum for gathering feedback in an effort to reach a broad consensus among interested parties. These meetings were successfully held in April through June of 2012, at which time a revised ordinance was brought back to the Board of Supervisors.

³ Kreisberg, J, *San Francisco Medicine Waste Characterization Study*, (2013), Teleosis Institute.
www.teleosis.org/wp-content/uploads/2012/02/San-Francisco-Medicine-Waste-Charaterization-Study.pdf

The Alameda County Safe Drug Disposal Ordinance was passed unanimously in July 2012. This landmark legislation was the first legislation passed in the United States that regulates household pharmaceutical wastes, and the first extended-producer-responsibility modeled ordinance passed into law by a county in the United States for any product. In June 2013, the King County Board of Health passed a similarly modeled ordinance for household pharmaceuticals.

The Alameda County Safe Drug Disposal Ordinance, passed on July 24th, by the Alameda County Board of Supervisors, amends the Alameda County Ordinance Code by adding Chapter 6.53, sections 6.53.010 through 6.53.120 which: “require any person who produces a drug offered for sale in Alameda County to participate in an approved drug stewardship program for the collection and disposal of unwanted drugs from residential sources, provide for implementation, enforcement, fees and penalties; and make environmental findings.” (The complete ordinance can be found in Appendix VI.)

In December 2012, a group of three trade organizations, the Pharmaceutical Research and Manufacturers of America (“PhRMA”), the Biotechnology Industry Organization (“BIO”), and the Generic Pharmaceutical Association (“GPhA”), challenged the ordinance in U.S. District Court for the Northern District of California, seeking to block the implementation of the ordinance. The trade groups declared that the ordinance violated the Commerce Clause of the U.S. Constitution and violates 42 U.S.C. § 1983, for three distinct reasons. They asserted that it directly regulates and burdens interstate commerce and its primary purpose by shifting the costs of a local regulatory program onto interstate commerce and out-of-state consumers; that it discriminates against interstate commerce by targeting interstate commerce and products delivered from outside the county; and that it favors local interests by deliberately shifting costs away from local consumers and taxpayers and onto drug manufacturers and pharmaceutical consumers nationwide.

The court did not find in favor of the trade organizations; an appeal has been filed in the United States Court of Appeals, Ninth Circuit, Northern District of California.

On February 26th 2013, the Alameda County Board of Supervisors approved the necessary regulations developed by the Alameda County Environmental Health Department. The Alameda County Safe Drug Disposal Regulations are available at www.acgov.org/aceh/safedisposal/index.htm (Appendix VII.) The regulations provide all the necessary rules for parties subject to the ordinance to meet the requirements of the ordinance. This includes the definition of producers, the process for petitioning for an exemption, the submission of a product stewardship plan, the plan evaluation, the ability to petition for an alternative method of disposal, the review and approval of plan, the appeal process, the creation of annual reports, and the plan renewal and fee schedule (Appendix VIII). In May of 2014, the initial date of compliance with the ordinance went into effect.

Currently, a third party stewardship plan is in development in consultation with the Alameda County Environmental Health Department. The Pharmaceutical Product Stewardship Work Group (PPSWG) is working with producers to meet the requirements of the regulations. As of June 1st, 2014, approximately 180 producers have filed a notice with the Environmental Health Department in an effort to comply with the regulations. The Environmental Health Department is currently working with PPSWG in a effort to support the development of a plan that meets the requirements of the ordinance and regulations.

WE WILL CONTINUE WORKING TO MAKE THIS SUCCESSFUL

Supervisor Nat Miley

Alameda County District Four

"It was one of the more challenging processes I've had to undertake. With alcohol it was mainly re-tailers, locally or statewide; with tobacco, people had a visceral reaction wanting to see reforms. The restaurant industry had to recognize that regulation wasn't going to hurt business. But with pharmaceuticals, it seemed like a national issue. I was surprised by the pharmaceutical industry sticking to their position. They said they were not prepared to absorb the cost, and they didn't see making it an act of goodwill. It was surprising that they didn't want to come up with a reasonable accommodation. We will continue to work with a product stewardship organization to try to showcase them as a model. We want to make this successful. If we have an ordinance and a model program, then it can be duplicated anywhere."

Agency Oversight

Contrary to the image of a unified program, the disposal services of the current Alameda County Safe Medication Disposal Initiative is really a collection of 11 different fiscal organizations operating 31* take-back sites throughout the county. Reviewing the list in Table 2 reveals the diversity of stakeholders operating take-back sites, including local governments, water and wastewater utilities, hospitals, law enforcement and a non-profit. There is as of yet little correlation between the great number of sites operating and the size and scope of the agencies.

TABLE 2
Types Of Agencies With Fiscal Oversight

Agencies Operating Programs	Organizations	# of Sites
Local Government	4	9 sites
Hospital	2	3 sites
Public Wastewater Utility	2	8 sites
Public Water Utility	1	10* sites
Law Enforcement	1	1 site
Non Profit NGO	1	1 site
Total	11	31 (32)* Sites

*EBMUD operates one site in Contra Costa included in this report.

The eleven organizations fiscally operating the 31 take-back sites are:

- Alameda County Sheriff's Department
- Alameda County Waste Management Authority
- City of Fremont
- City of Hayward
- City of San Leandro
- East Bay Municipal Utility District (EBMUD)
- Oro Loma Sanitary District
- Sutter Health/Eden Hospital (Funded by Castro Valley Sanitary District)
- Sutter Health/Alta Bates Summit Medical Center
- Teleosis Foundation
- Union Sanitary District

Location of Take-Back Sites

With a county population of just over 1.5 million people, 31 take-back sites in the program might seem to provide ample opportunities for citizens to have access to this public health service.

Using zip codes for planning distribution, accessibility of take-back site locations was evaluated. Alameda County has 49 distinct zip codes, with representative populations per zip code ranging from 715 persons for the smallest postal zone, all the way up to 94,606 persons. The 31 sites in the county, when mapped by zip code covers 40% of the county (20 zip codes). In terms of population, these 20 zip codes cover slightly more than half of the population of the county (798,000).

Simply put, half the population of Alameda does not live in close proximity to a take-back site. The most obvious example of this is the Tri-Valley region in the eastern part of the county, consisting of the towns of Dublin, Livermore and Pleasanton. For this region of 170,000 persons, the closest take-back site is Eden Medical Center in Castro Valley. Eden Medical Center is 10 miles from Dublin and 20 miles from Livermore.

Another approach is to consider take-back sites by types of host establishment. The county program offers take-back bins in 11 different types of businesses ranging from pharmacies, the most likely location for a take-back location, to household hazardous waste centers, medical clinics and hospitals. All of these host locations are either point of sales locations for medicines, healthcare establishments or committed waste disposal locations. There are also take-back bins inside the atriums of office buildings, senior centers, firehouses and police stations. Certainly these sites can serve as locations for take-back bins. Alameda County Sheriff's Station in San Leandro is the only site in the Alameda County that accepts controlled substances. This site is quite successful. These other locations are less common places for medications to be returned to. The data presented further in this report suggests that hospitals, pharmacies and law enforcement are the most effective location given the passive nature of current program promotion (Table 7 and 8). Figure 3 provides the summary of existent take-back locations in the program.

TABLE 3

Take-Back Site Location By Type	Number of Sites
Pharmacy <ul style="list-style-type: none"> • Alta Bates Milvia Outpatient Pharmacy • Alta Bates Peralta Outpatient Pharmacy • Haller's Pharmacy and Medical Supply • Haller's Pharmacy Newark • Medical Arts Pharmacy • Sal's Pharmacy • Ted's Drugs • United Pharmacy 	8
Household Hazardous Waste (HHW) Center <ul style="list-style-type: none"> • Alameda County HHW Drop-off Site - Fremont • Alameda County HHW Drop-off Site - Hayward • Alameda County HHW Drop-Off Site - Livermore • Alameda County HHW Drop-Off Site - Oakland 	4
Medical Clinic <ul style="list-style-type: none"> • Davis Street Clinic • Washington Township Medical Group • Washington Township Medical Group at Nakamura Clinic • Washington Township Medical Group at Warm Springs 	4
Hospital <ul style="list-style-type: none"> • Eden Medical Center • Washington Hospital Community Health Resource Library • Washington Hospital Main Lobby 	3
Senior Center <ul style="list-style-type: none"> • Albany Senior Center • City of San Leandro Senior Center • Emeryville Senior Center 	3
Recycling Center <ul style="list-style-type: none"> • Berkeley Transfer Station #3 • Fremont Recycling and Transfer Station • El Cerrito Recycling Center (in Contra Costa) * 	2 (3)*
Fire Station <ul style="list-style-type: none"> • Oakland Fire Station #3 • Oakland Fire Station #20 	2
Law Enforcement <ul style="list-style-type: none"> • Alameda County Sheriff's Office • City of Alameda Police Department 	2

TABLE 3

Take-Back Site Location By Type	Number of Sites
Government Office • California State Building	1
Public Utilities Administration Building • East Bay Municipal Utilities District	1
Public Works Center • City of San Leandro Public Works	1
Total Number Of Take-Back Sites	31 (32)*

Take-Back Collection Systems And Waste Collection

In December 2010, CalRecycle, the state agency responsible for managing environmental waste, published guidelines for model take-back programs. These guidelines can be found at <http://www.calrecycle.ca.gov/publications/Documents/1370%5C20110080.pdf>

Since many of the sites opened up after 2010, very few take-back sites are not following these state guidelines. The lock-boxes are likely the two-key security systems, which maintain one key in possession at the take-back site and the second key with the medical waste hauler. Other sites still operate with a single key security system kept at the location by a program manager, which allows for more flexibility if bins overflow, but does not provide the security of the two key system.



Typical Take-back Bins

Waste Disposal Services

The collection bins are serviced by licensed medical waste disposal contractors. These waste disposal companies range in size and scale from regional medical waste disposal companies such as Barnett Medical Services and Sharps Solutions, to large national companies such as Clean Harbors, which offer services beyond medical and sharps disposal. The list of companies contracting in Alameda County includes:

- Barnett Medical Services
- Clean Harbors
- Covanta
- Guarantee Returns
- North State Environmental
- Sharps Solutions

***The complete listing of waste disposal companies is available in Appendix III.

WHAT HAPPENS TO MEDICINES THAT ARE RETURNED

Larry McCarty

Owner of Sharps Solutions in Hayward California

"In the kiosks themselves, we use a reusable container. When the driver arrives, he pulls the reusable out. He ties off the bag and seals it. We put a tight-fitting lid on it. That material is taken to a transfer station the same evening, when the driver comes back in. Two or three o'clock the next morning, it's then taken on to a main consolidation point, which happens to be in our case, Fresno. All of the pharmaceutical waste, because it is incinerable, is now taken by rail to Curtis Bay, Maryland for high heat energy efficient waste-to-energy incineration mill. So it's high heat, cold chamber, all the stages up to 2,200 degrees, and it's basically reduced to 1 percent carbonized ash. Once that ash is done, it's then put into a permitted medical waste landfill.

"We used to go almost always directly to Anahuac, Texas, to the waste management incineration facility there. We have found that the cost was less expensive for us to ship by rail; we had railroad ties and capabilities directly outside our facility in Fresno. Waste-to-energy incinerator is also extremely efficient. So we're much happier with the impact that it has on the environment."

RESULTS

Total Collected Waste

When considering the effectiveness of the program, there are many data points of value. To date, given the lack of a single fiscal agency responsible for the program, it has been difficult to keep track of results. For example, for total weight of medicines returned and destroyed, not all the sites keep track of this data. This may seem like an oversight, however for the Alameda Household Hazardous Waste sites, household medications are such a small waste stream that in their facilities these wastes are commingled with other hazardous waste for disposal. Table 4 provides a summary of the total weight of collected and incinerated pharmaceutical waste disposed of by the sites reporting.

TABLE 4

Total Medication Collected and Disposed 2009-2013	(lbs)	# sites reporting	Total Sites
2009	473 lbs	1*	10**
2010	2,915 lbs	9*	18
2011	5,317 lbs	18	27
2012	9,702 lbs	27	29 (30)
2013	12,564 lbs	27	31 (32)

* mostly event based collection

** other sites were in operation at that time but were not part of this program and all have since ceased operations.

More complete data is available for the most recent year 2013. Table 5 presents current results. Given the economy of scale as well as on-going improvements in program operations and oversight, 2013's results provide data enough to calculate the average weight annually of returned per site. This is an average of 449 pounds per take-back location. Using this figure to extrapolate the total drugs collected for all 31 sites in the program, the total waste collected for 2013 is estimated as 13,919 lbs.

TABLE 5

Total Medication Collected and Disposed of in 2013

Total Sites Reporting Weights	27
Percentage of Sites Reporting	84%
Total Pounds of Medicines Disposed in 2013	12,564 lbs
Average Pounds Per Site	449 lbs
Calculated Total Medication Disposed (449 bs * 31 sites)	13,919 lbs

The results provided by site supervisors allow for some assessment of the effectiveness of individual take-back sites. Table 6 provides results for locations with the largest collections this past year. The sites with the largest collection of medication waste include the sheriff's station, two hospitals and a pharmacy. The smallest take back site in the county are the City of San Leandro Public Works and Medical Arts Pharmacy (Table 7). The results for the smallest sites are limited due to the fact that not all the agencies report waste collected by site.

TABLE 6

Sites with Largest Collection By Weight

Alameda County Sheriff's Station	1,100 lbs
Eden Medical Center	1,036 lbs
Washington Hospital	960 lbs
Ted's Pharmacy	936 lbs

TABLE 7

Sites with Smallest Collection By Weight

City of San Leandro Public Works	56 lbs
Medical Arts Pharmacy	169 lbs

I THOUGHT IT WAS A GOOD FIT FOR OUR HOSPITAL

Christine Graham

Injury Prevention Specialist at Eden Medical Center for Trauma Services

"I was the one who brought the idea to the hospital. I went right to our CEO because I thought it was an important service to provide the community and important for the environment. And I also thought it tied well with my injury prevention efforts, especially with teenagers. Looking at some of our trauma data, it was kind of surprising how the statistics showed that we had a high percentage of motor vehicle crashes and people coming in under the influence of drugs and alcohol. So I thought it was a good fit for our hospital.

"I think the key piece was going to the right person and getting the permission from the top, and having buy-in from administration. Then there were smaller pieces. You had to work with engineering to fit into the hospital and to make sure it was at a site that was secure through observation by security without asking too much of staff. It was a really good fit for our emergency department. I've never had any negative comments about our bin. No one's ever complained. And that bin is full every two weeks.

"I think it's a perfect fit because we have security there. We're open 24/7, and so you don't run any security risks that you might have if you're not open 24/7. It was a challenge to get the bin in the new hospital, but we got it done, and it's there up and running and busy. So it's worked out well in our emergency waiting room."

The following is a list of the sites that were not included in the overall weights collected in the program. All of these sites offer services far beyond the return of unused medicine. As mentioned previously, at these locations, pharmaceutical waste is regarded as a small percentage for the overall waste returned.

- Alameda County HHW Drop-off Site - Fremont
- Alameda County HHW Drop-off Site - Hayward
- Alameda County HHW Drop-off Site - Livermore
- Alameda County HHW Drop-off Site - Oakland
- Fremont Recycling & Transfer Station

Costs of Disposal

Collecting the results for assessing costs of disposal has been inconsistent. Initially, costs were not well reported. Sites with little waste might have the contents of their bins combined with other sites during pick-up. For the purposes of this report, the data is more reliable as of 2011, due to the small data sample for previously reported costs (see Table 8). In 2012, costs were considerably lower than in 2013. There is no obvious explanation for this. The trend downward in general is consistent with the tendency for the economy of scale to bring the cost of disposal down as larger quantities are collected and managed. This data does not take into consideration variations in the fees charged by the medical waste disposal companies. Rather, it reflects the total cost of disposal averaged across all sites. Given the fact that six companies are contracted for this services, costs of disposal can vary considerably. Using the average cost per pound based on actual disposal in 2013, the extrapolated cost of the full 13,939 pounds for Alameda County is \$27,838.

TABLE 8

Costs of Disposal: (sites reporting)		Costs	Average
2009	(1) *	\$1,186	\$2.51
2010	(1) *	\$4,650	\$2.64
2011	(15)	\$8,487	\$2.40
2012	(22)	\$13,752	\$1.70
2013	(24)	\$21,956	\$2.00
Extrapolated Total Costs of Disposal (13,919 X \$2.00)			\$27,838

EDUCATIONAL OUTREACH

Currently little if any direct active consumer education is occurring among the various agencies operating program. For the 11 agencies polled, most are providing information to consumers primarily on their websites. These websites have a brief description of the purpose for proper medication disposal, plus information as to the location and hours of operation for local take back sites.



Alameda County Household Hazardous Waste offers a direct call hotline providing consumers with information about disposal of various hazardous wastes ((877) STOPWASTE). According to Bill Pollock, program manager for Alameda HHW program, pharmaceutical waste disposal is a frequent inquiry by callers.

The Safe MEDS Workgroup keeps its website current plus a Facebook page and Twitter feed. Links are found in Appendix IV. The website has a total daily reach of 29 persons per day. The Facebook page is loaded with new content about once a week. Currently there are 192 likes, and the twitter feed has 106 followers, which reflects a limited engagement.

During the initial phase of take-back site development, all of the agencies developed press release material, and provided detailed information in newsletters or direct mailings to inform community members. East Bay Municipal Utility District has been the most active. It has been participating in take-back events since before the Safe Meds Workgroup began. Event-based take-back programs rely heavily on consumer information and promotion. EBMUD uses a bi-monthly newsletter that is enclosed and mailed with paper bills. The September-October 2013 featured a full page summary of the program for the 8 sites operated by EBMUD.

customer Pipeline EBMUD
September • October 2013

Keep San Francisco Bay off drugs

Not too long ago the public was told for safety reasons to flush their unused medicine down the toilet. We now know pharmaceutical drugs cannot be fully removed by traditional wastewater treatment processes and can end up in San Francisco Bay. Today, the best way to protect the Bay and safely get rid of your expired and unwanted medicines is to discard them at a designated collection site. Bring your unwanted or expired drugs to one of the following locations:

Alameda Alameda Police Station 1555 Oak Street Mon – Sun, 8am – 8pm	Oakland EBMUD Administrative Building Lobby 375 11th Street at Franklin St. Mon – Fri, 8am – 4:30pm, except EBMUD holidays
Berkeley Berkeley Transfer Station 1201 2nd Street Mon – Sat, 8am – 4:30pm	Elihu Harris State Building Lobby 1515 Clay Street Mon – Fri, 8am – 5pm, except state holidays
United Pharmacy 2929 Telegraph Ave. Mon – Fri, 9am – 6pm; Sat, 9am – 2pm	Oakland Fire Department 1401 98th Ave. at International Blvd., or 1445 14th Street at Mandela Parkway Every day 8am – 8pm (ring the doorbell!)
El Cerrito El Cerrito Recycling Center 7501 Schmidt Lane Mon – Fri, 8am – 4:45pm; Sat – Sun, 9am – 4:45pm	
Emeryville Emeryville Senior Center 4321 Salem Street Mon – Fri, 9am – 5pm	

Additional drop-off locations can be found at ebmud.com.

Empty all pills and capsules into a plastic zipper bag before discarding. Liquids may be disposed of in their original original leak-proof containers. Controlled substances (narcotics) should not be discarded in the disposal bins. Vitamins and supplements may be disposed of safely in your trash.

A CLEAN BAY BEGINS WITH YOU.
Remember to remove or black out prescription labels on liquid bottles before discarding. To protect your privacy, recycle your pill bottles at home.

This type of promotion has been utilized by many of the agencies operating the program.

GETTING IT OUT THERE TO MORE PEOPLE IS THE NEXT STEP

Mike Auer

Environmental Outreach Coordinator, Union Sanitary District

"I think that getting it out there to more people is the next step. There are always people who don't know about the program at our events. We have these locations and this is the practice that we want people to take, using these disposal sites, rather than throwing drugs down the drain. We just want to get more people using the disposal sites, because we feel that's the best method to keep it out of the waste stream.

"In terms of the running the programs, once we got them set up and got everything dialed in, it's been very little maintenance to keep them running."

Currently no take-back program in the county effectively collects data on how many people are using the program. Measuring effectiveness of the educational outreach beyond the annual assessment of weight of medications returned provides the only means of assessment, a rather vague measure. Costs of current efforts are minimal in terms of expense of staff time, given that so little active educational promotion is occurring. Most, if not all of these costs, are subsumed in more general programmatic staff budgets.

WHO USES THE PROGRAM

The Safe MEDS Workgroup has focused primarily on improving access to take-back sites and creating a sustainable funding system for this service. Less attention has been placed on the understanding program users and the motivations for participation. This information is not easy to obtain, as it has much to do with sociological behaviors and ethical beliefs. The sociological attributes of program users—such as age, gender, household annual income, and place of residence—appeal to a certain type of research. This contrasts the research methodology required to better understand motivations and ethics, which may include concern for safety, concern for the environment or a personal experience with trauma through a loved one misusing pills. Given limitations in time and funding, the focus of the research is on the sociological perspectives—who uses the program.

Little research has been published on the demographics of individuals returning medicine using currently available take-back systems in the United States. The only study to date is a report by Owens and Anand⁴, in which 445 residents were contacted by phone in an effort to identify their age, race, household income distribution and attitudes about drug disposal. In the case of the current initiative in Alameda County, short of stationing a person at several sites to collect data directly, which was prohibitively costly, data was collected using a written survey on location set in a visibly convenient place on the take-back bin at nine of the 31 sites. Site representatives were instructed to encourage participation in the survey, but responses from users were voluntary.

⁴ Owens, L & Anand, S (2009) Medication Disposal Survey, University of Illinois at Chicago, Survey Research Lab.

The nine sites were selected in an effort to be most representative of the broad variation of populations the initiative reaches, as well as to allow for variations due to type of take-back sites (police station versus pharmacy, for example). Given the voluntary nature of the collection systems, the most significant responses were collected at two pharmacies, Ted's Pharmacy and Sal's Pharmacy in Berkeley. The reason is that at each of these locations the pharmacists are highly committed to take-back services. Monta Patel at Ted's Pharmacy in Hayward and Sal Nasser at Sal's Pharmacy in Berkeley encouraged participation in the survey. The other seven sites, without much encouragement, only returned a small number of samples. The total number of responses collected over a three month period was 62.

Considering the voluntary nature of the survey, the questions were deliberately designed to be simple and easy to complete. The survey was limited to one page with mostly multiple choice answers. The complete survey can be found in Appendix IX. Discussion and analysis of survey responses are found in the Assessment and Recommendations section.



Emergency Department take-back bin at Eden Medical Center.

Characteristics of Users

In terms of age of users, an approximately equal portion of persons 41 to 65 and persons over 65 was identified as using the program. These two age groups were represented twice as often as the number of users between 26 and 40 years old. There were no respondents under the age of 26. This data is presented in Table 9. The survey reveals that three times as many women use the program over men. This is reported in Table 10.

In terms of the household annual income, reported in Table 11, the program is used by citizens across the spectrum of income levels. Of note, persons living close to or below the poverty line are well represented in the survey results, with 28% of the respondents, the same percentage of users in the income level \$71,000 to \$105,000. Most of the respondents have health insurance, with only 2% being uninsured, which is far below the national average of uninsured. This data is presented in Table 12.

TABLE 9

Age Of Respondent

Below 26	0
26-40	20%
41-65	40%
Over 65	40%

TABLE 10

Gender Of Respondents

Female	65%
Male	22%
Declined to state	13%

TABLE 11

Annual Household Income Of Respondents

Under \$30,000	28%
\$31,000-\$50,000	21%
\$51,000-70,000	4%
\$71,000-105,000	28%
\$105,000 and above	19%
Number of persons declining to disclose household income	8

TABLE 12

Health Insurance Status Of Respondents

Currently has health Insurance	98%
Currently does not have health insurance	2%

Number of Persons Represented by the Returned Medicines

A question that continues to puzzle administrators and researchers of take-back systems has to do with this simple issue: when a person brings medicine back to a take-back site, the medicine they bring may be just their own, or it may come from a group such as a family. Assuming that one person bringing drugs back is bringing medicine for only one person might be easy but it is inaccurate. Table 13 offers the responses to the question “How many people are you returning these medicines for?” Fifty-six percent of the respondents reported returning their own medications. Forty-four percent of the respondents were returning medication for more than just themselves. Table 14 offers the results of the follow-up question which asks how many persons are in respondents household. While Table 13 and Table 14 are not directly correlated, half the respondents were returning medicine of their own, however, only 24% of the respondents live alone. While no conclusions can be made from this data, it does confirm the challenge of calculating how much medicine an individual disposes.

For deceased persons, someone else brings medicine to the take-back site. Table 16 reveals these results. Twenty-three percent of the respondents completing the survey were returning medications for a deceased person. This is a significant greater than the number mortality rate in Alameda County. This result suggests significant value for service providers working in end-of-life situations.

TABLE 13

Number Of Persons Represented By The Returned Medicines

1	56%
2	27%
3	15%
4	4%
More than 4	3%

TABLE 14

Number Of Persons in Household Of Respondents

1	24%
2	39%
3	8%
4	10%
5	5%
6	6%
8	2%
Declined to respond	2 persons

TABLE 15

Percentage Returning Medications For A Deceased Person	23%
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Characteristics Of The Collection Data

Over 70% of the data collected was from the two independent pharmacies, Ted's Pharmacy in Hayward and Sal's Pharmacy in Berkeley. As previously discussed, this seemed to be a function of two committed pharmacists that promoted the survey in a manner similar to the way they promote their program. Table 16 shows the number of surveys collected from the nine sites. Table 17 presents the distribution of the surveys by zip code, which was the only geographic data collected. With data so overly weighted to these two locations however, one would assume that the data results skew towards representing disproportionately more affluent populations.

TABLE 16

Respondents By Site	
Sal's Pharmacy	39%
Ted's Pharmacy	32%
Davis Street Clinic	6%
Eden Hospital	4%
United Pharmacy	3%
Alameda County Sheriff	3%
Medical Arts Pharmacy	3%
San Leandro Senior Center	3%
Haller's Pharmacy	2%

Sal's Pharmacy	39%
Ted's Pharmacy	32%
Davis Street Clinic	6%
Eden Hospital	4%
United Pharmacy	3%
Alameda County Sheriff	3%
Medical Arts Pharmacy	3%
San Leandro Senior Center	3%
Haller's Pharmacy	2%

TABLE 17
Zip Codes Represented By The Respondents

Zip Code	Number Of Respondents
94707	9
94545	6
94577	4
94579	4
94708	4
94544	3
94546	3
94578	3
94702	3
94706	3
94541	2
94542	2
94580	2
94805	2
94520	1
94530	1
94547	1
94549	1
94560	1
94583	1
94587	1
94602	1
94608	1
94618	1
94705	1
94804	1
Total number of zip codes represented	26

ASSESSMENT AND RECOMMENDATIONS

The Safe MEDS Workgroup is a collection of people representing public agencies and private organizations that provide the guidance for developing a service to address an emerging public health threat by a potential contaminant. Given the structure of the initiative and this workgroup, what outcomes are expected and what is the best measure of these outcomes? Is “success” defined as reducing the ongoing growing stock of unused pharmaceuticals in households? Yes, but how do we measure that? Is success providing improved access for more vulnerable populations? Yes. Does success include a more cost-effective program? Yes.

An alternative method of measuring success would be to consider the five years reviewed here as the first of a several-step developmental process in public health policy. This step involved birthing a methodology for collecting a potential source of harm and initiating public policy for seeing it happen in an organized manner. This process included a free market organization of services with the overall aim of providing an increasingly useful service at a cost that could be absorbed by the larger system without unnecessary burden. The initiation and development of public policy that facilitates the growth of the service as an effective method to improve program goals and outcomes followed. In this regard, the Alameda County Safe Medicine Disposal Initiative is successful in meeting its intended goals.

We do, however, live in an age of information. Information that we collect and use to measure progress towards a good and just society. In this regard, there is often a mix-up between outcomes and outputs. Outcomes in this instance would be less teenage prescription drug abuse, less accidental poisonings of children under six and lower concentrations of pharmaceuticals in the water to name a few. Outputs, far easier and cheaper to measure, include number of sites available for take-back, number of pounds collected and safely incinerated, and cost efficiencies improving. We can usually feel good about achieving our goals in terms of program outputs but we have to accept that program outcomes are harder to measure and even harder to attain, with multi-factorial causes. Program outputs are what is most often celebrated as success. Should we not strive for noble outcomes? The Safe Medication Disposal Initiative confronts this limitation. The data presented in this report is primarily assessing outputs rather than outcomes.

Still another assessment is qualitative rather than quantitative, focusing on what can we learn from what we are measuring. This is the difference between concluding that we need more sites to improve access to all zip codes, for example, versus recognizing that the data suggests that installing take-back sites in hospitals, the lobby and the emergency department, is likely the most efficient strategy and will produce the greatest output for the investment. Information and results can be used in many ways. More is not always better in a contemporary world that has to manage resources skillfully. With this as a backdrop, some of the key findings will be discussed from this assessment.

Agency Oversight

This initiative “grew up,” so to speak as a grassroots brick and mortar movement. For this stage of development, whenever a door opened that provided a willingness to extend a hand, likely an ally was found, and a stakeholder joined the workgroup or a take-back site opened. In its sixth year of growth it’s easy to see that so many agencies overseeing eleven small regions is an inefficient way to manage this service. While these variances may have value, in truth, so many micro managers at the regional level suggests considerable amounts of redundancy. None of these agencies itemize internalized expenses and overhead (or they did not report this information). A locally distributed system possibly keeps supervisory costs low. What this means is that each of these local organizations stays within

their current scope of services and rightfully so. However, the potential for improving overall impact, for measuring success, and for refining programmatic goals remain low at this level of municipal management. From this perspective, it is easy to see a further value of the Alameda County Safe Drug Disposal Ordinance, it at least suggests a unified, county wide program. This certainly means the potential for improving program outcomes and providing the most effective service.

Involving so many agencies is costly in terms of management, though this may be indirect. This translates into waste and redundancy throughout the system. When there is one overriding agency operating this program, not only will the services be provided more effectively, (assuming competency by that agency), but it will likely drive the costs of disposal down due to the economy of scale of the waste disposal industry. It will likely improve program outputs by streamlining educational efforts to more effectively reach the citizens of the county.

Recommendation: *Establish one centralized product stewardship organization to oversee a county-wide program with the potential of growing to manage a regional or state program.*

Location and Access

In some respects current locations for take-back sites are haphazardly set. The criteria used to establish a take-back site was partly a willingness by the location operator to allow for the service to be provided in a location that is safe to provide this service. Other criteria did play a role into attempts to maximize local access, however, sites required voluntary acceptance. The diversity of location types does not reflect an executed plan as to how to meet the needs of citizens of the county.

It's likely easy to understand the thinking behind placing take-back bins in such diverse settings as firehouses, hospitals and government buildings. Yet, similar to post office boxes on street corners, depending on what phase of development of the program one examines, more is not always better. The logic of a point of sales take-back system is consistent with the premise that a business distributing medicine will be a good place to bring back unused medicine to the same location. The data collected here shows that a well-placed box in a pharmacy with a pharmacist who promotes its use can certainly be successful. What is essential is the professional commitment to reducing healthcare's footprint and to promoting public health and safety. Educating pharmacists and possibly physicians and nurses is essential for improving outputs and likely outcomes.

In stark contrast, take-back bins in medical settings—hospitals and medical clinics, certainly locations people naturally associate with drugs—require less professional advocacy, at least to users. Both of these locations distribute medicine, though sometimes as a prescription filled in a pharmacy outside the facility. Yet these are locations citizens are likely to have to come to during their lives, possibly regularly. Staffing and supervision is already present. Emergency Departments are open all the time. Unlike the pharmacy, a lobby of a hospital and an Emergency Department waiting room requires little if any retail promotion. In fact, these locations seem to attract and collect unused medications rather effectively, with just passive promotion. Without any other explanation, it is logical to take advantage of this trend. In terms of physical distribution of access, the distance one has to travel to find a take-back bin—hospitals are well positioned in general.

Transfer stations and hazardous waste facilities seem like good places for take-back bins given the overall function of these locations is waste reduction. Operational costs remain very low. Other sites, including senior centers, firehouses, office buildings, while seemingly good locations, have not been proven to be as effective to date. Each type of site has a unique niche. Senior centers, for example, provide an easy location for a population that has frequent contact with medicine. Data at this point does not suggest these sites are any more effective. These other sites may prove to be inefficient once a more unified program throughout the county is developed. More research is required. With 51% of the citizens of the county living within reasonable proximity of a take-back sites, the development and opening of new sites is necessary for those not currently close to current take-back sites. It is reasonable to expect that a well-constructed plan to provide this service in accessible locations throughout the county will create larger collection results and improved outcomes.

Recommendation: *Medical centers are very successful locations for providing take-back services. Beginning with larger medical institutions such as hospitals, then moving into smaller clinical facilities, providing take back services in these settings is likely the most efficient initial choice to make. Given the concentration of medical professionals and hospital administrators, this is also the most efficient manner to stir professional awareness of the issue and the solution. Pharmacies also provide an effective means for providing take back services when coupled with educational opportunities for pharmacists to better understand the value and reason for participation. Other take-back sites should be considered more strategically with further research into overall efficiency. Overall, more take-back sites are necessary to provide easy access to all citizens of the county.*

Costs of Disposal

None of the sites participating in this survey reported the costs of administration, operation or setup for the sites. This is not to say that this data is not available, rather, it is often blended into other staffing costs. Thus, the only costs easily accessed were cost of disposal. Due to the diversity and the overlap of site supervision, it is likely that the costs of operating the program would likely be reduced if program operations were consolidated. This is likely true for cost of disposal as well. In the Alameda County program, with 11 agencies operating the 31 sites, the collection for disposal by medical waste company contractors are not able to set up a regular service run. Instead, due to small size, many sites have pick-up on demand. In contrast, the program operating in San Francisco, which is administrated through one agency, the San Francisco Department of the Environment, is able to contract with one medical waste company to service all pharmacies and another to collect from the police stations. The 13 pharmacies sites in San Francisco, which collect most of the waste, have a regularly scheduled pick-up every two weeks.

Recommendation: *Streamlining redundancy in terms of waste management would reduce disposal costs.*

Educational Outreach

Aside from direct-to-consumer public education, there are several constituencies that, if proper educational programs were developed, could significantly affect program results. Most notably are pharmacists, hospice nurses, physicians and nurses practitioners. These four professional health providers are the most closely connected with individual consumer medication usage.

Given that all four of these health professionals have ongoing required continuing education, a minimum of one-hour educational program, designed to provide the necessary evidenced-based information to these constituents could greatly improve take-back participation and advocacy. These programs would indicate the need for and the value of minimizing pharmaceutical waste as well as provide information about local take-back sites. This would likely influence the public, given the role of health professionals in general. Educating providers is perhaps the most cost-effective method of reaching consumers, given that direct-to-consumer marketing is expensive.

Another constituency that must be educated is hospital and medical administrators. Based on experience, it is likely that the healthcare administration will either lead the way or prove to be an obstacle to providing this valuable service. Both Eden Hospital and Washington Hospital have successful programs because both Chief Executive Officers recognized the value of the service.

Given the stream of ongoing marketing and promotional materials so many levels of healthcare, public health and environmental health systems, regularly informing the public as to the purpose, value and access to take-back disposal services is necessary for improving program outputs, though it can be costly to compete with other public health needs. The current system of educational promotion is inadequate to the task. Given the amount of waste collected annually and the increased demand and consumption, the outputs will continue to climb.

Recommendation: *Educational efforts directed at medical providers and medical administrators will improve citizen's knowledge, supporting increased utilization of take-back programs. On-going promotion of take-back services should use conventional and social media channels.*

Program Users: Socio-demographics

Program users were evenly split between people 41-65 years old and 65 and older. They were three-to-one likely to be female, and only half were bringing in medications solely for themselves. In terms of annual household income, there was a spread with 28% of the users earning under \$30,000, 28% earning \$71,000 to 105,000 and roughly 20% earning \$31,000-\$50,000 or above \$105,000. While the sample size was too small to draw conclusions from this data, the service is clearly reaching a broad spectrum of citizens. Given the concern for access, 28% participation from disadvantage community members in the program represents a positive result. With 23% of the respondents returning medicines for a deceased person, take-back services will continue to be essential for end-of-life service providers and families of the deceased.

Recommendations: *Further studies into the characteristics of program users are warranted. As the program outputs grow, opportunities for data collection will improve. Committing time and energy for a research assistant to canvas several take-back sites for one week would provide improved results.*

I CONSIDER IT A SUCCESSFUL PROGRAM

Liz Jimenez

Solid waste and Recycling Coordinator, City of San Leandro

"It's been a very successful program. It's welcomed by the community. And I can tell you that I don't get as many calls asking, "Where do I drop off my medication? I can't go the HHW facility." It seems to be a program that residents talk about and that they're communicating with one another. "You can go here. You can go there." So I consider it to be a successful program, definitely."

NEXT STEPS

The Safe MEDS Workgroup meetings have been visited by people outside of the county. The issue of unused medication in homes and teenage prescription abuse is not limited to the borders of the county. In 2011, the Safe MEDS Workgroup hosted its first conference, the *Safe Medicine Disposal Conference* at the Castro Valley Library. With over 100 attendees, the conference highlighted much of the regional progress in setting up take-back initiatives. Lieutenant Shelly James discussed the Contra Costa Program. Bill Chiang, legislative Aide to Adrienne Tissier, presented the San Mateo program, and Caitlin Sanders, San Francisco Department of the Environment, shared material from the launching of San Francisco's pilot program. Also featured at this conference was Burke Lucy, of CalRecycle, reviewing the assessment of take-back programs throughout California and the recommendations for a model take-back programs for the state.

On May 30 2013, the Safe MEDS Workgroup hosted the *2nd Alameda County Safe Medication Disposal Conference*, with the goal of sharing the ordinance and regulations with the wider audience. This second conference, created in partnership with the California Product Stewardship Council (CPSC) and Product Stewardship Institute (PSI) in Boston, MA, represented locations far beyond Alameda County. Heidi Sanborn, Executive Director of the CPSC, discussed current legislative efforts in California. Scott Cassel, Executive Director of PSI, reviewed more than a dozen states in the United States with take-back initiatives. Ginette Vanasse, the Executive Director of The Post Consumer Pharmaceutical Stewardship Association in Ottawa, Canada, shared her work overseeing fully operational programs in several provinces of Canada. Keynote speaker Stevan Gressitt, MD, of the International Institute of Pharmaceutical Safety, shared his thoughts on the movement towards safe medication disposal internationally.

In the 2014 legislative session for the state of California, the Senate recently passed SB 1014 on May 27th. This bill amends CalRecycle's Model Guidelines for Take-back Programs. SB 1014 would require CalRecycle to adopt regulations reauthorizing local entities to establish a voluntary program to collect and properly dispose of home-generated pharmaceutical waste. The regulations would be based on the Model Guidelines issued by CalRecycle in 2009 that allow local entities to operate voluntary drug take-back programs. The preexisting guidelines expired January 1st, 2013, but by reauthorizing and updating them, SB 1014 will provide clear direction for local governments, pharmacies and police departments that would like to operate safe and secure pharmaceutical take-back programs. Several key elements in

this Senate Bill include: the definition of Home Generated Pharmaceutical Waste (HGPW); an amendment to the current CalRecycle classification of HGPW as separate and distinct from Medial Waste; and authorization of pharmacies to accept the return of HGPW. Previous to SB 1014, unused medicine from consumers was still considered medical waste, meaning it was highly regulated and quite costly to capture for disposal. The bill still has not passed in the California State Assembly.

SB 1014 was authored by Senator Hannah-Beth Jackson, 19th district of the California Senate and it was co-sponsored in part, by the Alameda County Board of Supervisors and the California Product Stewardship Council, both organizations with regular members serving on the Safe MEDS Disposal Workgroup: Supervisor Nat Miley and Heidi Sanborn.



NOBODY WOULD HAVE TAKEN THIS ON AT THE STATE

Heidi Sanborn

Executive Director, California Product Stewardship Council

"Nobody would have taken this on at the state level had Alameda not done what it did. The reason is the lobby Pharma exerts its most influence at the federal level, the next most influence at the state level, and much less influence at the local level. So going from local to state is much harder, and nobody would have done that except to defend a county that had stuck its neck out trying to help prove that local governments could in fact pass resolutions and ordinances requiring that producers be responsible for what is sold in their jurisdiction. This was the first such requirement in the country not just for pharmaceuticals, but for anything. So, this entire movement to get producers to share in responsibility is literally hanging on the court case that Alameda is defending.

"We're one of five co-sponsors of SB 1014, and we're very proud of the co-sponsorship—Clean Water Action, Alameda County, City of San Francisco, California Association of Retired Americans along with CPSC. Everybody is pulling their weight, and they all bring different, important pieces to the bill. Everyone is working hard. I'm very proud of this coalition and the enormous amount and breadth of support we have received for the bill. If you look at the list of supporters versus opposition on the bill, I've never in my time seen a more lopsided list. Just a few associations of pharmaceutical companies are in opposition. And everyone from the sheriff's association to the veterinarian association to retired Americans and water groups and environmental groups, all supporting. It's astounding. Everyone in the capitol building is aware of the safe medicine disposal issue.

CONCLUSION

Certainly the Alameda County Safe Medication Disposal Initiative has had an impact. In simple terms, close to 14 tons of household generated pharmaceutical waste has been collected in 2013 alone from 31 sites distributed in about half of the county. As well, the initiative has led development and implementation of public policy that is currently in operation, though, regulatory legitimacy is disputed through a legal challenge that has the potential impede. Without knowing what the future brings, it is difficult to offer a firm conclusion. Yet, much has happened and will continue to happen. The 31 take-back sites continue to be open for collection.

The Pharmaceutical Product Stewardship Work Group, based in Washington, DC, is currently in discussion with the Alameda County Environmental Health Department in an effort to develop a stewardship plan that will provide a roadmap for the future of the program. The work of the Safe MEDS Workgroup provided a useful jumpstart for any new program run by the PPSWG. The gaps are easy to identify. Eden Hospital, Washington Hospital and the Alameda Sheriff's Station are the most productive take-back sites. Given the access to these sites as well as the ease of operations, locating and opening similar sites throughout the county would be cost-effective. With the success of these models, educating health executives and professionals should be the next priority.

Several policy changes are close to resolution at the time of writing this report. First, the United States Drug Enforcement Agency will update its regulations as to who can handle unused household controlled substances. This is expected to improve the ability for programs to safely collect and disposed of controlled medicines, which make up about 10% of this waste stream. The current regulation limits this to only law enforcement agents. Second, SB 1014 could become law in California. While not requiring take-back programs throughout the state, it would certainly continue the momentum towards improving the regulatory conditions for programs such as the Alameda County initiative to thrive. And finally, there is the legal challenge of the Alameda County Safe Drug Disposal Ordinance. If it is upheld, the regulations and the stewardship plan will continue to channel efforts towards improved program results. If overturned, the process will be reassessed. The 31 take-back locations in Alameda will continue to operate. Lessons learned from this report will inform next steps either way.

The Safe Medication Disposal Initiative continues to work its way through the channels of public policy, healthcare agencies, environmental health organizations and through the actions of citizens and professionals alike. The need for a method of stewarding home-generated pharmaceutical waste from our healthcare system will likely grow. The broader vision, cradle-to-cradle approaches to product development and distribution, is just beginning to be considered by the health care industry. The Safe MEDS Workgroup and Initiative has raised considerable awareness for those working for the health of all citizens.

APPENDICES

Appendix 1:

Agencies Operating Take-Back Sites

Alameda County Sheriff's Office (1)

Sergeant Bret Scheuller
510-667-7721
bscheuller@acgov.org

- Alameda County Sheriff's Office

Alta Bates Summit Medical Center (2)

Mary Reiter, Assistant Director of
Pharmacy-Outpatient Services ABSMC
510-869-8451
reiterm@sutterhealth.org
Hospital

- Milvia Outpatient Pharmacy
- Peralta Outpatient Pharmacy

City of Fremont (1)

Bruce Fritz, Household Hazardous Waste Manager
510-252-0500
bfritz@blt-enterprises.com
Government

- Fremont Recycling & Transfer Station
- Recycling Center

City of Hayward (1)

Erik Pearson, Environmental Services Manager
510-583-4770
erik.pearson@hayward-ca.gov
Government

- Ted's Drugs

City of San Leandro (3)

Liz Jimenez, Solid waste and
Recycling Coordinator
510-577-6026
ljimenez@sanleandro.org
Government

- City of San Leandro Public Works
- City of San Leandro Senior Center
- Davis Street Clinic

Alameda County Department of Environmental Health (4)

Bill Pollock, Program Manager
800-606-6606
bill.pollock@acgov.org
County Government

- Alameda County HHW Drop-off Site – Fremont
- Alameda County HHW Drop-off Site – Hayward
- Alameda County HHW Drop-off Site – Livermore
- Alameda County HHW Drop-off Site – Oakland

East Bay Municipal Utility District (10)

Audrey Comeaux, Environmental Services
Representative
510-287-1199
acomeaux@ebmud.com
Water Utility Agency

- Alameda Police Department
- Albany Senior Center
- Berkeley Transfer Station #3
- California State Building
- East Bay Municipal Utility Administration Bldg.
- El Cerrito Recycling Center*
- Emeryville Senior Center
- Oakland Fire Station #20
- Oakland Fire Station #3
- United Pharmacy

Eden Medical Center (1)

Christine Graham, Injury Prevention Specialist
510-727-3176
GrahamCJ@sutterhealth.org
Sponsored by
Castro Valley Sanitary
Jordan Figueiredo
jordan@cvsan.org

- Eden Medical Center

Appendix 1:

Agencies Operating Take-Back Sites

Oro Loma Sanitary District (1)

Rodney Smith, Industrial Waste Inspector
510-481-6971

rsmith@oroloma.org

Wastewater Utility Agency

- Medical Arts Pharmacy

Teleosis Institute (1)

Joel Kreisberg, Executive Director
510-558-7285

drkreisberg@teleosis.org

Non-profit

- Sal's Pharmacy

Union Sanitary District (7)

Mike Auer, Environmental Outreach Coordinator
510-477-7621

mikeauer@unionsanitary.com

Public Wastewater Utility

- Haller's Pharmacy and Medical Supply
- Haller's Pharmacy Newark
- Washington Hospital Community Health Resource Library
- Washington Hospital Main Lobby
- Washington Township Medical Group
- Washington Township Medical Group (at Nakamura Clinic)
- Washington Township Medical Group at Warm Springs



Haller's Pharmacy has been taking back medication for many years.

Appendix 2:

Take-Back Sites with Contact Information

Alameda County Sheriff's Office (1)

- Alameda County Sheriff's Office
15001 Foothill Blvd.
San Leandro, CA 94578
Sergeant Bret Scheuller
510-667-7721
Law Enforcement

Alta Bates Summit Medical Center (2)

- Milvia Outpatient Pharmacy
2500 Milvia Street, Suite 130"
Berkeley, CA 94704
Cathy Beachamp, Pharmacist
510-204-6550
beauchc@sutterhealth.org
Pharmacy
- Peralta Outpatient Pharmacy
3300 Webster Street,
Oakland, CA 94609
Sharon Leaf, Pharmacist
510-869-8835
leafs@sutterhealth.org
Pharmacy

City of Fremont (1)

- Fremont Recycling & Transfer Station
41149 Boyce Road
Fremont, CA 94538
800-606-6606
Recycling Center

City of Hayward (1)

- Ted's Drugs
27453 Hesperian Blvd.
Hayward, CA 94545
510-782-6494
Monta Patel, Pharmacist
tedsrx@yahoo.com
Pharmacy

City of San Leandro (3)

- City of San Leandro Public Works
14200 Chapman Rd.
San Leandro, CA 94578
510-577-3440
Liz Jimenez, Solid waste and
Recycling Coordinator
ljimenez@sanleandro.org
- City of San Leandro Senior Center
13909 E. 14th St
San Leandro, CA 94578
510-577-7990
Heather Hafer, Recreation Supervisor
510-577-6079
hhafer@sanleandro.org
Senior Center
- Davis Street Clinic
3081 Teagarden Street
San Leandro, CA 94577
510-347-4620
Carol Alvarez, Behavioral Health Director
iscalvarez@davisstreet.org
Medical Clinic

Alameda County Department of Environmental Health (4)

- Alameda County HHW Drop-off Site – Fremont
41149 Boyce Road
Fremont, CA 94538
Household Hazardous Waste Facility
- Alameda County HHW Drop-off Site - Hayward
2091 West Winton Avenue
Hayward, CA 94545
Household Hazardous Waste Facility
- Alameda County HHW Drop-off Site – Livermore
5584 La Ribera Street
Livermore, CA 94550
Household Hazardous Waste Facility
- Alameda County HHW Drop-off Site – Oakland
2100 E. 7th Street
Oakland, CA 94606
Household Hazardous Waste Facility

Appendix 2:

Take-Back Sites with Contact Information

East Bay Municipal Utility District (10)

- Alameda Police Department
1555 Oak Street
Alameda, CA 94501
510-337-8340
Barbara Leahy, Property Technician
510-337-8432
bleahy@ci.alameda.ca.us
Law Enforcement
- Albany Senior Center
846 Masonic Avenue
Albany, CA 94706
510-524-9122
Mary McKenna, Senior Services Coordinator
mmckenna@albanyca.org
Senior Center
- Berkeley Transfer Station #3
1201 2nd Street
Berkeley, CA 94710
510-981-7270
Wayne Anderson, Supervisor
510-812-5064
wanderson@CityofBerkeley.info
Recycling Center
- California State Building
1515 Clay Street
Oakland, CA 94612
510-287-1651
Bill Johnson, Water Resources Control Board
510-622-2354
bill.johnson@waterboards.ca.gov
Office Building
- East Bay Municipal Utility Administration Bldg.
375 Eleventh Street
Oakland, CA 94607
866-403-2683
Audrey Comeaux, Environmental Services
Representative
510-287-1199
acomeaux@ebmud.com
Office Building
- El Cerrito Recycling Center*
7501 Schmidt Lane
El Cerrito, CA 94530
510-215-4350
Garth Schultz, Operations and Environmental
Services Manager
510-559-7684
gschultz@ci.elcerrito.ca.us
Recycling Center
- Emeryville Senior Center
4321 Salem Street,
Emeryville, CA 94608
510-596-3730
Brad Helfenberger, Youth and Adult Services
Manager
510-596-3779
bhelfenberger@ci.emeryville.ca.us
Senior Center
- Oakland Fire Station #20
1401 98th Avenue at International Blvd.
Oakland, CA 94603
510-569-2568
Dan Girard, EMS Officer
415-317-0615
DGerard@oaklandnet.com
Fire Station
- Oakland Fire Station #3
1445 14th Street at Mandela Pkwy.
Oakland, CA 94607
510-238-4003
Dan Gerard, EMS Officer
415-317-0615
DGerard@oaklandnet.com
Fire Station
- United Pharmacy
2929 Telegraph Avenue
Berkeley, CA 94705
510-843-3201
Pamela Gumbs, Pharmacist
510-843-3201
Pharmacy

Appendix 2:

Take-Back Sites with Contact Information

Eden Medical Center (1)

- Eden Medical Center
20103 Lake Chabot Road
Castro Valley, CA 94546
510-537-1234
Linda Scott Hickman
510-727-3211
hickmanl@sutterhealth.org
Hospital

Oro Loma Sanitary District (1)

- Medical Arts Pharmacy
13847 E. 14th Street
San Leandro, CA 94578
510-357-1881
Roland Cong, Pharmacist
510-357-1881
Pharmacy

Teleosis Institute (1)

- Sal's Pharmacy
1831 Solano Avenue
Berkeley, CA 94707
510-525-6500
Sal Nassar, Pharmacist
info@salspharmacy.com
Pharmacy

Union Sanitary District (7)

- Haller's Pharmacy and Medical Supply
37323 Fremont Blvd
Fremont, CA 94536
510-797-2772
Aarondeep Basrai, Pharmacist
510-366-8287
aarondeep@hallsrx.com
Pharmacy
- Haller's Pharmacy Newark
6170 Thorton Ave
Newark, CA 94560
510-797-4333
Russell Blowers, Pharmacist
russ@hallsrx.com
Pharmacy

- Washington Hospital Community Health
Resource Library
2500 Mowry Ave
Fremont, CA 94538
510-477-7621
Paul Kelley, Director of Biomedical Engineering,
Green Initiative and Asset Redeployment
510-791-3493
paul_kelley@whhs.com
Hospital
- Washington Hospital Main Lobby
2000 Mowry Ave
Fremont, CA 94538
510-797-1111
Paul Kelley
510-791-3493
paul_kelley@whhs.com
Hospital
- Washington Township Medical Group
6236 Thornton Ave
Newark, CA 94560
510-477-7621
Paul Kelley
510-791-3493
paul_kelley@whhs.com
Medical Clinic
- Washington Township Medical Group
(at Nakamura Clinic)
33077 Alvarado Niles Rd
Union City, CA 94587
510-477-7621
Paul Kelley
510-791-3493
paul_kelley@whhs.com
Medical Clinic
- Washington Township Medical Group
at Warm Springs
46690 Mohave Drive
Newark, CA 94560
510-477-7621
Paul Kelley
510-791-3493
paul_kelley@whhs.com
Medical Clinic

Appendix 3:

Waste Disposal Services Companies

Barnett Medical Services

barnettmedservices.com

Guarantee Returns

www.guaranteedreturns.com

Clean Harbors

www.cleanharbors.com

North State Environmental

www.north-state.com

Covanta

www.covanta.com

Sharps Solutions

www.sharps-solutions.com

Appendix 4:

Websites and Promotion

Alameda County Safe Medicine Disposal Initiative

www.acseniors-medisposal.net/index.html

Alameda County Safe MEDS Facebook page

www.facebook.com/AlamedaSafeMeds

Alameda County Safe Medicine Disposal Twitter Feed

@AICoSafeMeds

California Product Stewardship Council/Pharmaceuticals

www.calpsc.org/products/pharmaceuticals

City of San Leandro: Safe Medication Disposal

www.sanleandro.org/depts/pw/es/safe_medicine_disposal.asp

East Bay Municipal Utility District: Dispose Medicine Safely

www.ebmud.com/water-and-wastewater/pollution-prevention/dispose-medicines-safely

Save The Bay Pharmaceutical Disposal Sites

www.savesfbay.org/pharmaceutical-disposal-sites

StopWaste: Proper Pharmaceutical Disposal

<http://www.stopwaste.org/home/index.asp?page=1170>

Teleosis Institute

www.teleosis.org/green-pharmacy

Union Sanitary District Permanent Medicine Drop-off Sites

www.unionsanitary.com/safeMedicineDisposal.htm

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance**

http://www.acgov.org/sustain/documents/ac_safe_drug_disposal_ordinance.pdf

ORDINANCE NO. O-2012-27

ORDINANCE AMENDING THE ALAMEDA COUNTY ORDINANCE CODE BY ADDING CHAPTER 6.53, SECTIONS 6.53.010 THROUGH 6.53.120 TO: REQUIRE ANY PERSON WHO PRODUCES A DRUG OFFERED FOR SALE IN ALAMEDA COUNTY TO PARTICIPATE IN AN APPROVED DRUG STEWARDSHIP PROGRAM FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS FROM RESIDENTIAL SOURCES; PROVIDE FOR IMPLEMENTATION, ENFORCEMENT, FEES, AND PENALTIES; AND MAKING ENVIRONMENTAL FINDINGS.

WHEREAS, the County of Alameda has a substantial interest in, and a substantial need for, a drug stewardship program; and

WHEREAS, the health and welfare of the residents of the County of Alameda, particularly children and the elderly, would be improved and advanced by the proper disposal of unwanted, expired or unneeded prescription drugs;

NOW THEREFORE, the Board of Supervisors of the County of Alameda ordains as follows:

Title 6 of the Alameda County Health and Safety Code is hereby amended by adding Chapter 6.53, Sections 6.53.010 through 6.53.120, to read as follows:

6.53.010 - Declaration of findings.

The Board of Supervisors hereby finds and declares the following:

- A. Prescription Drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives;
- B. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription drugs and the illegal re-sale of prescription drugs;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription drugs passing through our wastewater and treatment centers;
- D. There is no mandatory statewide drug stewardship program for unwanted drugs in California, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

Section 6.53.020 - Title

This Chapter may be cited as the "Alameda County Safe Drug Disposal Ordinance."

Section 6.53.030 - Definitions.

For the purposes of this Chapter, the following terms have the meanings given.

1. "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.
2. "Cosmetics" means (i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (ii) articles intended for use as a component of any such articles, and (iii) cosmetics as defined above with expiration dates.
3. "Covered Drug" means all drugs as defined in 21 U.S.C. § 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. § 353(b)(1) of the FFDCA, including both brand name and Generic Drugs.

"Covered Drug" does not include: (i) Vitamins or supplements; (ii) Herbal-based remedies and homeopathic drugs, products, or remedies; (iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, 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 ("FFDCA") (21 U.S.C. Sec. 301 et seq. (2002)); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1); (v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Section if the Producer already provides a take-back program; (vi) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems; and (vii) nonprescription drugs.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

4. "Department" means the Alameda County Department of Environmental Health.
5. "Drug Wholesaler" means a business that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.
6. "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.

"Drugs" does not mean medical devices, their component parts or accessories, or a Covered Drug contained in or on medical devices or their component parts or accessories.
7. "Entity" means a person other than an individual.
8. "Generic Drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.
9. "Mail-Back Program" means a system whereby Residential Generators of Unwanted Products obtain prepaid and preaddressed mailing envelopes in which to place Unwanted Products for shipment to an Entity that will dispose of them safely and legally.
10. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.
11. "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal Entity, however organized.
12. "Plan" or "Product Stewardship Plan" means a product stewardship plan required under this Chapter that describes the manner in which a Product Stewardship Program will be provided.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

13. "Prescription Drug" means any drug that by federal or state law may be dispensed lawfully only on prescription.
14. "Producer" shall be determined, with regard to a Covered Drug that is sold, offered for sale, or distributed in Alameda County as meaning one of the following:
 - (i) The Person who manufactures a Covered Drug and who sells, offers for sale, or distributes that a Covered Drug in Alameda County under that Person's own name or brand.
 - (ii) If there is no Person who sells, offers for sale, or distributes the Covered Drug in Alameda County under the Person's own name or brand, the producer of the Covered Drug is the owner or licensee of a trademark or brand under which the Covered Drug is sold or distributed in Alameda County, whether or not the trademark is registered.
 - (iii) If there is no Person who is a producer of the Covered Drug for purposes of paragraphs (i) and (ii), the producer of that Covered Drug is the Person who brings the Covered Drug into Alameda County for sale or distribution.

"Producer" does not include (i) a retailer that puts its store label on a Covered Drug or (ii) a pharmacist who dispenses Prescription Drugs to, or compounds a prescribed individual drug product for a consumer.
15. "Product Stewardship Program" or "Program" means a program financed and operated by Producers to collect, transport, and dispose of Unwanted Products.
16. "Residential Generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned. "Residential Generators" do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.
17. "Stewardship Organization" means an organization designated by a group of Producers to act as an agent on behalf of each Producer to operate a Product Stewardship Program.
18. "Unwanted Product" means any Covered Drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance****Section 6.53.040. - Product Stewardship Program.**

A. Requirement for sale. This Chapter shall apply only to a Producer whose Covered Drug is sold or distributed in Alameda County. This Chapter shall apply to all of Alameda County including unincorporated and incorporated areas, except for those incorporated areas (cities) where the governing body of that incorporated area (city) has authorized its own local health officer or environmental health director to administer and enforce the provisions of California Health and Safety Code section 117800. This Chapter shall be administered and implemented by the Alameda County Department of Environmental Health. Each Producer must:

1. Operate, individually or jointly with other Producers, a Product Stewardship Program approved by the Department; or
2. Enter into an agreement with a Stewardship Organization to operate, on the Producer's behalf, a Product stewardship Program approved by the Department.

B. Product Stewardship Program costs.

1. A Producer, group of Producers, or Stewardship Organization must pay all administrative and operational fees associated with their Product Stewardship Program, including the cost of collecting, transporting, and disposing of Unwanted Products collected from Residential Generators and the recycling or disposal, or both, of packaging collected with the Unwanted Product.
2. A Producer, group of Producers, or Stewardship Organization must pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.), if required, for a specific Product Stewardship Program and product stewardship Plan.
3. No Person or Producer may charge a specific point-of-sale fee to consumers to recoup the costs of their Product Stewardship Program, nor may they charge a specific point-of-collection fee at the time the Unwanted Products are collected from Residential Generators or delivered for disposal.
4. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the County of Alameda, including but not limited to the Department, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the County of Alameda shall only recover its actual costs of administration and enforcement under this Ordinance and shall

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

not charge any amounts under this Ordinance in excess of its actual administrative and enforcement costs.

6.53.050 - Product stewardship plan.

A. Plan content. Each Product Stewardship Program shall have a product stewardship Plan that contains each of the following:

1. Certification that the Product Stewardship Program will accept all Unwanted Products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the Plan;
2. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program;
3. A description of the methods by which Unwanted Products from Residential Generators will be collected in Alameda County and an explanation of how the collection system will be convenient and adequate to serve the needs of Alameda County residents;
4. A description of how the product stewardship Plan will provide collection services for Unwanted Products in all areas of Alameda County that are convenient to the public and adequate to meet the needs of the population in the area being served.
5. The location of each collection site and locations where envelopes for a Mail-Back Program are available (if applicable);
6. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each Person that will be involved in transporting Unwanted Products and each medical waste or hazardous disposal facility proposed to participate in the Product Stewardship Program;
7. A description of how the Unwanted Products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;
8. A description of the public education and outreach activities required under this Chapter and how their effectiveness will be evaluated;

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

9. A description of how the scope and extent of the Product Stewardship Program are reasonably related to the amount of Covered Drugs that are sold in the County of Alameda, by the Producer or group of Producers;
 10. A starting date when collection of Unwanted Products will begin;
 11. A description of how support will be provided to any law enforcement agencies within Alameda County that have, or later agree to have, a collection program for Controlled substances, including: (i) the provision of a collection kiosk with appropriate accessories and signage, (ii) an ability to accept Controlled Substances and other Covered Drugs, (iii) technical support up to and including an appropriate Person to provide on-site assistance with the sorting and separation of Controlled Substances at no cost to a participating law enforcement agency. Otherwise, Controlled Substances are expressly excluded from this Chapter notwithstanding any other provision contained herein;
 12. A description of how collection sites for Unwanted Products may be placed at appropriate retail stores in Alameda County including a description of the involvement of the retail store. Retailers are not required or mandated to host collection sites and nothing in this Ordinance shall be interpreted as requiring such participation; and
 13. If more than one Producer will be involved in a proposed Product Stewardship Program, then the product stewardship Plan for that Program must include a fair and reasonable manner for allocating the costs of the Program among the participants in that Program, such that the portion of costs paid by each Producer is reasonably related to the amount of Covered Drugs that Producer sells in the County of Alameda.
- B. Department review and approval; updates.
1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with this Ordinance until it has received written approval of its product stewardship Plan from the Department.
 2. Product stewardship Plans must be submitted to the Department for approval. The initial Plans must be submitted by July 1, 2013, or at a later date as approved in writing by the Department.
 3. Within 180 days after receipt and review of a product stewardship Plan, the Department shall conduct a noticed public hearing and

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

determine whether the Plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter.

- a) As part of its approval, the Department may set reasonable performance goals for the Program.
 - b) If the Department approves a Plan, it shall notify the applicant of its approval in writing.
 - c) If the Department rejects a Plan, it shall notify the applicant in writing of its reasons for rejecting the Plan. The Department may reject a Plan without conducting a public hearing.
 - d) An applicant whose Plan has been rejected by the Department must submit a revised Plan to the Department within 60 days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, in its sole discretion, the Department may develop, approve and impose its own product stewardship Plan or an approved Plan submitted by other Producer(s) pursuant to this Ordinance. The imposed Plan will be presented at the public hearing. The Department is not required, and nothing in this Ordinance shall be interpreted as requiring, the Department to create or impose a product stewardship Plan.
 - e) If the Department rejects a revised Product Stewardship Plan or any other subsequently revised Plan, the Producer(s) at issue shall be out of compliance with this Chapter and are subject to the enforcement provisions contained in this Chapter. If the Department imposes its own or another Plan the Producer(s) at issue shall not be considered out of compliance with this Chapter if they comply with that Plan. However, the Producers shall be subject to the enforcement provisions contained in this Chapter as they relate to compliance with an approved Plan.
4. At least every three years, a Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program shall update its product stewardship Plan and submit the updated Plan to the Department for review and approval.
 5. A Producer who begins to offer a Covered Drug for sale in the County of Alameda after July 1, 2013, must submit a product stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within 180 days following the Producer's initial offer for sale of a Covered Drug.

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance**

6. Any proposed changes to a product stewardship Plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

6.53.060 - Disposal of Unwanted Products.

A. Compliance with applicable law. Each Product Stewardship Program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of medical waste and Controlled Substances.

B. Disposal at medical waste or hazardous waste facility. Each Product Stewardship Program must dispose of all Unwanted Products by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must be in possession of all required regulatory permits and licenses.

C. Producers with Product Stewardship Programs may petition the Department for approval to use final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for Covered Drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

1. Monitoring of any emissions or waste;
2. Worker health and safety;
3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and,
4. Overall impact on the environment and human health.

D. Packaging separation. Each Product Stewardship Program shall encourage Residential Generators to separate Unwanted Products from their original containers, when appropriate, prior to collection or disposal.

6.53.070 - Product Stewardship Program promotion and outreach.

A. A Product Stewardship Program must promote the Product Stewardship Program to Residential Generators, pharmacists, retailers of Covered Drugs, and health care practitioners as to the proper and safe method to dispose of Unwanted Products.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

B. A Product Stewardship Program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of Covered Drugs. These materials may include, but are not limited to, one or more of the following:

1. Signage that is prominently displayed and easily visible to the consumer.
2. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
3. Advertising and/or other promotional materials related to the Product Stewardship Program.

C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Alameda County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The Program also must establish a website publicizing collection locations and Program operations and a toll-free telephone number that Residential Generators can call to find nearby collection locations and understand how the Program works.

6.53.080 - Report

A. On or before July 1, 2014 (or at a later date as approved in writing by the Department) and in each subsequent year, every Producer, group of Producers, or Stewardship Organization operating a Product Stewardship Program must prepare and submit to the Department an annual written report describing the Program's activities during the previous reporting period. The report must include the following:

1. A list of Producers participating in the Product Stewardship Program;
2. The amount, by weight, of Unwanted Products collected from Residential Generators collected at each drop-off site and in the entire County of Alameda and , if applicable, the total amount by weight collected by a Mail-Back Program;
3. A description of the collection system, including the location of each collection site and , if applicable, locations where envelopes for a Mail-Back Program are provided;

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

4. The name and location of disposal facilities at which Unwanted Products were disposed of and the weight of Unwanted Products collected from Residential Generators disposed of at each facility;
5. Whether policies and procedures for collecting, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;
6. Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;
7. A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and Program activities;
8. How the Product Stewardship Program complied with all other elements in the product stewardship Plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the Program; and
9. Any other information that the Department may reasonably require.

B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

6.53.090. – List of Producers. The Department shall provide on its website a list of all Producers participating in Product Stewardship Programs approved by the Department and a list of all Producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

6.53.100. - Regulations and fees.

A. The Director of the Department of Environmental Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter.

B. As soon as practicable, the Department shall submit to the Board of Supervisors a proposed schedule of fees to be charged to the Producers to cover Alameda County's costs of administering and enforcing this Ordinance.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

6.53.110. - Enforcement.

A. The Department of Environmental Health shall administer the penalty provisions of this Chapter.

B. The Department of Environmental Health may issue an administrative citation to a Producer for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written warning to the Producer as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The Producer shall have 30 days after receipt of the warning to comply and correct any violations.

C. If the Producer fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.

D. Any Person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Alameda 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 and distinct violation.

E. In determining the appropriate penalties, the Department of Environmental Health 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.

F. Any Producer receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County of Alameda holiday, then the deadline shall be extended until the next regular business day.

The request to appeal must:

1. Be in writing;
2. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
3. Specify the basis for the appeal in detail;

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance**

4. Be postmarked within 21 days from the date the administrative citation was issued; and
5. Be sent to the address as set forth on the administrative citation.

G. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a hearing officer designated by the Director of the Department of Environmental Health. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the Producer appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.

H. Failure of any Producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that Producer's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that Producer to exhaust administrative remedies.

I. The Producer requesting the appeal may request the Director of the Department of Environmental Health to recuse a hearing officer for reasons of actual prejudice against the party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence as follows:

1. A valid administrative citation shall be prima facie evidence of the violation;
2. Testimony shall be by declaration under penalty of perjury except to the extent the hearing officer permits or requires live testimony concerning the violation.
3. The hearing officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The hearing officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.
4. The hearing officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer Decision"). The Hearing Officer Decision shall be served by first class mail on the Producer appealing and the Department. The Hearing Officer Decision affirming or dismissing the administrative citation is final, unless a timely notice of appeal is filed for hearing by the Board of Supervisors of the County of Alameda.

- J. A second appeal may be filed with the Board of Supervisors within ten calendar days after the date of service of the Hearing Officer Decision.

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

1. The appeal may be taken by any Producer or the Department within said ten-day period, by filing with the clerk of the Board of Supervisors a notice of appeal specifying the grounds for such appeal. The Board of Supervisors shall not hear any appeal that is untimely filed.
2. Upon receiving an appeal, the Clerk of the Board of Supervisors shall indicate upon every notice of appeal received the date upon which it was filed. The Department shall immediately arrange for an administrative record to be made available to the Board of Supervisors of all of the documents constituting the record upon which the action appealed was taken.
3. The Board of Supervisors shall give written notice of the time and place for a public hearing on any appeal filed pursuant to this section to the appellant and the Department.
4. The Board of Supervisors may hear additional evidence in its sole discretion and may sustain, modify or overrule any order brought before it on appeal.
5. The Board of Supervisors may make such findings and decisions as are consistent with state law and the County of Alameda Ordinances. If no motion relative to the Hearing Officer Decision appealed attains a majority vote of the Board of Supervisors within thirty (30) days from the date of the hearing by said board thereon, the Hearing Officer Decision shall stand sustained and be final.

K. The Department of Environmental Health may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

L. Upon the failure of any Producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the Alameda County Counsel's Office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such Person from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not permit the County of Alameda or any court of competent jurisdiction to restrain the sale of any Covered Drug in Alameda County.

M. 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 may be prosecuted by the Alameda County District Attorney's Office. A conviction for a misdemeanor violation under this Chapter is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500) for each day per

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance**

violation, or by imprisonment in the Alameda County Jail for a period not to exceed six (6) months, or by both such fine and imprisonment.

6.53.120 - Additional provisions.

A. **Disclaimer.** In adopting and implementing this Chapter, the County of Alameda is assuming an undertaking only to promote the general welfare. Alameda County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any Person or Entity who claims that a breach proximately caused injury.

B. **Conflict with State or Federal Law.** 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 Alameda County 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. Alameda County shall suspend enforcement of this Ordinance to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted.

C. **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.

D. **Environmental Findings.** The County of Alameda 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.).

E. **Nothing in this Ordinance, or the Program of stewardship in which manufacturers of pharmaceutical products who sell Prescription Drugs in Alameda County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Ordinance be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of California or of the United States.**

F. **This Ordinance shall be construed in accordance with California state law, including but not limited to the Medical Waste Management Act set forth at California Health and Safety Code sections 117600, et seq., and shall not be construed in a way that would result in conflict with, or preemption by, any such state law.**

G. **This Ordinance is entitled to a categorical exemption of the California Environmental Quality Act ("CEQA") pursuant to 14 California Code of Regulations section 15307, which exempts "actions taken by regulatory agencies, as authorized by state or local ordinance, to assure the maintenance, restoration, enhancement, or**

Appendix 5:**Alameda County Safe Medicine Disposal Ordinance**

protection of the environment where the regulatory process involves procedures for protection."

H. This Chapter shall be in effect for a period of ten (10) years following enactment.

Adopted by the Board of Supervisors of the County of Alameda, State of California, on July 24, 2012, by the following called vote:

AYES: Supervisors Carson, Chan, Haggerty, Valle and
President Miley -5

NOES: None

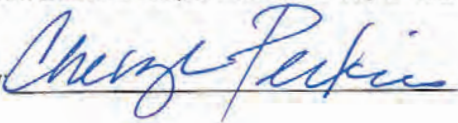
EXCUSED: None



NATE MILEY, President
Board of Supervisors
County of Alameda, State of California

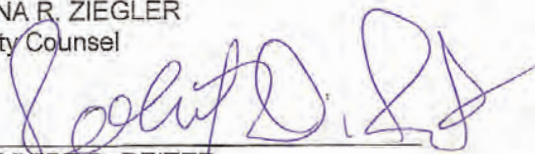
ATTESTED TO:

Clerk Board of Supervisors, County of Alameda

By: 

APPROVED AS TO FORM:

DONNA R. ZIEGLER
County Counsel

By: 
ROBERT D. REITER
Deputy County Counsel

Appendix 5:

Alameda County Safe Medicine Disposal Ordinance

ALAMEDA COUNTY BOARD OF SUPERVISORS

MINUTE ORDER

The following was action taken by the Board of Supervisors on July 24, 2012

Approved as Recommended ☒ Other ☐

Read title, waived reading of ordinance in its entirety and adopted Ordinance O-2012-27

Unanimous ☒ Carson ☐ Chan ☐ Haggerty ☐ Haggerty ☐ Miley ☐ - 5

Vote Key: N=No; A=Abstain; X=Excused

Documents accompanying this matter:

☐ Resolution(s) _____

☒ Ordinance(s) O-2012-27

☐ Contract(s) _____

File No. 28292

Item No. 69

Copies sent to:

Kamika Dunlap

Special Notes:



I certify that the foregoing is a correct copy of a Minute Order adopted by the Board of Supervisors, Alameda County, State of California.

ATTEST:

Crystal Hishida Graff, Clerk of the Board
Board of Supervisors

By: 

Deputy

Appendix 6:**Alameda County Safe Drug Disposal Regulations**

<http://www.acgov.org/aceh/safedisposal/documents/SDD-Regulations.pdf>

Alameda County Safe Drug Disposal REGULATIONS

Section 1 – Authority for Regulations

These Regulations were developed under the authority of the Alameda County General Ordinance Code, Chapter 6.53, the Alameda County Safe Drug Disposal Ordinance (the "Ordinance") to provide clarification and direction for its implementation.

Unless defined herein, the capitalized terms in these Regulations have the same meaning as set forth in the Ordinance.

Section 2 – Definitions

"Administrative Citation" means a citation issued by the Department for a violation of the Ordinance or Regulations.

"Alternative Plan" means a Plan imposed by the Department as a result of failure to timely submit an adequate Revised Plan.

"Annual Report" means the annual report required to be submitted by Plan Owners for each approved Plan describing the activities during the previous reporting period and other information as required by the Ordinance, Regulations and the Department.

"Annual Report Data" means the portion of the Annual Report containing numerical data relating to activities under the Plan.

"Annual Report Narrative" means the portion of the Annual Report containing descriptions, summaries and explanations of the collection efforts, other Plan efforts over the previous year, and future goals of the Plan.

"Collection Point" means a physical location with a secure drop-off kiosk to receive Unwanted Products at no cost to the individual. Collection Points may be located at hospitals, pharmacies, or other convenient physical sites.

"Department" means the Alameda County Department of Environmental Health.

Appendix 6:**Alameda County Safe Drug Disposal Regulations**

"Disposal Facility" means a facility that receives, holds or incinerates Unwanted Products collected under a Plan.

"Department Liaison" means the Environmental Health Safe Drug Disposal Liaison, who is the contact for the Department for issues relating to the Ordinance or Regulations.

"Fee Schedule" means the schedule of estimated time and cost to the Department for administration and enforcement of the Ordinance and Regulations, and includes the hourly rate which has been approved by the Alameda County Board of Supervisors.

"Law Enforcement Liaison" means the individual that will act as a liaison to law enforcement agencies for the Plan, and may be the same person as the Plan Liaison.

"Petition For Exception" means a written request to the Department for an exception from or exemption to any requirement of the Ordinance or Regulations.

"Plan Deposit" means the money lodged with the Department to be applied by the Department to cover the fees to be charged to cover the actual cost for administration and enforcement of the Ordinance and Regulations.

"Plan Liaison" means the primary contact for a Plan.

"Plan Owner" means the entity, individual or organization that submits and implements a Plan.

"Producer Contact" means the primary contact for a Producer of a Covered Drug. The Producer Contact is the person authorized to receive notices related to the Ordinance, Regulations and Plan. The Producer Contact cannot be the Plan Liaison.

"Public Hearing" means the noticed public hearing at which the Department will determine whether a Plan complies with the requirements of the Ordinance and these Regulations.

"Revised Plan" means the proposed Plan that must be submitted following rejection of an initial Plan by the Department.

"Transporter" means an individual or entity that is registered with the United States Environmental Protection Agency as a Hazardous Waste Hauler and that is permitted and authorized to haul medical waste under the California Medical Waste Management Act (Health and Safety Code Section 117600 et seq.).

Appendix 6:

Alameda County Safe Drug Disposal Regulations

Section 3 – Fees

- A. Fees shall be charged based on an hourly rate that is approved by the Board of Supervisors. The Fee Schedule can be found at the Alameda County Environmental Health web site at <http://www.acgov.org/aceh>.
- B. The activities and estimated hours contained in the Fee Schedule may from time to time be amended by the Department and the hourly rate may from time to time be amended as approved by the Board of Supervisors.
- C. Upon request by the Department, the Plan Owner shall pay to the Department an initial sum of at least \$10,000 for a Plan Deposit to cover the actual cost for administration and enforcement of the Ordinance and Regulations. At any time a deposit is required, if the balance of the Plan Deposit is less than cost of the action(s) to be taken by the County to administer or enforce the Ordinance or Regulations (based on an estimated of hours to conduct the actions), an additional payment to bring the Plan Deposit balance to the greater of \$2500.00 or the estimated cost of the activity being requested. Failure to pay a Plan Deposit or fees or costs as required pursuant to the Fee Schedule is a violation of the Ordinance and Regulations.
- D. In addition to the fees and costs to the Department identified in the Fee Schedule, the County may also charge Producers for actual costs incurred by other departments and agencies of the County that assist in administration and enforcement of the Ordinance.
- E. The fees collected by the County pursuant to the Ordinance or Regulations shall not exceed the County's actual cost of administering and enforcing the Ordinance and Regulations.

Section 4 – Communications with Department

- A. **Department Contact Information.** The contact for the Department for all issues relating to the Ordinance and Regulations shall be the Department Liaison. All information or notices required by the Ordinance or Regulations to be sent to the Department shall be sent to the Department Liaison by e-mail, unless the Ordinance or Regulations specify otherwise.
 - i. **Written Submissions:**
 - a. All Plans and other materials should be submitted electronically to the Department Liaison at:

SafeDrugDisposalLiaison@acgov.org

Appendix 6:**Alameda County Safe Drug Disposal Regulations**

- b. The Department Liaison's mailing address is:

Safe Drug Disposal
Alameda County Environmental Health
1131 Harbor Bay Parkway
Alameda, CA 94502-6577

- ii. **Questions.** Questions regarding the Ordinance or Regulations should be directed to the Department Liaison at (510) 567-6700 or by sending an e-mail to the Department Liaison.

B. Producer Contact Information

- i. **Initial Contact.** Producers subject to the Ordinance shall identify themselves by a letter delivered to the Department prior to the date on which Plans must be submitted to the Department. The initial letter should include the e-mail address, telephone number and mailing address for the Producer Contact. The Department may request that a Producer provide the information required by this section prior to the date on which Plans are required to be submitted to the Department.
- ii. **Notification of Participation in Product Stewardship Organization.** A Producer that participates in a Stewardship Organization must notify the Department. The notification must identify the Producer and include the name, address, e-mail, telephone number and contact person for the Stewardship Organization.

- C. **Department Consultation.** The Department Liaison is available to discuss the requirements of the Ordinance and Regulations, to discuss draft Plans, to answer questions about the Ordinance and Regulations, and to assist Producers or Stewardship Organizations, including setting goals and estimates for Plans. The Department encourages Producers and Stewardship Organizations to consult with the Department Liaison prior to filing a Plan.

Section 5 – Producers

- A. **Determination of Producer.** The Department shall determine who qualifies as a Producer of a Covered Drug. The Safe Drug Disposal Ordinance is based on the principle of Extended Producer Responsibility and requires that the cost of disposal of

Appendix 6:

Alameda County Safe Drug Disposal Regulations

Covered Drugs be borne by the person(s) who sells, offers for sale, or distributes the Covered Drugs into Alameda County.

- i. Any prescription drug sold, offered for sale, or distributed in Alameda County in any form including, but not limited to, drugs in medical devices and combination products, both brand name and generic drugs and drugs for veterinary use are considered Covered Drugs.
- ii. Medical devices and their component parts or accessories are not drugs even if there are residuals of a Covered Drug contained in or on used medical devices or their component parts or accessories.
- iii. A manufacturer or distributor of medical devices that when sold do not have covered drugs in them will not be considered a Producer, unless they also separately meet the definition of Producer.
- iv. A Producer is a person or entity that causes a Covered Drug to be manufactured. A manufacturer that does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if the Covered Drug it manufactures is sold, offered for sale, or distributed in Alameda County by another Person. Accordingly, as used in Section 6.53.030 of the Ordinance, paragraph 14(i), the terms "sells, offers for sale, or distributes" includes all sales, offers for sale, or distribution regardless of whether or not the Covered Drug is sold, offered for sale, or distributed by someone other than the manufacturer, such as by an independent wholesaler or distributor.
- v. A person or entity that has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County who does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if that Covered Drug is sold, offered for sale, or distributed in Alameda County by any other Person. Accordingly, as used in Section 6.53.030, paragraph 14(ii) of the Ordinance, the terms "sells, offers for sale, or distributes" includes all sales, offers for sale, or distribution regardless of whether by a Person who has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County or by someone else.

Appendix 6:**Alameda County Safe Drug Disposal Regulations**

- vi. The following are considered biological products which are not Covered Drugs if the Producer already has a take back program in place: vaccines derived from biological products and therapeutic serum. (Biological products are defined in 21 Code of Federal Regulation 600.3(h)).

B. Petition for Exemption

- i. A Producer whose Covered Drugs are made available exclusively to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act, may petition the Department for an exemption from the Ordinance.
- ii. A Petition for an exemption under this section must include the following:
 - a. The petitioning Producer's name and United States business address;
 - b. The trade and chemical name of the Producer's Covered Drugs;
 - c. A description of the uses of each of the Producer's Covered Drugs;
 - d. A description of how each Covered Drug is distributed in Alameda County;
 - e. A declaration under penalty of perjury that the Producer's Covered Drugs are exclusively available to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act and that the Covered Drugs are not dispensed directly to the public;
 - f. A showing that Producer's Unwanted Products are being safely disposed; and
 - g. A deposit for the estimated cost to the County of review, consideration and response to the petition, as set forth in the Fee Schedule.
- iii. The Department shall have the discretion to grant or deny any Petition for exemption made under this section.
- iv. Any exemption, if granted, will specify the time period for the exemption, up to three (3) years. A request for renewal of an exemption must be submitted to the

Appendix 6:

Alameda County Safe Drug Disposal Regulations

Department at least six (6) months before the expiration date. Late requests for exemption renewals will be subject to penalties, including but not limited to late fees and costs to be determined by the Department.

Section 6 – Submission of Plans

- A. **Submission.** For Producers subject to the Ordinance on or before July 1, 2013, Plans must be submitted no later than May 1, 2014.
- B. **Petition For Later Submission Date.** A written petition may be filed for an extension of the deadline to submit a Plan to the Department. Petitions for a later submission date must be received by the Department Liaison no later than five (5) weeks prior to the deadline for submission of a Plan.
 - i. **Petition Contents.** A written petition for an extension must include the following:
 - a. The proposed extension date;
 - b. An explanation of why an extension is needed;
 - c. Justification for the proposed extension;
 - d. A brief summary of the current status of the draft Plan; and
 - e. A deposit for the estimated cost to the County of review, consideration and response to the petition.
- C. **Late Plan Submissions.** If any Producer does not submit a Plan by the date set forth in paragraph A, or has not submitted a Plan by a later date granted by the Department, such Producer(s) shall be subject to the enforcement provisions of Section 6.53.110 of the Ordinance, including penalties.
- D. **Plan Owners.** A Plan shall be submitted by its Plan Owner, which may be a Producer or any other organization, entity or individual. A Plan may be submitted for approval even if no Producers are participating in the Plan. A Product Stewardship Program may be a Plan Owner. A Product Stewardship Program may be (1) financed and operated by a Producer or Producers or (2) operated by a company, individual or other entity that is retained and compensated by a Producer or Producers to meet the obligations of the Producer or Producers under the Ordinance.
- E. **Preliminary Review of Plan.** Plan Owners may submit a draft Plan prior to the date set forth in paragraph A deadline for preliminary review and comment by the Department. Plan Owners are encouraged to contact the Department to discuss their Plan at least three months prior to the deadline for Plan submission.

Appendix 6:**Alameda County Safe Drug Disposal Regulations****Section 7 – Plan Content**

A. **General Information.** A Plan must contain the following general information:

i. **Contact Information.**

a. **Plan Participants.** Identification of the Plan Owner(s) and the Producer Contacts for all Producers participating in the Plan. Identification of the Producer Contact shall include an e-mail address, telephone number and mailing address. Any change in Plan Owner or the Producers participating in a Plan must be provided to the Department within 30 days of the change.

b. **Plan Liaison.** Identification of the Plan Liaison shall include an e-mail address, telephone number and mailing address. The Plan Liaison must be familiar with the Plan, the Covered Drugs of each Producer participating in a Plan, and potential issues related to implementation of the Plan. The Plan Liaison must have authority on behalf of all of the Plan Owners and all participating Producers to make binding representations and determinations related to the Plan. Notice to the Plan Liaison shall be considered notice to the Plan Owner and each Producer participating in the Plan.

ii. **Website.** A Plan must include the address of a website on which the Collection Points, educational materials, public outreach events, and other components of the Plan will be made publicly available. The website does not need to be devoted exclusively to the Plan.

iii. **Telephone Number.** All Plans must include a toll-free telephone number that will be available to Residential Generators to obtain information about Collection Points, educational materials and other aspects of the Plan.

iv. **Other.** All information required by the Ordinance.

B. **Collection Measurement and Goals.** A Plan must contain an estimate for the quantity of Unwanted Products that will be collected under the Plan and how the quantity of collected Unwanted Products will be measured.

C. **Implementation Description.** A Plan must contain a discussion of how and when the Plan will be implemented, including but not limited to:

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- i. The number of initial Collection Points and Collection Points that will be phased in over time.
- ii. The dates on which Unwanted Products will begin to be collected at each Collection Point, which must be within 90 days of Department approval of the Plan. Collection Points may include established Collection Points for which the Plan will assume responsibility.

D. Multiple Collection Components. A Plan may have multiple collection components, which may include:

- i. Collection Points with secure drop-off kiosks at hospitals, pharmacies and other convenient locations;
- ii. A mail-back program, such as providing consumers with a container in a prepaid self-addressed package for mailing Unwanted Products to be destroyed;
- iii. Public collection events, including at senior citizen facilities, health fairs, and recycling events. Plan Owners and Producers are encouraged to coordinate with community organizations, public entities, and local government regarding the Plan.

E. Transporter Information. Transportation from the Collection Points to the disposal facility must be performed by a Transporter. The Plan must include the following information for each Transporter to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of Transporter;
- iv. Environmental Protection Agency identification number;
- v. Permit status;
- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Transporter will be utilized under the Plan .

F. Disposal Facility Information. The Plan must include the following information for each Disposal Facility to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of facility;
- iv. Environmental Protection Agency identification number;
- v. Permit status;

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Disposal Facility will be utilized under the Plan.

A list of eligible Disposal Facilities that are properly permitted to dispose of Unwanted Products and information regarding such sites located in California may be obtained from the California Department of Public Health (CDPH). Information is available on its website located at www.cdph.ca.gov.

- G. **Copies of Materials.** A Plan should include copies of any educational or public outreach materials that are proposed to be used under the Plan, including a copy of any signage, with the dimensions of the proposed actual sign.
- H. **Plan Goals.** A Plan should include a proposal as to the short term and long term goals under the Plan for collection, education and public outreach. The Department may modify Plan goals as a condition of approval. As set forth below, Plan goals shall be reviewed in each Annual Report, at which time the Department, working with the Plan Liaison, will set the goals for the next reporting period.
- I. **Public Document:** Any Plan submitted to the Department or Board of Supervisors or any other governmental agency under the Ordinance or Regulations will be considered a public record. No part of the Plan should be marked as confidential or proprietary. This provision is not intended to require the disclosure of records that are exempt from disclosure under the California Public Records Act (Government Code section 6250, et seq.). If any Plan Owner or Producer participating in a Plan contends that information it is required to provide is exempt from disclosure under the California Public Records Act, such information must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether the documents or information are exempt from the California Public Records Act.

Section 8 – Plan Evaluation

- A. Plans will be evaluated by the Department based on the following:
 - i. **Adequate Collection.** Whether the Plan's collection program is adequate to serve the needs of Alameda County residents, including but not limited to:

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- a. Whether the Plan provides for adequate collection of Unwanted Product for each area of the County where the Covered Drugs of the participating Producer(s) are offered for sale, sold, or distributed; and
 - b. Whether residents who procure their medications outside of physical pharmacies, such as online, will be adequately served by the Plan.
- ii. **Adequacy Of Collection Points.** Whether the Plan has an adequate number of Collection Points and whether these Collection Points are accessible and located throughout Alameda County. Possible Collection Points can include, but are not limited to pharmacies, medical and veterinary offices, clinics, hospitals, law enforcement agencies, and governmental buildings. The Department encourages Plan Liaisons to contact the Department before Plans are due if they are having difficulty identifying suitable or sufficient Collection Point locations.
- iii. **Management Practices.** Whether the Plan includes adequate management and administrative practices, including but not limited to:
 - a. Training to be provided at the Collection Points;
 - b. General security procedures;
 - c. Procedures for pickup and disposal of Unwanted Products;
 - d. Frequency of pickup from Collection Points and disposal;
 - e. Procedures if a collection vessel is full prior to scheduled pick-up and disposal; and
 - f. Management and administration of alternative collection methods, such as mail-back containers.
- iv. **Tracking.** Whether the Plan provides for the collected Unwanted Products to be safely and securely tracked and handled from collection through disposal.
- v. **Controlled Substances.** Whether the Plan adequately addresses collection of Controlled Substances.
- vi. **Education and Public Outreach.** Whether the Plan complies with the public education and outreach requirements of the Ordinance, including but not limited to whether the Plan adequately provides for education regarding the safe collection and disposal of Unwanted Products for:
 - a. Medical providers and their patients;
 - b. Veterinary providers and animal owners;
 - c. Pharmacies, including education for dispensers of Covered Drugs and their patients; and
 - d. The general public.

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- vii. **Educational Materials.** Whether the Plan adequately incorporates educational materials for the public and whether such materials adequately address:
 - a. The importance of promptly and properly disposing of Unwanted Products;
 - b. How to find and use Collection Points;
 - c. Alternative methods of returning Unwanted Products under the Plan (such as mail-back programs);
 - d. How to properly dispose of Unwanted Products; and
 - e. Privacy issues, such as removing Unwanted Products from labeled prescription containers, which may disclose private information, and placing them in unlabeled bags or containers.
- viii. **Public Outreach.** Whether the Plan provides for adequate public outreach, including but not limited to sufficient use of print and social media, radio, television, signage, and public events.
- ix. **Cost.** The Plan does not need to include an itemized cost breakdown for the Plan or the charges to, or financial contributions from, any Producer, so long as a statement is provided from each Producer that it is their reasoned opinion that the proposed Plan meets the criteria of Section 6.53.040(B) of the Ordinance.

- B. When considering a Plan for approval, the Department assumes the truth and accuracy of all information provided in connection with the Plan. Plan Owners and all Producers participating in a Plan are jointly and severally responsible for the truth and accuracy of their representations. If the Department determines that any information provided to it in connection with a Plan is false or inaccurate, the Plan Owner(s) and Producer(s) participating in the Plan shall, at the discretion of the Department, be subject to the penalty provisions of the Ordinance and Regulations.

Section 9 – Petitioning For Alternative Method Of Disposal

A Plan Liaison may petition for a method of disposal other than incineration as required by Section 6.53.060 (B) of the Ordinance by submitting a written petition to the Department Liaison by e-mail. The following information must be included in the petition:

- A. An explanation as to how the proposed alternative method of disposal adequately meets the requirements of the Ordinance, including Section 6.53.060 (C), and Regulations;
- B. A deposit for the estimated cost to the County to review, consider and respond to the petition, based on the Fee Schedule.

Appendix 6:

Alameda County Safe Drug Disposal Regulations

The Department will contact the petitioner if additional information is required to make a determination on the petition. The Department shall have discretion to grant or deny any petition filed under this Section.

Section 10 – Review, Public Hearing and Approval of Plan

- A. **Review:** Following receipt of a Plan by the Department, the Department Liaison may review the Plan with the Plan Liaison. If the Department Liaison does not recommend approval of the Plan as submitted, a Revised Plan may be submitted by a date set by the Department Liaison. It is within the discretion of Department to continue a noticed public hearing to allow for submission of a Revised Plan.
- B. **Public Hearing.**
 - i. **Public Hearing:** A Public Hearing shall be noticed and conducted by the Department to determine if a Plan complies with the Ordinance and Regulations
 - ii. **Availability of Plan:** Within 10 days of the Department providing notice of the public hearing, the proposed Plan will be made available to the public by the Department at no cost on the Department website. A copy will also be made available for public viewing at the Department office.
- C. **Approval of Plan.** Within 30 days following the public hearing, the Department will notify the Plan Liaison by e-mail whether the proposed Plan has been approved or denied, whether any changes to the Plan are required for approval and/or whether additional time, information, and/or documents are needed for the Department to make a determination on the Plan. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations.
- D. **Posting of Approved Plan.** All approved Plans shall be posted by the Department on its website within fifteen (15) days of notification to the Plan Liaison of approval.
- E. **Rejection of a Plan.** If a Plan is rejected by the Department, the Plan Liaison must submit a Revised Plan to the Department within 60 days after receiving notice of the rejection. If a Revised plan is not timely submitted and approved, Producers participating in the rejected plan may have an Alternative Plan imposed on them.
- F. **Alternative Plan.** At the Department's discretion, an Alternative Plan may be, but is not limited to, a Plan developed by the Department, or a Plan submitted by another Plan Owner(s) or Producer(s).

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- i. All costs incurred by the County relating to an Alternative Plan shall be paid by the Producer(s) participating in the Plan. Such costs shall be determined in accordance with the Fee Schedule, Ordinance and Regulations, and shall not exceed the actual costs of the County.
 - ii. The Department in its discretion may contract with a third party to create an Alternative Plan. Any fees or costs for such a consultant shall be paid by the Producer(s) participating in the Plan.
 - iii. Producer Contact(s) will be sent notification of the imposition of an Alternative Plan by e-mail and first class mail, which will include a webpage where a copy of the Alternative Plan may be downloaded.
- G. **Appeal.** A Plan Liaison or Participating Producer may appeal an Alternative Plan, or a portion of an Alternative Plan, to the Board of Supervisors within ten (10) calendar days after receiving notice of imposition of the Alternative Plan.
- i. The appeal may be initiated by filing a Notice of Appeal with the Clerk of the Board of Supervisors. A courtesy copy of the Notice of Appeal shall be sent to the Department Liaison.
 - ii. The Notice of Appeal shall specify the grounds for the appeal, the specific changes requested to the Alternative Plan, and the appellant's contact information.
 - iii. The appeal process before the Board of Supervisors for an Alternative Plan shall follow the procedures set forth for administrative citations in Section 6.53.110 (J) of the Ordinance. If the Board of Supervisors cannot attain a majority vote as to whether to grant or deny an appeal of an Alternative Plan, the Alternative Plan shall be upheld.

Section 11 – Request To Modify an Approved Plan

- A. Only a Plan Liaison may request modifications to an approved Plan. All such requests must be made in writing and submitted to the Department Liaison with a Modification Request Fee, as set forth on the Fee Schedule. No material modifications may be made to a Plan without prior Department approval, including but not limited to:
- i. Collection Point changes;
 - ii. Changes to collection methods or collection events;
 - iii. Material changes to educational or public outreach efforts.

The Department must be promptly notified, in writing, of any non-material changes to the Plan, including a change in Plan Liaison, but prior Department approval is not required for such non-material changes.

Appendix 6:

Alameda County Safe Drug Disposal Regulations

- B. The Department will notify the Plan Liaison within 30 days of receipt of a request to modify an approved Plan as to whether the requested modification has been approved, denied, approved in part, or if additional information, documents and/or time are needed to make a determination. The Department shall have discretion to determine whether to allow modifications of an approved Plan.

Section 12 – Plan Compliance

The Department may, but is not required to, monitor Plan compliance, including but not limited to visiting Collection Points or educational events or engaging a third party to do so. Costs incurred by the County in monitoring Plan compliance shall be borne by Producers participating in a Plan.

Section 13 – Enforcement and Penalties

- A. **Written Warning.** If the Department Liaison determines that a Plan is in violation of the Ordinance or Regulations or is not being implemented as approved, the Department Liaison shall send by e-mail a written warning to the Plan Liaison. Since Producers are the parties responsible for payment of all fines and penalties, all Producers participating in a Plan shall be sent a copy of the written warning at the address identified on the Plan for their Producer Contact. The written warning will be deemed received the day after it is sent by e-mail.
- B. **Recommendation for Administrative Citation.** If any violation(s) identified in the written warning is not corrected within 30 days, a recommendation will be made by the Department Liaison that the Department issue an Administrative Citation to the offending Producer(s).
- C. **Administrative Citation.** An Administrative Citation issued by the Department shall include a description of the violation, the section of the Ordinance or Regulation that has been violated, the date the warning was issued, and the administrative fines and civil penalties to be assessed against the Producer(s). The fines and penalties shall begin accruing on the 31st calendar day after the written warning. The Department has discretion as to when to issue an Administrative Citation.
- D. **Per Day Violation and Penalties.** Each day a Plan is in violation of the Ordinance or Regulations after the 30 day cure period shall constitute a separate and distinct violation, and penalties may, at the Department's discretion, be assessed on a daily basis until the violation is cured. The amount of the penalty for each violation shall be determined at the discretion of the Department, up to a maximum amount of one

Appendix 6:

Alameda County Safe Drug Disposal Regulations

thousand dollars (\$1,000) per day per violation. Any civil penalty is separate and distinct from any fines imposed in connection with any criminal conviction.

- E. **Payment of Penalties.** All penalties shall be paid within 30 days of the date the Administrative Citation was issued. Any penalty amounts that are not paid within the 30 day period shall accrue interest at the rate of 10% per annum. Penalties shall be payable to the Department.

Section 14 – Appeal of Administrative Citations

- A. **Submission of Appeal.** Any appeal of an Administrative Citation shall follow the process set forth in the Ordinance at Section 6.53.110.
- B. **Department Review.** Appeals shall be sent to the Department Liaison for review to determine if the appeal is complete according to the requirements of Section 6.53.110 of the Ordinance.
- C. **Contact Information.** The appeal must set forth the contact person for purpose of the appeal and the appellant's telephone number, e-mail and mailing addresses.
- D. **Incomplete Appeal.** If any appeal is determined by the Department Liaison to be incomplete, it shall be returned to the appellant with the basis for the determination.
- E. **Notification of Hearing.** If the Department Liaison determines that an appeal is complete, a hearing officer will be designated, and the Department will provide written notice of the hearing as set forth in Section 6.53.110 (G) of the Ordinance.
- F. **Appeal to Board of Supervisors.** A Producer or the Department may appeal the Hearing Officer Decision to the Board of Supervisors by following the process set forth at section 6.53.110 (J) of the Ordinance. A copy of any appeal filed with the Clerk of the Board of Supervisors shall be sent by the appellant to the Department Liaison or, if filed by the Department, to the Plan Liaison.

Section 15 – Annual Reports

- A. **Submission of Reports.** An Annual Report must be submitted to the Department Liaison for each Plan on or before the annual report date set by the Department at the time the Plan is approved.
- B. **Report Format:** The Annual Report shall be in two parts: a Report Narrative section containing a narrative description of the activities under the Plan for that year and a Report Data section containing the data described below. In addition to elements

Appendix 6:

Alameda County Safe Drug Disposal Regulations

required in the Ordinance and below, the Annual Report shall contain any changes to contact information for any Plan Owner or Producer participating in a Plan.

- C. **Report Narrative.** The narrative section of the Annual Report shall include the following brief subsections:
- i. **Executive Summary.** The purpose of the Executive Summary is to provide a broad understanding of the Plan as a whole and context for the data and information that will follow. This summary should include a brief description of collection and disposal efforts during the reporting period. The executive summary should also include a description of proposals to improve collection efforts and challenges encountered during the reporting period, and how they will be addressed. (Security issues must be addressed separately as set forth below.)
 - ii. **Reporting on Goals.** The Report Narrative should include a summary of the Plan goals and the degree of success in meeting those goals in the past year. The discussion should include a summary of the efforts to meet the goals, any difficulty in meeting the goals, and if any goals have not been met, what effort will be made to achieve such goals in the next year.
 - iii. **Future Goals.** The Report Narrative should include proposed goals to be accomplished in the upcoming year. If the proposed goals differ from the original Plan goals, the Annual Report should include a discussion of the reasons for the suggested change(s).
 - iv. **Collection Practices.** The Report Narrative shall include a brief description of the collection efforts over the past year.
 - v. **Educational Efforts and Public Outreach Activities.** The Report Narrative shall include a brief description of education and public outreach efforts over the past year.
 - vi. **Safety and Security Report:** This section shall be provided on a separate page and clearly marked "Safety and Security Report". This section shall:
 - a. Identify any known security or safety incidents at Collection Points, events and during transportation or disposal. For each such incident, the report must include the following:
 - 1. What, if any, corrective or other action was taken in response to the incident;

Appendix 6:**Alameda County Safe Drug Disposal Regulations**

2. Any law enforcement or regulatory agencies involved in the incident; and
 3. Any litigation, arbitrations or other legal proceedings arising out of, or involving, the incident.
 - b. If the Plan Owner or a Producer participating in a Plan contends that information it is required to provide in the Safety and Security Report is exempt from disclosure under the California Public Records Act, this section of the Annual Report may be submitted conditionally under seal. It must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. Submission of a written claim that the document, or information contained in a document, is exempt from disclosure under the California Public Records Act does not in itself create an exemption. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether documents or information are exempt from the California Public Records Act.
- D. **Report Data:** The data section of the annual report must contain all items required by the Ordinance and the following information:
 - i. All Producers participating in the Plan;
 - ii. For each Collection Point:
 - a. Location, host site name, and address;
 - b. Collected Unwanted Products by weight over the past year; and
 - c. Number of times Unwanted Products was picked up for transportation per location.
 - iii. For any mail-back program:
 - a. The number of mail-back containers distributed;
 - b. The number of mail-back containers returned; and
 - c. Collected Unwanted Products by weight.
 - iv. For each Disposal Facility:
 - a. The facility name, address and telephone number; and
 - b. The total weight of collected products disposed of at each Facility,

Appendix 6:

Alameda County Safe Drug Disposal Regulations

E. Failure to Submit Adequate Annual Report.

- i. If the Department finds any Annual Report to be inadequate, it may request additional information or a revised report.
- ii. If a Plan Owner does not provide an adequate Annual Report after a request by the Department for additional information or a revised report, any Producers participating in the Plan may be subject to enforcement actions and penalties under the Ordinance and Regulations.

Section 16 – Plan Renewal

Once a Plan is approved it is valid for three (3) years, unless the Department specifically sets forth a different term, which is within the Department's discretion. Plan Liaison should set up an appointment with the Department Liaison six (6) to eight (8) months prior to the end of the three (3) year term, and no later than 60 days prior to the expiration of the term of the existing Plan, to discuss renewal of the Plan and how the Plan may be improved or modified. The Department will advise the Plan Liaison within 30 days following this meeting as to whether the Plan will need to be revised prior to renewal.

The Department shall have discretion to determine whether a public hearing will be held prior to renewal of a Plan.

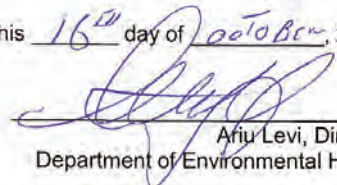
Section 17 – Request for Exception

- A. **Petitions for Exception.** A Plan Liaison or a Producer may make a request of the Department for an exception, exemption, or allowance from any requirement of the Ordinance or Regulations.
- B. **Petition Content.** Any Petition for Exception must be made in writing to the Department Liaison and contain all of the following:
 - i. The name and contact information of the Plan Liaison or Producer seeking the exceptions;
 - ii. The Ordinance section or Regulation to which the request relates;
 - iii. The reason and justification for the request; and
 - iv. A deposit for the estimated cost to the County of review, consideration and response to the Petition based on the Fee Schedule.
- C. **Department Discretion.** The Department shall have the discretion to grant or deny any Petition for Exception.

Appendix 6:**Alameda County Safe Drug Disposal Regulations****Section 18 – General Provisions**

- A. **Severability.** If any part or provision of these Regulations or the application thereof to any person or circumstances is held invalid, the invalid provision(s) shall be severed, and the remainder of the Regulations, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect.
- B. **Compliance with all Laws and Regulations.** Plan Owners and Producers participating in a Plan, and not the Department, are jointly and severally responsible for creating and maintaining a Plan that is in compliance with all federal and California laws and all city and county ordinances and regulations. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations. Any statement by the County, including the Department Liaison, that the Plan may contain a component that violates any federal, state, city, or county law, ordinance, or regulation shall not be interpreted as an opinion that any other component of the Plan is in compliance with any federal, state, city, or county laws, ordinances or regulations.
- C. **Separate and Distinct Compliance.** Adherence to the Ordinance and Regulations is not meant to replace or meet the requirements of any other federal, state, city, or county laws, ordinances, or regulations. Any review or approval pursuant to the Ordinance or Regulations is not meant to and shall not be indicative of compliance with or violations of any other federal, state, city, or county laws, ordinances or regulations.

These Regulations, as amended, are hereby adopted this 16th day of October, 2013.


Ariu Levi, Director
Department of Environmental Health

Appendix 7:**Alameda County Safe Drug Disposal Fee Schedule and Cost Recovery****Alameda County Safe Drug Disposal****FEE SCHEDULE / COST RECOVERY**

The approved hourly rate for cost recovery, effective April 1, 2013, is \$245.68.

The following is a schedule of estimates of the minimum amount of time that each type of activity will take a staff person. When the Ordinance or Regulations require a deposit of the estimated cost, the following schedule may be used as a base line to estimate the deposit amount.

ACTIVITY**ESTIMATED
HOURS**

Petition for Exemption (Section 5B)	2.00
Preliminary Review of Plan – pre-formal submittal (Section 6)	4.00
Plan Evaluation (Section 6)	6.00
Petition for Late Submission Date for a Plan (Section 6)	1.00
Review of Revised Plan (Section 10E)	6.00
Request to Modify an Approved Plan (Section 11)	2.00
Petition for alternative method of disposal (Section 9)	2.00
Public Posting, Hearing and Noticing (Section 10)	4.00
Appeal Hearing of Alternative Plan (Section 10G)	2.00
Request for Exception (Section 17)	2.00
Alternative Plan Developed (Section 10F)	16.00
Monitoring Plan Compliance (Section 12)	8.00
Appeal of Administrative Citations (Section 14)	2.00
Review of Annual Report (Section 15)	6.00

General work such as assistance with educational outreach, training, meetings, website management, complaints, and inspections shall be estimated at the time that work is requested or completed.

This schedule is an estimate and the actual time and amount will vary depending on the complexity of the petition, or matters at issue, size of the Plan and other individual factors. At the time the activity is requested, the Department may request a deposit in excess of the estimated hours on this schedule, if it believes the actual time will exceed the estimated hours.

The amount ultimately charged will be that of the actual time spent, whether it is more or less than the time estimated.

Appendix 8: Survey Questions

1. Please enter your zip code: _____
2. For how many people are you returning these medicines for?
(Are you bringing in medicine for more than one person?)
 - a. Only yourself
 - b. 2
 - c. 3
 - d. 4
 - e. More than 4
3. Are you returning medications for someone who is deceased?
 - a. Yes
 - b. No
4. Your Gender (circle one): Male Female
5. Your age:
 - a. Under 25
 - b. 26-40
 - c. 41-65
 - d. Over 65
6. Number in your household: _____
7. Your household Annual Income range:
 - a. Under \$30,000
 - b. \$30,000- \$50,000
 - c. \$51,000 – \$70,000
 - d. \$70,000-105,000
 - e. 105 and above
8. Do you have health insurance?
 - a. Yes
 - b. No

Appendix 9:**Safe Meds Workgroup Participants**

Angela Griffiths, Await & Find
 Angelica Gums, Supervisor Miley's Office
 April Rovero, Contra Costa County Resident
 Ariu Levi, Alameda County Environmental Health
 Aubrey Schreck, Await & Find
 Audrey Comeaux, East Bay Municipal Utility District
 Avani Desai, CommPre
 Barbara Woody, United Seniors of Oakland and Alameda County
 Bill Pollock, Alameda County Hazardous Waste
 Brian Washington, County Counsel
 Charles Woody, United Seniors of Oakland and Alameda County, Alameda County Sheriff's Department
 Christine Graham, Eden Hospital, Supervisor Nate Miley's Office, Senior Injury Prevention Partnership
 Dan Arritola, San Lorenzo resident
 David Silva, Castro Valley Community Action Network
 Francesca Lomotan, CommPre
 Heidi Sanborn, California Product Stewardship Council
 Herb Lester, Fremont Unified School District Risk Manager
 Janice Watkins, Cherryland resident
 Jen Jackson, East Bay Municipal Water District
 Jennifer Auletta, City of San Leandro
 Jennifer Ong, Alameda County Hepatitis B Free Campaign
 Jesse Garrett, CommPre
 Joel Kreisberg, Teleosis Institute
 Jorge Goitia, Alameda County LEA/Environmental Health Department
 Garrett Wong, Irvington High School Seniors
 Kamika Dunlap, Supervisor Miley's Office
 Kay Iwata, KIA, Inc
 Karla Goodbody, Davis Street Family Resources Center
 Kathleen Pacheco, County Counsel
 Kathy Arritola, San Lorenzo resident
 Linda Hambrick-Jones, United Seniors of Oakland & Alameda County
 Linda H. Jones, United Seniors of Oakland & Alameda County
 Linda Pratt, CommPre
 Marie Haugen, San Leandro resident, Sandpiper Apartments
 Mark Harvey, EXP Pharmaceutical Services Corp
 Mark Hymel, Davis Street Resource Center
 Mary Bradd, United Seniors of Oakland & Alameda County
 Michael Auer, Union Sanitary District
 Millie Gee-Poon, Supervisor Lai Bitker's office
 Miriam Rabinowitz, Alameda County Senior Injury Prevention Program
 Morola Adjibodou, Teleosis Institute
 Nate Harrison, United Seniors of Oakland & Alameda County
 Paul Schafner, Supervisor Nate Miley's Office
 Pauline Von Stetten, Castro Valley resident
 Peter Denyer, Irvington High School
 Rachel Jeffers, Lifelong Medical Care
 Robert Reiter, Alameda County County Counsel
 Ronda Freyslaben, Senior Injury Prevention Partnership
 Scott Seery, Alameda County Environmental Health Department
 Steve Aguiar, City of Livermore
 Sylvia Stadmire, United Seniors of Oakland and Alameda County
 Teresa McGill, Davis St. Family Resource Center
 Traci Cross, Castro Valley Community Action Network



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