

# MEMO

**To:** Kitsap Public Health Board

**From:** John Kiess, Environmental Health Director

**Date:** December 2, 2016

**Re:** Packet Addendum for the Proposed Secure Medicine Return Ordinance: Regulations Requiring Safe Medicine Disposal

The Health District has received additional comments about the draft Secure Medicine Return ordinance since your packet was sent to you on November 30. Attached you will find the following information:

- A support letter from Zero Waste Washington
- A support letter from the Healthcare Distribution Alliance
- A letter expressing concerns and not supporting the proposed regulation from the Pharmaceutical Research and Manufacturers of America (PhRMA)
- An updated response summary document including responses to these letters

Please feel free to contact me at any time regarding this proposed ordinance. I can be reached at (360) 337-5290, or [john.kiess@kitsappublichealth.org](mailto:john.kiess@kitsappublichealth.org) with any questions or comments.

## Proposed Secure Medicine Return Ordinance Feedback

	How feedback submitted	By whom	Comments	In favor / against	Issue/concerns	Response
1	Web submission	Karen Johnson	I think this is a great idea. I know personally we hold on to medicines we no longer need and hope we don't miss the drop off date at the sheriff's office. My concern, however, is that the pharmaceutical companies will just add the cost to them of providing this program by increasing the price of prescription medicine. It won't wind up being a "free" program to us at all.	IN FAVOR	Cost passed on from drug companies to public	Unfortunately, it is very likely that drug companies will pass the cost of this program on to consumers as has happened with other programs such as electronics recycling. These regulations are in place in King and Snohomish Counties, and are under consideration in Pierce County as well. Because of the huge volume of prescriptions filled in these counties and state-wide, it is expected that the cost increase would be less than 1 cent per subscription. Prescription drug coverage would also make the impact of this small increase to Kitsap residents negligible. The Kitsap Public Health Board believes that the benefits of this program outweigh the possibility of a small increase in prescription costs.
2	Web submission	anonymous	Concern: proposed drug take back needs to happen and soon. I work where people constantly come and ask if we take drug for disposal and we don't. I send them to the Kitsap County Sheriff's office which is the only place that does. Even Group Health no longer takes back their own drugs for disposal because of the expense and the laws. this also should be something the pharmaceutical company should have to pay for since not only is it their problem but they get enough money from their prescriptions that this would not be a huge expense for them	IN FAVOR	n/a	n/a
3	Web submission	Steve and Kate Shaughnessy	We support the proposed secure prescription drop off ordinance. Thanks!	IN FAVOR	n/a	n/a
4	Web submission	Dr. Chris Bock, DMD	I'm fully in favor of the proposed new regulation.	IN FAVOR	n/a	n/a

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5	Email	Doug Washburn, Kitsap County Dept. of Human Services	We highly support you on this and our prevention coalition folks lead by Laura have been watching with great enthusiasm as you move forward. Thanks.	IN FAVOR	n/a	n/a
6	11/10 listening session	Doug Washburn, Kitsap County Dept. of Human Services	n/a	IN FAVOR	n/a	n/a
7	Web submission	Susan Woolley	<p>This year I dropped off unused medications for myself and my 94 year old mother at the sheriff's office. I had been saving them in a plastic bag for about three years, because I could never make it to the previous "take back" events due to scheduling conflicts on the weekend, or due to simply not hearing about it in time. I believe this project is potentially valuable for the following reasons:</p> <ul style="list-style-type: none"> <li>*Removes unused prescription drugs from senior's homes, where misuse or overdose might occur due to simple confusion.</li> <li>*Hopefully assisted living facilities would promote and facilitate "take back" day.</li> <li>*Removes unused meds from home medicine cabinets where teens, housekeepers, contractors might access them</li> <li>*Keeps them out of the watershed. My guess is that a lot of people are still flushing or putting in household garbage.</li> <li>*Prevents access to meds which could be used to overdose for an individual having a mental health crisis. Contrary to popular stereotypes, people will use anything in an attempt to overdose, not just sedatives or opiates, so removing unused prescription pharmaceuticals would curtail access to meds most likely to have a small margin of</li> </ul>	IN FAVOR	No concerns but has implementation ideas/suggestions.	<p>Outreach has been done in the community about the proposed ordinance, and additional outreach will be done if the ordinance passes. The regulations require pharmaceutical manufacturers to develop and pay for a coordinated secure medicine return system in Kitsap County which includes outreach in the community to generate awareness of the program. Most manufacturers will combine their resources and hire a company to coordinate the system. This is already in process in King and Snohomish Counties.</p> <p>The Kitsap Public Health District will review all pharmaceutical stewardship plans for the program, and make sure that there is adequate outreach locally – including outreach to assisted living communities.</p> <p>If this ordinance passes, any business or location that meets the Drug Enforcement Agency requirements for drug take-back organizations would be</p>

## Proposed Secure Medicine Return Ordinance Feedback

			<p>safety and most likely to create kidney damage or other long term health problems.</p> <p>Suggestions: Consider doing the take-back in <b>libraries</b>, once/month, staffed by vetted volunteers or health care professionals. Law enforcement in Kitsap is stretched as it is. Or, would the pharmacies be willing to release staff one day a month for this as community service?</p> <p>Consider enlisting aid of health care organizations such as Franciscan to have take-back containers available one day a month at all clinics so that people could turn in their meds to front desk staff as they arrive for their PCP appointments. Thank you.</p>			<p>allowed to participate – at no cost. The DEA requires that a take back location:</p> <ul style="list-style-type: none"> <li>• Be a registered pharmacy with the Washington State Pharmacy Assurance Commission.</li> <li>• Amend registration with the Drug Enforcement Administration (DEA) to become a collector.</li> <li>• Authorize two employees to maintain keys to the secure drop-box.</li> <li>• Lock the drop-box when the site is closed.</li> <li>• Manage and maintain required documentation</li> </ul> <p>So unfortunately, while convenient, the library would not qualify because it does not meet the DEA criteria.</p> <p>We encourage people to reach out to their pharmacies or medical facilities that do qualify under the DEA rules and encourage them to participate.</p>
8	Web submission	Heather Carrell	Please support this proposal so medicines are not dumped into septic systems, sewage systems, landfills, and our streams and ocean.	IN FAVOR	None	n/a
9	Web submission	Robin Villiers-Furze	<p>I believe the pharmaceutical companies SHOULD provide convenient drop off locations (any pharmacy) and they should pick up disposal charges, including needles.</p> <p>We currently have to pay, at Fred Meyer, for needle returns. By charging and inconvenient drop off locations, it encourages people to just throw drugs and bio hazard waste into landfill.</p>	IN FAVOR	Concerned about disposal of sharps.	Sharps disposal is not included in this proposed ordinance. However, free disposal for syringes and needles (known as "sharps") is available. Sharps can take sharps to one of the following drop-off facilities listed on <a href="#">Kitsap County's website</a> free of charge. Before dropping them off at one of these facilities, the sharps should be placed in a manufactured sharps

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						<p>container or a 2-liter PET plastic pop bottle (such as a plastic pop bottle or juice container). Manufactured sharps containers can also be purchased at most pharmacies. The lid must fit tightly and should be taped shut for added safety. If a plastic pop bottle or other container is used, it should be labeled with the warning: "SHARPS, DO NOT RECYCLE." This is a <a href="#">short tutorial video</a> on properly disposing of household sharps.</p> <p>The Health District also has <a href="#">information on the website</a> on what to do if discarded sharp are found in public. The District has staff trained and available to handle discarded sharps.</p>
10	Web submission	Denise Hughes, MSN, RN, GMHC	Thank you for taking this step toward making our citizens safer. I am a psychiatric nurse and have clients who have multiple medications with a polypharmacy abuse history. Assisting them to reduce the sheer number of medications is usually one of my goals and when we can do this we often have the problem of disposal. Designated stations in convenient locations would go a long way in helping reduce medication mismanagement by some of our most vulnerable citizens.	IN FAVOR	None	n/a
11	Web submission	Patricia Gordon-Rice	Concern: This is in response to the secure medicine return proposal. This county definitely needs a way to safely dispose of all medications. This is not only to keep medications out of the hands of others but also to keep them out of our landfills and water. I fully support a safe way to do this! However, as someone who	IN FAVOR	Inquired about how to handle illicit drugs.	<p>While the Kitsap Public Health Board recognizes that illicit drug use is a serious issue, this ordinance does NOT address disposal of illicit drugs.</p> <p>The Kitsap Public Health District's Solid &amp; Hazardous Waste staff reached out</p>

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			<p>has worked in the drug abuse treatment field for over 30 years, I know you also need to find a way for citizens to get rid of street drugs. Currently, there is no way to get rid of them! So what does a person or family member who has/finds heroin, methamphetamines and other street drugs to do with them? You don't hear about this because people are afraid and don't know what to do. This is a big problem as most people give them to another, throw them in the trash or flush them. We really don't want that. Please develop a way for people to securely, anonymously and safely get rid of them! The county needs to take responsibility to rid our county of these drugs. Thank you.</p>			<p>to several other agencies to determine the best course of action in the situation you describe. KPHD recognizes that while the most appropriate and legal response anytime illicit drugs are found is to contact law enforcement, many parents would be too scared to do that.</p> <p>If a parent or family member finds a small amount of illicit drugs, law enforcement recommends that they 1) contact law enforcement and/or 2) destroy the drug by putting it in wet coffee grounds and throwing it in the trash or taking it to a household hazardous waste facility.</p> <p>If someone finds illicit drugs in public (at a park, etc.) or a large quantity of illicit drugs, they should immediately notify law enforcement.</p>
12	Web submission	Alice D Gray	<p>Thank you for this. Please also get this word out to physicians! I was told recently BY A DOCTOR that throwing medications in the trash is okay! Not! I make every effort to dispose of medications properly, and having the facilities to do this makes it so much easier to protect our fragile and precious environment. I take my medications to the Kitsap County Sheriff's Office. Having more locations for proper disposal would be immensely helpful. Thank you.</p>	IN FAVOR	<p>Suggested we do outreach to physicians about regulations.</p>	<p>Outreach has been done to inform medical clinics, pharmacies and physicians about the proposed ordinance, and additional outreach will be done in the medical community if the ordinance passes.</p>

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13	Web submission	Barbara Burns	Kitsap Public Health Board seeks feedback on proposed ordinance requiring pharmaceutical companies to fund local medicine return program. My feedback is YES YES YES, a thousand times YES! If you need me to submit my comments via some other avenue, please let me know. I am happy to do that.	In FAVOR	n/a	n/a
14	Web submission	Janine Rinehart	1. The US Mail should not be used to return drugs. Drug users steal mail all the time and that would be an additional incentive. 2. Does this proposal include needles? If not, it should, both used and unused.	IN FAVOR	1) Concerns about mail theft 2) Concerns about proposal not including needles	1) The mail-order option is intended to serve those that may be home-bound. While there may be a risk of mail theft, the Health District believes the benefit of this program greatly outweighs these risks. 2) This proposal does not include sharps. Please see response to #7 above.
15	Letter of support	Dr. Gary Goldbaum, MD, MPH  Health Officer and Director, Snohomish Health District	Submitted letter of support sent to Dr. Susan Turner. Copy available upon request.	IN FAVOR	n/a	n/a
15	Web submission	Steven and Kathleen Shaughnessy	We support the proposed return program (second statement of support submitted).	IN FAVOR	n/a	n/a
16	Web submission	Barbara Meyers	I strongly support a program to provide a pick up location for unused medications. Having to drive to Silverdale to the Sheriff's office is inconvenient. I believe the best alternative would be return unused medications to businesses that fill prescriptions as they already are set up to secure meds that may be of interest for illegal use.	IN FAVOR	n/a	n/a

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17	Letter of support	Dr. Aaron Leavell, superintendent  Bremerton School District	Submitted letter of support sent to Dr. Susan Turner. Copy available upon request.	IN FAVOR	Concerns about mail theft	The mail-order option is intended to serve those that may be home-bound. While there may be a small risk of mail theft, the Health District believes the benefit of this program greatly outweighs this risk. Drugs being sent via mail is not uncommon - mail order pharmacies mail medication every day.
18	11/29 listening session	Laura Hyde  Human Services, Kitsap County	Attended in support of proposed regulations. Dept. of Human Services willing to help with distribution of materials for program when implemented.	IN FAVOR	Wanted to make sure that pick-up frequency at sites would be adequate to ensure that boxes would not get full or overflow.	KPHD will ensure that pick-up frequency is addressed in plan review and that adequate educational materials are available for distribution.
19	Web submission	Thomas J. Shandera, RN, MPH, CIC  Infection Preventionist	<p><b>Programmatic Suggestions</b></p> <ol style="list-style-type: none"> <li>1. Expand <b>Section 3</b> to specifically state how this Ordinance applies on Federal Land such military installations as well as how it applies on Tribal Land.</li> <li>2. Expand <b>Section 7.D.1 &amp; 2</b> to specify how stewardship will be provided in <u>unincorporated</u> portions of the county to meet the “<u>service convenience goal</u>”.</li> <li>3. Expand <b>Section 16.C</b> to include a) environmental monitoring listed in <b>Section 9.C.1-4</b> as well as b) data related to antibiotic resistant organisms identified in water and fish and c) results of reports listed in <b>Section 8.B.4 &amp; 5</b>.</li> <li>4. Sharpen focus on “...individuals with limited English proficiency.” (<b>Section 8.B.3</b>) by using this language each time public education, signage, forms, and public telephone/internet communications are addressed throughout the ordinance (e.g., <b>Section 7.F,G, Section 8.A,B.1,C,D,E</b>).</li> </ol>	IN FAVOR	Programmatic and formatting suggestions.	<p><b>Programmatic Suggestions</b></p> <ol style="list-style-type: none"> <li>1. This ordinance covers all city and county jurisdictions and all residents regardless of where they live.</li> <li>2. Comments related to convenience will be addressed on a case by case basis as part of the plan review process.</li> <li>3. Outside the focus of this regulation. Section 8.B.4 does not appear to be relevant to Section 9C.</li> <li>4. Comments related to convenience and outreach will be addressed on a case by case basis as part of the plan review process.</li> <li>5. Reverse distribution is not a component of this program. Can only be used by Pharmacies and other industry entities prior to being prescribed to consumer. Once a drug has been</li> </ol>

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			<p>5. Address how a producer, a group of producers and a stewardship organization shall report/utilize revenue generated by Reverse Drug Distribution (e.g., <b>Section 10, Section 11.A.8, Section 17.D</b>). For example, should these monies be a line item in a report and should these monies be reinvested exclusively into stewardship activities?</p> <p>6. Clarify <b>Section 1.A</b> compared with <b>Section 1.B</b>. These two section seem to be inconsistent. Section A speaks about "...provisions shall be liberally construed for the accomplishment of these purposes." Section B states in part "...is not intended to impose any duty whatsoever upon the Health District or any of its officers or employees, for whom the implementation or enforcement of this Ordinance shall be discretionary and not mandatory." <i>I suggest breaking Section B into two sentences. Consider placing a period at the end of line 2 after "...within its scope". Then phrase the second sentence such as: The duty upon the Health District, its officers and employees is to implement and enforce this Ordinance.</i></p> <p>7. Clarify <b>Section 4.C.2</b> compared with <b>Section 4.H.1</b>. Section H defines a drug to include "...Articles recognized... in the Homeopathic Pharmacopoeia Convention". However Section C.2 specifically <u>excludes</u> "...homeopathic drugs, products or remedies." <i>I suggest deleting the conflicting language in Section C.2.</i></p> <p>8. Modify <b>Section 5.C</b> to lean proactively when drugs are brought into system after adoption of this Ordinance. <i>I</i></p>		<p>prescribed to consumer it is no longer eligible for reverse distribution.</p> <p>6. Language is required by our legal counsel to protect KPHD against litigation</p> <p>7. The Health District will modify these sections to be consistent. It may not be possible to address homeopathic drugs under this ordinance as they are produced by a different group of producers. "Drugs" are a larger universe than covered drugs. The Ordinance only applies to covered drugs.</p> <p>8. Agree.</p> <p>9. Comments related to convenience or implementation will be addressed on a case by case basis as part of the plan review process.</p> <p>10. Comments related to convenience or implementation will be addressed on a case by case basis as part of the plan review process.</p> <p><b>Readability Suggestions</b></p> <p>11. We will take this recommendation under advisement and modify where intent is not clear.</p> <p>12. Outline and other format inconsistencies will be addressed in editing prior to publishing the final regulation.</p>
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## Proposed Secure Medicine Return Ordinance Feedback

			<p><i>suggest changing the last sentence of the Section from "...within six months of the date of initiating sales..." to read <u>before initiating sales.</u></i></p> <p>9. Expand <b>Section 7.E &amp; F</b> to specify if liquids, ointments/prescription toothpastes and chemotherapeutic agents will be placed in separate containers. As you know, only tablets may be placed in container at Sheriff's office.</p> <p>10. Expand <b>Section 8.B.4 &amp; 5</b> to specify exactly which person or organization is responsible for generating the report and the biennial survey. I further suggest that some standards should be stipulated for the creation and administration of the survey as well as methodology for evaluating effectiveness so that useful, actionable information is obtained.</p> <p><b>Readability Suggestions</b></p> <p>11. Reevaluate <b>Section 4.D</b> and <b>Section 4.O</b> so that the terminology meets common usage and, more importantly, so that the same terms are used consistently throughout the Ordinance.</p> <ol style="list-style-type: none"> <li>a. Common usage would define "covered entity" using language in Section 4.O.</li> <li>b. Common usage would define "person" using language in first sentence of Section 4.D.</li> <li>c. Within this Ordinance, a human being living in Kitsap county is identified by seven various terms, including: resident, covered entity, public,</li> </ol>			
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## Proposed Secure Medicine Return Ordinance Feedback

			<p>individual, customer, consumer, and even person.</p> <p>12. Evaluate <b>Section 15.E.4.b</b> from this point to end of Section 15. I think that the outlining ceases to be consistent. The word “Extension” looks to be the heading for the next subsection, which then impacts the remainder of the section’s outline organization.</p>			
20	Letter submitted	Zero Waste Washington	Please see Industry Responsiveness Summary pages 11-13.	IN FAVOR		Please see Industry Responsiveness Summary pages 11-13.
21	Letter submitted	Healthcare Distribution Alliance	Please see Industry Responsiveness Summary pages 11-13.	IN FAVOR		Please see Industry Responsiveness Summary pages 11-13.
22	Letter submitted	Pharmaceutical Research and Manufacturers of America (PhRMA)	Please see Industry Responsiveness Summary pages 11-12.	AGAINST		Please see Industry Responsiveness Summary pages 11-13.

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### INDUSTRY RESPONSIVENESS SUMMARY

By whom	Comment/concern	Response
Zero Waste Washington	Zero Waste Washington believes that program creates a safer and more environmentally-sound alternative to home disposal which is currently prohibited in Kitsap County.	n/a
Zero Waste Washington	Appreciated that definitions in ordinance were consistent with other counties which helps avoid confusion.	n/a
Zero Waste Washington	Stressed the importance of adequate pick-up from pharmacies so collection boxes don't get overfilled.	KPHD will ensure that pick-up frequency is addressed in Secure Medicine plan review.
Zero Waste Washington	Requested edit to Section 9, Part C regarding disposal.	District legal counsel believes the current language is appropriately clear. Language is also consistent with other Puget Sound area Local Health Jurisdictions' regulations.
Zero Waste Washington	Requested edit to language in Section 7.D.2 regarding adequate number of collection sites.	District legal counsel believes the current language is appropriately clear. Language is also consistent with other Puget Sound area Local Health Jurisdictions' regulations.
Zero Waste Washington	Requested that stewardship plans be required to include periodic drop-off events if take-back sites are limited.	This will also be addressed as a part of the plan review to ensure we have an adequate number of take-back locations.
Zero Waste Washington	Requested edit to Section 5.D.3 implementation timeline.	District legal counsel believes the current language is appropriately clear. Language is also consistent with other Puget Sound area Local Health Jurisdictions' regulations.
Zero Waste Washington	Requested that Section 7.H. be clarified for the mail-back services.	District legal counsel believes the current language is appropriately clear. Language is also consistent with other Puget Sound area Local Health Jurisdictions' regulations.
Pharmaceutical Research and Manufacturers of America (PhRMA)	The Kitsap County proposed regulation is a carbon copy of the unsuccessful County of Alameda's drug take-back program.	While there have been delays and full implementation has not yet been achieved, the County of Alameda program is currently functioning with more than 30 take-back sites.

## Proposed Secure Medicine Return Ordinance Feedback

		While there may be similarities to the Alameda program, our regulations were intentionally written to mirror other Western Washington local health jurisdictions' take-back programs for consistency.
PhRMA	Draft regulation only implicates drug manufacturers – does not include requirements for other stakeholders in the drug supply chain.	That is correct. This is a stewardship model that puts the responsibility on drug manufacturers, consistent with other medicine take-back programs in other local health jurisdictions.
PhRMA	Regulations will be difficult to implement; Many complications associated with disposal of unused medicines.	These regulations are intended to mitigate these complications and simplify the process of medicine return in Kitsap County.
PhRMA	It will be difficult to secure community-wide kiosks because the kiosks are visible, making them a target for diversion so pharmacies don't want to participate.  Program will be severely limited because of the rigorous safety standards necessary to comply with the DEA regulations	Participating take-back locations must meet all DEA security requirements. Should the stewardship plan allow for "kiosks" they will be located at supervised locations that meet DEA requirements. Although participation in the program is voluntary, based on feedback from local pharmacies and the fact that many large pharmacy chains are participating in other counties we believe that pharmacies will participate in the program despite any additional DEA requirements. The regulation requires a minimum number of drop-off sites, and the required plan should outline the steps that will be taken to secure at least this minimum number.
PhRMA	Medicine return programs do not address concerns regarding environment or prescription drug abuse.	The impetus of these regulations is to provide a secure and an environmentally sound way to dispose of leftover and/or expired medicines and are a part of a comprehensive approach to address prescription drug abuse.
PhRMA	Program will result in higher prices for prescription and non-prescriptions; this is inconsistent with shared goal of keeping medicines affordable.	The ordinance is intended to follow a product stewardship model that puts the responsibility on drug manufacturers, consistent other stewardship programs for products such as electronics or fluorescent lighting.
PhRMA	Opposed to inclusion of sharps in take-back programs.	n/a – The proposed regulations do not include sharps.
PhRMA	Concerns about diversion that could occur with mail-in option. Drug take-back mailers would be a target. There is no secure way to track	While there may be a risk of mail theft, the Health District believes the benefit of this program greatly outweighs these risks. Drugs being sent via mail is not uncommon - mail order pharmacies currently mail medication every day.

## Proposed Secure Medicine Return Ordinance Feedback

	medicines sent from the patient to a DEA-compliant facility.	
PhRMA	DEA requires on-site and immediate destruction of mailed-back packages and no certified facility exists in US to do this.	Currently there are well-functioning mail-back programs operating throughout the United States. All program participants are required to comply with all DEA regulations.
PhRMA	Alternative is in-home secure disposal.	Disposal in the solid waste stream is illegal in Kitsap County per KCBH Ordinance 2010-1, <i>Solid Waste Regulations</i>
Healthcare Distribution Alliance (HDA)	Recommending newer technology enabling at-home disposal for end-users with sealable, disposable, biodegradable pouch.	Disposal in the solid waste stream is illegal in Kitsap County per KCBH Ordinance 2010-1, <i>Solid Waste Regulations</i>
HDA	Suggests that we revise definition of “producer” by providing specific exemptions for non-manufacturing entities such as wholesale distributors and wholesalers who re-package medications. HDA would like obligation for take-back and disposal efforts to lie with the original manufacturer of the product – not wholesale distributors. (References San Francisco ordinance)	We believe that wholesaler and repackager exemptions exist within the current language. District legal counsel believes the current language is appropriately clear. Language is also consistent with other Puget Sound area Local Health Jurisdictions’ regulations.
HDA	Request inclusion of a set timeline to ensure companies are able to rectify any violation and correct the violation in a timely manner (such as written notice followed by 30 days to achieve compliance).	The Health District always works to establish reasonable time frames for compliance based on the severity of the violation. In some cases, this can be longer than 30 days.
HDA	Requested review and feedback on the regulations’ right of entry and inspection.	District legal counsel believes the current language is appropriately clear and consistent with other local Board of Health ordinance enforcement language. Reasonable time of inspection is required in the ordinance and all inspections must be performed in accordance with federal and state laws.



November 30, 2016

Kitsap Public Health District Board  
Secure Medicine Return Regulation  
Kitsap Public Health District  
345 6th St., Ste. 300  
Bremerton, WA 98310

**RE: Proposed Secure Medicine Return Regulations (Ordinance 2016-02)**

Dear Board members,

We are writing to express our strong support for your proposed Ordinance for Secure Medicine Return Regulations. Unused, unwanted and expired medicines in homes pose a risk to community members and to the environment. This ordinance will be an important step forward by providing safe, convenient and legal disposal options for unused medications in Kitsap County. It sets up a program provided and financed by drug manufacturers, which will ensure sustainable ongoing funding for an ongoing program.

Zero Waste Washington is a nonprofit group that represents the public on recycling and zero waste issues, and we've supported product stewardship approaches for unwanted medicines and other products for well over a decade. The proposed policy creates a safer and more environmentally-sound alternative to flushing medicines into our water systems or throwing them in the trash. Wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Mixed pharmaceutical wastes from residents are household hazardous wastes that should not be disposed in the trash. Kitsap County already prohibits Moderate Risk Waste from being deposited in the general municipal solid waste collection system.

Our specific comments are:

- **Consistent definitions.** We are pleased that the definitions section is clearly written and is consistent with the Snohomish County ordinance and the proposed Pierce County ordinance. It is critical that the definitions be consistent for various local jurisdictions, in order to avoid confusion.
- **Convenience.** It is important that the program provide adequate pick up from pharmacies so that their collection boxes do not get overfilled.
- **Disposal.** Zero Waste Washington requests one specific clarifying change to Section 9. Stewardship Plans – Disposal of Covered Drugs. The following sentence is confusing as written, and we suggest the following edit to Part C:

A producer or group of producers participating in a stewardship plan may petition the Health Officer for approval to use alternative final disposal technologies that provide superior environmental and human health protection, or equivalent protection at a lower cost, ~~environmental and human health protection~~ than permitted hazardous waste disposal facilities or municipal waste combustors in each of the following areas.

- **Collection.** We recommend a couple clarifications in Section 7. Stewardship Plans – Collection of Drugs.
  - The following change in Part D.2. would address situations where there are not enough potential authorized collectors in a city or where potential authorized collectors exist in a city but do not voluntarily offer to participate. Here is suggested language: *If there is no potential authorized collector within the geographic boundaries of a city or if the minimum required number of drop sites cannot be achieved by the plan due to a lack of potential drop-off sites in specific areas of the county, service to those geographic areas shall be supplemented with periodic collection events, mail-back services or a combination of periodic collection events and mail-back services.*
  - Drop-boxes in long term care facilities are only for use by their resident patients, not the general public. It's a good idea to allow these facilities to provide drop-off for unwanted medicines to their resident patients as part of the product stewardship program. However, if retail pharmacies, hospitals and clinics with on-site pharmacies and law enforcement agencies are unavailable or unable to provide a drop-off site in a particular geographic area, the plans should be required to utilize periodic collection events, mail-back services or a combination of periodic collection events and mail-back services as specified in D.2. Therefore, we recommend that the following be deleted in Part D. 3.: *All collection systems shall prioritize locating drop-off sites at retail pharmacies, hospitals and clinics with on-site pharmacies and law enforcement agencies. ~~If retail pharmacies, hospitals and clinics with on-site pharmacies and law enforcement agencies are unavailable or unable to provide a drop-off site in a particular geographic area, collection plans may consider alternative authorized collectors, potential authorized or long-term care facilities collectors for drop-off sites.~~*
- In Section 5. Stewardship Plan- Participation, Section D.3., we recommend that language be changed so that it's clear that the program must be fully implemented – not partially implemented – three months after the plan is approved. We recommend the following change: “Within three months of the Health Officer's approval of the stewardship plan: . . . b) ~~Begin operating or participating~~ Operate or participate in a stewardship plan in accordance with this Ordinance.

Thank you so much for your consideration. If you have any questions or comments, I can be reached at (206) 351-2898 or [heather@zerowastewashington.org](mailto:heather@zerowastewashington.org).

Sincerely,



Heather Trim  
Executive Director



November 30, 2016

Secure Medicine Return Regulations  
Kitsap Public Health District  
345 6th St., Ste. 300  
Bremerton, WA 98310

Sent via email to: [infoweb@kitsappublichealth.org](mailto:infoweb@kitsappublichealth.org)

To Whom It May Concern:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the proposed regulations for Kitsap County, Washington regarding secure medicine return. The biopharmaceutical industry in the United States remains committed to working with multiple stakeholders to help address issues associated with adhering to prescription medicines and prescription drug abuse, safe disposal of prescription medicines and sharps. We appreciated the opportunity to engage with the County and relevant stakeholders on these important issues. However, we are disappointed that the draft regulation appears to be nothing but a carbon-copy of the flawed and still not fully implemented Alameda County Ordinance. Despite the guiding principles underlying this entire process, the draft regulation only implicates the manufacturing community and does not include requirements for other stakeholders in the drug supply chain, and the regulation will not be easily or effectively implemented, as seen in Alameda which still has not operationalized ongoing collection as envisioned by the law, and will not have any meaningful impact on environmental or drug abuse concerns.

PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has significant and science-based concerns in opposition to this "Alameda-like" regulation, even if revised. There are a myriad of complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of such a product take-back program and have resulted in a severely limited program in Alameda – not to mention a substantial and unnecessary price tag. PhRMA fundamentally opposes mandates to take-back unused pharmaceutical products that place sole responsibility and are fully-funded by biopharmaceutical manufacturers. Our opposition is hinged on the fact that these programs will not address concerns regarding the environment or prescription drug abuse. It is the prescribers and the insurers that decide the amount of medicine a person is prescribed and can purchase.

Our main areas of concern with the regulation as drafted are incorporated below:

**Alameda: A Fundamentally Flawed Program:**

The Kitsap County proposed regulation is almost a carbon copy of the County of Alameda's drug take back program, with the addition of several other harmful provisions. As seen in Alameda, the drug take back program will be severely limited because of the rigorous safety standards necessary to comply with the necessary regulations issued by the U.S. Drug Enforcement Administration (DEA). In fact, kiosk collection in Alameda has yet to commence. Per the DEA regulations, any kiosk-based take-back program that will or could reasonably be

expected to collect controlled substances will need to be located at only a handful of regulated sites, specifically, law enforcement offices, pharmacies, certain hospitals with pharmacies, long term care facilities, and pharmaceutical manufacturers (but regulations only allow manufacturers to collect at their physical DEA registered locations).

This difficulty in securing community-wide kiosk locations is evident in Alameda as well. And for good reason: kiosks are necessarily a collection point – a very visible one – for prescription medications. Unfortunately, this also makes them a target for diversion, so we understand why pharmacies do not want to take on this liability. This is why recommendations for in-home disposal, as is widely accepted throughout the healthcare system, are so attractive. In-home disposal has the dual advantage of not amassing a publicly accessible collection of prescription medicines, but it also makes the entire process intuitive and accessible to the widest range of consumers. Moreover, such a disposal method avoids the regulatory complexities of a program that must comply with multiple state and federal regulations.

### **DEA Regulations:**

The regulation completely fails to recognize the complexities of the DEA regulations. Take-back programs, whether industry funded or not, are regulated by the DEA if they collect, or may reasonably be expected to collect, controlled substances. In programs that contain consumer-facing collection, it is a virtual certainty that consumers will deposit controlled substances, thus triggering the oversight of the DEA. And, to be sure, even if there is an explicit warning to not deposit controlled substances, the DEA regulations apply even if these products are *inadvertently* returned.<sup>1</sup> Since no collection program will be able to be monitored at all times, any realistic program will need to operate in compliance with DEA regulations to ensure complete protection from inadvertent controlled substance liabilities.

Like the program in Alameda, simply shifting the funding and coordination activities of such a take-back program on to industry does not mitigate the responsibilities for compliance of the local pharmacies and law enforcement agencies that might serve as hosts for these kiosks. In fact, the DEA rules prohibit the mitigation of a pharmacy's regulatory burden by having a distributor or other entity maintain the collection receptacle at the subject pharmacy for them.

### **Cost:**

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

This regulation includes fees, penalties, and other mandated costs that will unquestionably result in higher prices for prescription and non-prescription medications across the United States. Not only are manufacturers required to cover all the costs associated with administering, operating, collecting, transporting, and disposing of returned products, but companies are likewise required to cover the costs borne by the County in administering and enforcing the provisions of the program itself, not to mention funding promotion, education and outreach to local residents about this program to increase awareness.

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<sup>1</sup> See 79 Fed. Reg. 5320, 5329 (Sept. 9, 2014) (“[A]ll [DEA] regulations and laws relevant to controlled substances will apply if controlled substances are collected, even if inadvertently.”).

## Sharps:

PhRMA strongly opposes take back mandates for drugs **and** sharps. Unfortunately, illicit drug use is also a significant source of sharps in the waste stream and a sharps disposal mandate would not solve this issue. No matter what, those who handle municipal waste will need to protect themselves from any item in the waste stream that could puncture or cut their protective gear, including sharps used by users of illicit drugs. The envisioned program will likely not impact this waste stream.

In Washington, there is significant existing infrastructure to help patients dispose of their used sharps at the city or county level. For example, the City of Tacoma encourages proper disposal using a container with a lid and never in the garbage or toilet. Seattle/King County prohibits sharps in the home garbage or recycling and encourages disposal at the recycling and disposal stations or public health clinic drop off boxes.

In addition to many sites for disposal currently available in Washington state, a recent study by the University of California, Berkeley for the Commission on Health and Safety and Workers Compensation in March of 2015 entitled "Infection Risk from 'Sharps' Injuries for Non-healthcare Workers" found that "needlestick injuries in non-healthcare settings are uncommon and the risk from any needlestick resulting in chronic disease is very small...**We find no evidence that additional statutory and regulatory action covering home-health sharps waste or sharps injuries to non-healthcare workers is warranted.**"<sup>2</sup>

Specifically the report stated that:

- A review of research literature on non-healthcare, occupational sharps injuries found an extremely small number of confirmed cases of either HIV or HCV being transmitted by needlestick injuries outside healthcare settings. The combined number in developed, western countries appears to be less than 10 total for all countries from the onset of the AIDS epidemic through 2008.
- An analysis of the research on the mechanism of transmission was consistent with the findings of very few cases. We estimate that the risk of HIV from a work related needlestick injury converting to an HIV infection was 1/1 million to 75/1 million when the needle was from an intravenous (IV) drug user. For home-health sourced waste, the risk of infection may be as small as 1/100 million needlesticks.
- A review of data from the Division of Workers' Compensation Information System found that needlestick injuries were uncommon. In non-healthcare settings, approximately 1/10,000 workers will experience a needlestick injury in any year. These numbers are higher in specific industries and occupations, but still in the area of 1/1,000 workers per year.
- Prophylactic treatment after needlesticks, a measure of the risk perceived by healthcare providers and patients, is also infrequent. Only 1.2% of these injuries received prophylactic treatment.

Educating the patient on the proper collection and disposal of home generated sharps is one of the most important ways to ensure that needle-stick injury exposure is minimized. A patient's first source of information should be the physician prescribing the self-injected medicine. The physician, nurse or other healthcare

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<sup>2</sup> Neuhauser, F., Shor, G., & Jackson, R. (2015). "Infection Risk from 'Sharps' Injuries for Non-healthcare Workers." University of California, Berkeley

provider should instruct the patient on how to inject the medicine as well as how to properly dispose of the sharp once it has been used. The type of product and how it is injected will determine the most appropriate disposal method for that particular patient.

Pharmaceutical companies provide patient support information, though the prescribing physician and directly to the patient through prescription package inserts, websites, brochures, videos, or 1-800 numbers. The industry partners with healthcare providers to ensure that education pertaining to home generated sharps use and disposal is delivered efficiently and in a manner that each individual patient can understand.

PhRMA member companies have worked to develop safe, convenient and cost-effective methods for disposing of used sharps. During the development of innovative home-injectable medicines, pharmaceutical companies strive to employ safe needle technologies which will protect patients and those assisting in the disposal of used sharps. In fact, some injection devices are designed to retract or shield the needle. Other types of injectable products utilize a needle cap that locks in place when attaching the needle prior to injection or for safe disposal.

#### **Mail-back Programs: Increased Risk of Diversion:**

The final regulation includes a mail-back option for all residents to return unused medicines, specifically for disabled and homebound residents of the County. PhRMA has serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative.

Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. Presently, our research has not identified such a certified facility in the U.S.

#### **An Alternative for Safe and Secure Disposal of Unused Medicines: In-Home Secure Disposal**

Instead of implementing a flawed and potentially unsuccessful program, we urge the County to consider meaningful, measurable and comprehensive mechanisms to educate consumers on how to safeguard medicines in the home, how to ensure patients are taking their medicines as prescribed – thereby significantly mitigating unused medicines in the first place – and how to safely and securely dispose of their truly unused medicines in the household trash.

Research demonstrates that household trash disposal is effective for disposing of unused medicines. For many, in-home medicine disposal offers a simple, convenient way to dispose of unwanted, unneeded or expired medication. Because all households already participate in the collection of household trash, in-home drug disposal is a safe and preferred way of disposing of unused, unwanted or unneeded medicine.

In-home medicine disposal offers many benefits. It removes the medicines from the home immediately so that the medicine is not available for misuse or abuse, and it does not create any additional environmental impact or cost. It also gives community members the ability to handle medicine disposal discretely and independently, and protects medical privacy when done properly.

In-home disposal effectively manages any potential environmental issues given that household waste in the U.S. is either incinerated or disposed of in capped, double-lined landfills equipped with leachate collection and treatment systems. Both technologies effectively isolate waste from the physical environment. In-home disposal also avoids the environmental carbon footprint and costs of trips to a collection site and of separately shipping the collected pharmaceuticals for destruction.

PhRMA believes that any stakeholder approach should focus on educating patients on how to securely dispose of unused pharmaceutical products. The "MyOldMeds" Program (<http://myoldmeds.com>) is a consumer educational program that instructs patients on how to safely dispose of medicine in the home or where to find current take back programs in their community. To safely dispose of medicines in the home, PhRMA recommends these easy steps:

- Step 1: Pour medication into a sealable plastic bag. If the medication is in solid form (pill, liquid capsule, etc.), add water to dissolve it.
- Step 2: Add kitty litter, sawdust, coffee grounds or another mixing material to the plastic bag to make the solution less appealing for pets and children.
- Step 3: Seal the plastic bag and put it in the trash.
- Step 4: Remove and destroy all identifying personal information (for example, the prescription label) from the medication containers before recycling them or throwing them away. This helps to ensure medical privacy.

We know that educating consumers on safely storing and disposing of medicines in their own home works.

In conclusion, PhRMA recommends that Kitsap County focus their efforts on promoting adherence to medication treatment regimens and educating their constituents on the safe disposal of unused medicines and sharps. As the County discusses the important public health issues of adherence to prescription drug medicines, secure disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with the County, the state and multiple stakeholders to help address these issues. We look forward to working with you to assess opportunities for you and the residents of your County.

Sincerely,



Sharon Brigner  
Deputy Vice President, State Advocacy, PhRMA



Healthcare Distribution Alliance

PATIENTS MOVE US.

November 25, 2016

Secure Medicine Return Regulation  
Kitsap Public Health District  
345 6th St., Ste. 300  
Bremerton, WA 98310

Dear Members of the Kitsap Public Health Board:

On behalf of the Healthcare Distribution Alliance (HDA) and our distributor members serving Kitsap County, please accept the following comments in response to the Public Health Board's proposed draft *Secure Medicine Return Regulations*. As the national trade association representing primary healthcare distributors, HDA has been consistently tracking the policy issue of "pharmaceutical product stewardship" and believe our insights related to the pharmaceutical supply chain can be beneficial to the Kitsap Public Health Board.

Primary distributors are the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and other settings of care nationwide. HDA's members work daily to efficiently deliver life-saving medicines and healthcare products, provide value and efficiency, and achieve an estimated \$42 billion in cost savings each year to our nation's healthcare system.

HDA and our primary distributor members recognize the importance of efforts to ensure the safe, secure, and convenient disposal of unused, unwanted, or expired medications. While HDA distributor members do not manufacture pharmaceuticals or interact directly with patients<sup>1</sup>, primary healthcare distributors are dedicated to responsibly processing saleable returned products and when appropriate, arranging for the reverse distribution and disposition of expired or damaged pharmaceuticals returned from our customers and within member warehouses as permitted by state and federal law.

HDA members are also finding ways to lend their expertise in relation to their position in the supply chain, and are trying to raise awareness and encourage the safe drug disposal of unwanted or expired medications. As part of public policy initiatives, HDA member companies have engaged in a variety of activities such as assistance with public service announcements, customer invoice messaging, educational opportunities at business meetings, and producing educational materials to provide our pharmacy customers with information and resources to help their patients understand their options for safe disposal.

Moreover, we want to bring to your attention a newer technology enabling at-home disposal for the end-user via a sealable, disposable, biodegradable pouch that some of our member companies currently distribute to healthcare providers. The technology is highly effective in adsorbing and firmly binding pharmaceuticals, rendering them inactive and ineffective for misuse and safe for the environment. This technology was recently reviewed as a pilot in Florida and we believe it may offer local and state governments, and individual consumers, a more practical option of disposal. Further, HDA believes that safe disposal methods such as this

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<sup>1</sup> Note that the core business of pharmaceutical distributors is wholesale distribution of drug and other healthcare products; however, some of HDA's member companies do have other, separate business units that are engaged in other supply chain roles.

may eliminate leftover medicines in the home, and prevent unauthorized use or diversion, and subsequent abuse, of prescription medications.

With respect to the Kitsap County draft regulation, we attach for your consideration, a redlined version with our suggested edits and comments. Key areas of focus are summarized below for your consideration.

### Definition of “Producer”

In review of the draft regulation, it appears the County recognizes the role of the wholesale distributor in the supply chain and shares the intent that the manufacturers of brand name and generic medicines are in the best position to manage the stewardship and final disposition of the products they manufacture.

In many cases, the primary wholesale distributor is the entity who brings the product into the County. In this example, primary distributors purchase products from manufacturers, take title to the products, store, handle, pick, pack and ship, selling them to virtually every pharmacy setting (independent, chain, hospital, institutional, clinical). This unique business model ensures the safety and efficiency of the U.S. pharmaceutical supply chain and enables patients to have confidence that their pharmacy or provider will have the medicine they need, when they need it.

Our recent experience working with other localities on this issue and educating about HDA distributors' role in the supply chain has led to revisions to the definition of “producer” by providing specific exemptions for non-manufacturing entities. Doing so has led to further clarity among the stakeholders to ensure the appropriate entities are identified for producer financing and shared stakeholder responsibilities. In this case, HDA requests the Kitsap County Public Health Board to bolster the definition of “producer” by exempting repackagers. An example of such language can be found within the San Francisco City and County ordinance.<sup>2</sup> Furthermore, we ask the Kitsap County Public Health Board to advance the exemption language pertaining to those “whose store label appears on a covered drug” to also account for private label distributors<sup>3</sup> (see next comment section).

Product stewardship proposals target reduction of waste and elimination from the environment of products introduced into commerce. The obligation for such take-back or disposal efforts related to pharmaceuticals should lie with the original manufacturer of the product in its finished dosage form. In other words, the manufacturer that first introduces the product into commerce. These original manufacturers are in the best position to manage product stewardship activities and ways to reduce waste generation, rather than those entities in the middle of the pharmaceutical supply chain that “handle” medicines such as wholesalers, private label distributors, repackagers, etc.

### Exemption of Repackager and Private Label Distributors

Other county ordinances have recognized the utility of exempting wholesalers who provide repackaging services as well as private label distributors, firms that do not participate in the manufacturing or processing of a drug but instead labels, markets and distributes the drug under its own trade name. Exempting private label distributors and repackagers of finished dose products manufactured by an “original” manufacturer simply recognizes what has already been targeted in these other exempted groups – these specialized types of entities and business arrangements are not responsible for the product’s first entry into the environment, and the original manufacturer is in a better position to manage and orchestrate product stewardship plans for their own

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<sup>2</sup> San Francisco County, March 26 2015; Ordinance No. 31-15; Division I: Safe Drug Disposal, Sec. 2202. Definitions (see manufacture, producer, and repackager; ex. “manufacture” means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a Repackager or Wholesaler)

<sup>3</sup> King County Board of Health Secure Medicine Return Regulations; Title 11, 11.50.030 Definitions (P)(1)

products. Again, a good example of such language can be located in the San Francisco ordinance whereby entities who repackage or relabel covered drugs of identified producers are exempted.<sup>4</sup>

### Right of Entry and Inspection

HDA requests further review and feedback on this section. Potential options:

- Request this section apply to producers, groups of producers or stewardship organizations
- Request a notice prior to inspection within a reasonable timeframe
- Request its removal since this section is not found within other county ordinances and the ability to enter a facility is already defined under federal and state law

### Notice and Order to Correct Violation

HDA appreciates the foresight of the Kitsap County Public Health Board and allowing companies to correct a violation. While we appreciate the inclusion of this section, we request the inclusion of a set timeline to ensure companies are able to rectify any violation and correct the violation in a timely manner. As seen in other county ordinances, individuals and companies are provided with a written notice of a violation and then have 30 days to achieve compliance. We request the Board consider implementing a similar provision to the language seen in the San Francisco County Ordinance<sup>5</sup>.

In summary, HDA members are committed to working with our supply chain partners and government officials to ensure the safe and secure disposal of unused, unwanted, or expired medications. Thank you for your consideration of our views and attention to our comments. Should you have any questions or need additional information, please contact me at [llindahl@hda.org](mailto:llindahl@hda.org) or 303-829-4121.

Sincerely,



Leah Lindahl  
Senior Director, State Government Affairs, Western Region  
Healthcare Distribution Alliance

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<sup>4</sup> San Francisco County, March 26 2015; Ordinance No. 31-15; Division I: Safe Drug Disposal, Sec. 2202. Definitions: Producer (Notwithstanding the previous sentence, "Producer" does not include: (1) a retailer *[and private label distributor]* whose *[store]* label appears on a Covered Drug or the drug's packaging if the Manufacturer from whom the retailer obtains the drug is identified under Section 2203 (d) of this Division I (2) a Repackager if the Manufacturer from whom the Repackager obtains the Drug is identified under Section 2203(d) of this Division I) (*NOTE: [and private label distributors] and the elimination of [store] is suggested amendment language that accounts for noted relabeling services*)

<sup>5</sup> San Francisco County, March 26 2015; Ordinance No. 31-15; Division I: Safe Drug Disposal, Sec. 2213. Stewardship Plans – Enforcement and Penalties, subsection (b)