King County

King County Board of Health

Staff Report

Agenda item No: 7
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Subject

The King County Board of Health's Subcommittee on Secure Medicine Return has recommended a Rule & Regulation establishing an industry-funded product stewardship model to collect and safely dispose of unwanted household medicines from County residents.

Summary

The misuse of prescription drugs has emerged as a national epidemic over the last decade. Amounts of prescription drugs dispensed have increased overall; in particular, the quantity of prescription painkillers sold to pharmacies, hospitals, and doctors' offices quadrupled between 1999 and 2010. The rise in the amount of prescription drugs available has led to an increase in the number of drug-related fatalities as well as non-fatal poisonings —nationally and here in King County. Large amounts of prescription and over-the-counter medicines go unused for a variety of reasons.

A comprehensive system for safe disposal of unneeded prescription and over-the-counter drugs from residents does not yet exist in King County or nationally. A limited number of voluntary take-back programs in King County are collecting large amounts of medicines while demonstrating secure protocols. But these programs are not available in enough locations to adequately serve all County residents. Convenient and permanent drop-off locations and disposal options would help solve the problem but developing a sustainable financing model is one of the barriers.

Background

Problem Statement

Abuse, poisonings, and fatal overdoses from prescription and non-prescription medicines used in the home have emerged as an epidemic in recent years.
Prescription drug abuse is the fastest growing drug problem in the U.S., and prescription drug overdoses have been characterized by the Centers for Disease Control as a public health epidemic.[1] More people die from prescription medicines than from heroin and cocaine combined.[2] Overdoses in King County have surpassed car crashes as a leading cause of preventable deaths, with a majority of overdoses involving prescription opiates.[3] In 2006-2011 there were 1,360 drug overdose deaths in King County from prescription opiates (848) and sedatives (512).[4]

Medicines used in the home are the leading cause of poisonings reported to the Washington Poison Center[5], and preventable poisonings from medicines have been rising rapidly, especially among children and seniors.[6,7] Child Death Review data from King County (2008-2010) found that 7 out of 10 deaths of children aged 10-17 years were due to a drug or multiple drugs, with 86 percent involving prescription drugs and 29 percent involving non-prescription drugs.[8]

Unused, expired, and leftover drugs that accumulate in homes increase risks of preventable poisonings, drug abuse, and overdoses.
Large amounts of prescription and over-the-counter medicines go unused for a variety of reasons. Medicine cabinets provide teens and others with easy access to drugs. National survey data from 2010 shows over 70 percent of those who abused prescription pain relievers got them from friends or relatives, while only about 5 percent got them from a drug dealer or over the Internet.[9]

The White House Office of National Drug Control Policy recommends four "pillars" for the prevention of prescription drug abuse in its 2013 National Drug Control Strategy[10], which reiterated recommendations from the 2011 and 2012 strategies: (1) educate physicians about opiate painkiller prescribing; (2) expand prescription drug monitoring programs and promote links among state systems and to electronic health records; (3) increase prescription return/take-back and disposal programs; and (4) enforcement to address doctor shopping and pill mills. Washington state has one of the nation's strongest laws on provider education for opiate painkiller prescribing, prescription monitoring, and ongoing enforcement actions; however, a comprehensive system for safe disposal of unneeded prescription and non-prescription drugs from residents does not exist at this time nationally, in Washington state, or in King County.

Flushing and trash disposal are inappropriate for dangerous and hazardous waste medicines.
Flushing medicines releases drugs into waterways because wastewater treatment facilities do not effectively remove or degrade pharmaceutical compounds. Pharmaceuticals are household hazardous waste and should not be disposed of in the solid waste stream. Trash disposal of medicines is also an undesirable disposal option because trashcans are not secure. Garbage taken to King County's Cedar Hills Landfill generates millions of gallons a year of leachate, which is pumped to sewage treatment facilities not designed to remove complex chemicals prior to discharging effluent into Puget Sound.

Approximately 15 percent of medicines currently on the market are categorized as federal RCRA Hazardous Waste[11], and the Washington State Department of Ecology has found that "most" medicines are categorized as either state Dangerous Waste or federal RCRA Hazardous Waste[12]. King County Code (KCC 10.08.050)[13] and Seattle Municipal Code (SMC 21.36)[14] state that dangerous and hazardous wastes generated at residences should be disposed of not in the solid waste stream.

Medicine take-back programs provide secure collection and environmentally sound destruction of unwanted medicines to protect public health and the environment.
The White House Office of National Drug Control Policy, the Drug Enforcement Administration, the Food and Drug Administration, and the Environmental Protection

Administration all recommend medicine take-back programs as a more secure and environmentally safe disposal method than throwing medicines in the trash.[15]

Eleven city police stations, 12 Bartell Drug retail pharmacies, and 12 Group Health clinical pharmacies in King County currently offer medicine take-back using security protocols approved by the DEA and the Washington State Board of Pharmacy to prevent diversion and safely destroy collected medicines by high temperature incineration. Over 5,000 pounds of medicines have been collected at the law enforcement drop-off sites since 2009, and more than 48,000 pounds of medicines have been collected at the pharmacy drop-off sites since 2010 (see Attachment 3).

To help protect public safety, the Drug Enforcement Administration (DEA) has coordinated semi-annual National Prescription Drug Take-Back Days with local law enforcement, which have removed more than 2.8 million pounds, or 1,409 tons, of medications from circulation nationwide and more than 17,000 pounds in King County. Twenty-two law enforcement agencies in King County have participated as medicine drop-off sites during these DEA-coordinated take-back events. The DEA plans to stop coordinating national drug take-back events once new regulations for disposal of controlled substances are finalized (see below).

Use of these limited medicine take-back programs and collection events demonstrate a desire by King County residents to safely dispose of their leftover medications. Local law enforcement, pharmacies, health professionals, community organizations, and residents of King County are eager for the creation of community medicine take-back programs. However, key barriers to a comprehensive secure medicine return system in the County are the lack of a dedicated and adequate source of financing and the lack of coordination of take-back sites, transportation, disposal, and program promotion.

Barriers to a comprehensive secure medicine return system in King County.

1. **Convenience and access**. The voluntary medicine take-back sites are too limited in number and geographic distribution to meet the needs of the county's residents. There are no ongoing collection sites for narcotics and other controlled substances in the County's largest cities. Access to the existing voluntary take-back sites is particularly limited for County residents with limited mobility or access to transportation, such as seniors or disabled residents.
2. **Financing**. A dedicated and adequate source of funding is a key barrier to providing a comprehensive take-back system. Over-stretched local law enforcement and local government budgets cannot absorb the costs of providing a take-back system, leaving most of our communities without secure and environmentally sound options for disposal of leftover medicines. Existing voluntary programs lack funds for adequate education and promotion to increase effectiveness.
3. **Lack of an efficient system.** Without a comprehensive system, each law enforcement unit, municipality, or pharmacy has developed and implemented their medicine take-back program independently. The Local Hazardous Waste Management Program has provided technical assistance and some limited resources, but take-back sites lack coordination and any efficiency of scale for transportation, disposal or program promotion. Anecdotally, community partners and take-back locations report that residents are frustrated when they

look for, or hear about, medicine take-back programs then discover there is no convenient collection site in their neighborhood.

Changes to federal law and the DEA regulations on disposal of controlled substances will improve the convenience of medicine take-back programs by allowing retail pharmacies to accept controlled substances. About 11 percent of prescription drugs dispensed are legally prescribed controlled substances, such as OxyContin, Vicodin, and Ritalin. Current U.S. DEA regulations allow only law enforcement to collect medicines that are controlled substances. In December 2012, the DEA released a proposed regulation to implement the Secure and Responsible Drug Disposal Act of 2010 that would allow authorized retail pharmacies, drug manufacturers, drug distributors, and reverse distributors, as well as law enforcement, to operate drop-off sites and mail-back programs for controlled substances along with all other medicines.[16] The DEA's proposed rule states that collected controlled substances must be rendered "non-retrievable" by irreversibly altering the medicine's physical and/or chemical state to render it unavailable and unusable for all practical purposes. The DEA does not otherwise prescribe the destruction method but lists incineration and chemical degradation as examples of appropriate non-retrievable destruction. The DEA also states that flushing or mixing controlled substances with kitty litter or coffee grounds does not meet the non-retrievable standard.

Board of Health response to the problem.

On May 17, 2012 the Board of Health heard a briefing about safe disposal of unused and expired medicines as part of its ongoing interest in protecting the health and safety of King County. The briefing, held at the request of Board Member David Baker, provided the latest information about the limited number of medicine take-back programs in the County, as well as the perspectives of several community members and stakeholders. As a follow up, a subcommittee was convened to further study the issue. Subcommittee members included Chair McDermott, Board Member Conlin, Board Member Baker, Board Member Nicola and Director and Health Officer of Public Health David Fleming. The work of the Subcommittee had two phases: (1) hearing from interested stakeholders and (2) policy discussion and decisions, for a total of 10 meetings. The Subcommittee directed staff to develop a draft Rule & Regulation for consideration by the full Board of Health and has called for a public hearing to provide an opportunity for interested community stakeholders to comment on the proposed policy. This staff report provides a summary of information provided to the Subcommittee that served as background to the policies contained in the draft proposed Rule & Regulation. An initial public hearing was called to give the full Board of Health membership an opportunity to hear from interested stakeholders prior to the draft proposed Rule & Regulation being finalized.

Stakeholder and community engagement summary.

Outreach was conducted to engage a variety of stakeholders. These stakeholders included those who are currently involved in providing or regulating medicine take-back activities; the pharmaceutical industry; organizations representing impacted residents; and organizations that have historically supported medicine take-back including substance abuse professionals, health and medical organizations, community organizations, and environmental groups. A list of stakeholders that provided information to the Subcommittee is in Attachment 4.

Notifications about the Subcommittee's activities have also been made to the Sound Cities Association; the City Managers/City Administrators group; hazardous waste and recycling coordinators in King County; the King County Police Chiefs Association; the Coalition of Small Police Agencies; Solid Waste Advisory Committees for both King County and Seattle; the Metropolitan Water Pollution Abatement Advisory Committee (MWPAAC); and the Water Resource Inventory Areas in King County (WRIAs 8 and 9).

A website was created to provide access to the activities and materials of the Subcommittee process at http://www.kingcounty.gov/healthservices/health/BOH/MedicineTakeback.aspx.

Comment letters received during the Subcommittee process.
The Subcommittee has received letters of support from the King County Take Back Your Meds Coalition; the Association of Northwest Pharmacies; the King County cities of Covington, Kent, Kirkland, SeaTac and Shoreline; the Seattle Solid Waste Advisory Committee (SWAC); the Creeks, Drainage, & Wastewater Advisory Committee (CDWAC); and Zero Waste Washington. Letters of opposition have been received from Johnson & Johnson; the Consumer Healthcare Products Association; and PhRMA.

Overview of the proposed Rule & Regulation's secure medicine return system.
Under the proposed Rule & Regulation, residents would be encouraged to bring their leftover, expired, and unneeded medicines to secure drop boxes in retail pharmacies or law enforcement offices throughout the County. These collection sites would participate voluntarily, and if a medicine drop-off site is not available in a specific area then periodic collection events or pre-paid return mailers would be provided for those residents. Pre-paid return mailers may also be requested for residents who are home bound or disabled. Locations of drop-off sites and other collection services would be promoted to the community through a toll-free telephone line, a website, and other promotional methods.

Collected medicines would be securely handled, transported and disposed of according to federal and state laws, including policies of the Drug Enforcement Administration and the Washington State Board of Pharmacy. The drugs would be destroyed at properly permitted high temperature incineration facilities.

Drug producers selling medicines for residential use in or into King County would be required to finance and provide the secure medicine return system as part of their business expenses. Residents could not be required to pay a fee for secure medicine return when they purchase medicines or return them.

The proposed Rule & Regulation defines requirements and standards but allows drug producers to develop their own stewardship plan for providing an efficient medicine return system. Public Health-Seattle & King County (Public Health) will review and approve the stewardship plan and oversee the medicine return system to ensure safety and compliance with the proposed Rule & Regulation.

Medicines accepted for return ("covered drugs") and exempted drugs.
Prescription and non-prescription (over-the-counter) medicines that residents use in their homes or in other residential settings, for family members or for pets, will be accepted by the secure

medicine return system. Medicines in any form, e.g. pills, liquids, creams, will be accepted. Legally prescribed controlled substances, such as OxyContin, Vicodin, Valium, Ritalin, and stimulants, will also be accepted.

Some specific categories of medicines are exempted from "covered drugs" and instructions will direct residents not to return these medicines. These categories include:

- Over-the-counter drugs that are also regulated as cosmetics under the federal Food, Drug, and Cosmetics Act, such as sunscreens, toothpastes, and antiperspirants;
- Pet pesticide products like flea collars;
- Vitamins and supplements, herbal-based remedies and homeopathic drugs, products, or remedies;
- Drugs that have an established take-back system provided by the drug producer as mandated by the Food & Drug Administration;
- Drugs that are biological products if the producer already provides a take-back program.

The secure medicine return system will be provided for unwanted medicines from residential, non-business sources in King County. The system cannot be used by business generators of pharmaceutical waste, such as hospitals, clinics, doctor's offices, veterinarian clinics, pharmacies, airport security and law enforcement drug seizures. The proposed Rule & Regulation gives the Director of Public Health discretion to identify other "non-business sources" of unwanted medicines that may use the secure medicine return system, such as certain long-term care facilities where residents retain possession of some or all of their own medicines and need an appropriate disposal mechanism.

Operation of the system by drug producers.

Every drug producer selling medicines for residential use in or into the County must participate in the "standard" stewardship plan to comply with the proposed Rule & Regulation. If a producer or group of producers prefers to form a different partnership, they may propose to operate an "independent" plan. Both the standard plan and the independent plan must meet system requirements and standards and must be approved by Public Health before initiating operations. If multiple stewardship plans are approved, the plans must coordinate their promotional activities to ensure residents can easily understand and use the collection services of any plan.

The proposed Rule & Regulation defines a drug "producer" as the company that "manufactures" a covered drug sold in or into King County, including brand name or generic drugs. A definition of "manufacture" of drugs is taken from the Revised Code of Washington and includes production, preparation, and packaging of drugs. The proposed Rule & Regulation's definition of "producer" does not include compounding pharmacists preparing drugs for an individual patient or drug retail brand owners unless it is not possible to identify the manufacturer then the retail brand holder will be considered a producer.

System requirements & standards.

1. Collection

Drug producers are required to provide an ongoing, year-round collection system to equitably serve all King County residents. The stewardship plan(s) shall prioritize the use of secure drop

boxes at retail pharmacies and law enforcement offices as the primary collection method. Drop boxes must be available to the public during regular business hours at the collection location.

The proposed Rule & Regulation defines a "service convenience goal" to ensure convenient and equitable access to all residents, which has two key components:

1. Any retail pharmacy or law enforcement agency that volunteers to be a drop-off site must be included in the collection system to help ensure as many drop-off sites as possible.
2. Any city, town, or unincorporated community service area lacking a minimum number of drop-off sites will be served through periodic collection events and/or prepaid, preaddressed mailers.

Prepaid, preaddressed mailers for return of unwanted medicines must be provided for homebound or disabled residents upon request through the stewardship plan's toll-free telephone line or website. Periodic collection events, if utilized, must be arranged by drug producers with law enforcement through voluntary agreements and comply with DEA protocols and any additional requirements of participating law enforcement. Collectors may offer to serve as a collector voluntarily or may agree to serve in exchange for incentives or payment offered by the drug producers. Collectors may include pharmacies, law enforcement, mail-back services, and other appropriate collectors.

2. Drug handling

Handling of collected medicines by collectors, transporters, and waste disposal facilities must conform to all applicable federal and state laws and regulations, including applicable regulations and policies of the Drug Enforcement Administration and the Washington State Board of Pharmacy. Drug producers must define policies and procedures in their stewardship plan for how collected medicines will be safely and securely tracked. They must also address how patient information on drug packaging will be kept secure. Separation of packaging from loose pills and the recycling of packaging are encouraged where feasible.

Acceptance of controlled substances by stewardship plans and their participating collectors must comply with DEA regulations. Current DEA regulations allow only law enforcement to take-back controlled substances, either through ongoing drop-off sites in law enforcement offices or take-back events. The DEA's proposed rule to implement the Secure and Responsible Drug Disposal Act of 2010[16] would also allow authorized retail pharmacies, manufacturers, drug distributors, and reverse distributors to operate drop-off sites and mail-back programs for controlled substances, co-mingled with all other medicines. The DEA is in the process of finalizing the proposed regulation, and any changes to collection methods or policies of stewardship plans in response to new regulatory options can be accommodated through the plan review and plan changes processes of the proposed Rule & Regulation.

3. Final disposal

Collected medicines must be disposed of at a properly permitted hazardous waste facility, unless permission is granted to use a properly permitted large municipal waste combustor facility (e.g. a Waste-to-Energy facility) because of cost or logistical barriers. The stewardship plan may petition to use disposal technologies that provide superior environmental and human health

protection than a hazardous waste facility or a large municipal solid waste combustor, or that provide equivalent protection at lower cost.

These disposal standards match current EPA recommendations for disposal of medicines collected by residential take-back programs[17], which propose incineration to address both environmental and diversion concerns. EPA recommends the use of "a permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor" that meet specific regulatory standards.

Existing voluntary medicine take-back programs at pharmacies in King County currently use several different high-temperature incineration facilities, including:

- Clean Harbors (Utah), which is permitted as a hazardous waste facility; and
- Spokane Waste-to-Energy (Washington) and Covanta Waste-to-Energy (Oregon), which are both permitted as large municipal solid waste combustors.

4. Promotion and evaluation requirements

Drug producers are required to promote safe storage of medicines and the use of medicine return system to residents, pharmacists, retailers, and health care professionals so that collection options are widely understood. They must provide materials to pharmacies, health care facilities, and others and provide a website and a toll-free number. Drug producers must work with collectors to develop clear instructions on use of secure drop boxes and a readily recognizable, consistent drop box design.

Drug producers must report annually on the pounds of medicines collected by the stewardship plan. They must evaluate the effectiveness of their program promotion annually and conduct a survey of residents to measure awareness and program convenience after the first program year, and again at years five and nine.

The Local Hazardous Waste Management Program will develop template educational materials for use by pharmacies, law enforcement, health care providers and local governments. The program will also provide targeted education to key populations.

Pharmacies, health care providers, health professionals, and government agencies will be encouraged to inform consumers about the take-back program and proper disposal of medicines.

5. Oversight and enforcement

The Director of Public Health will oversee the program to ensure compliance and safety. Public Health oversight authority includes:

- Review of submitted stewardship plan(s) for compliance with the regulation's requirements and soliciting and considering public comments;
- Monitoring of plan operations and inspections as needed;
- Review and approval of substantive changes to the approved stewardship plan(s), and plan updates; and
- Review of annual reports on stewardship plan activities and results.

Under the proposed Rule & Regulation, Public Health has enforcement authority to ensure that the approved stewardship plan(s) is functioning according to the regulation. Drug producers who are not in compliance with the Rule & Regulation are subject to written warnings and civil penalties of up to $2,000 per day.

Oversight costs will be recovered through plan review and annual operating fees from producers, which will be detailed in a fee schedule that will be reviewed and approved by the Board of Health. Fee development will be consistent with existing practice for Environmental Health fees authorized under Title 2 of the Board of Health Code. The fee amounts will be based on the cost to provide the services and based upon the standard environmental health rate of $201 per hour.

Costs responsibilities.
In a product stewardship model, producers have the primary responsibility for financing and providing the take-back system because they have the greatest ability to internalize costs into their business model. The proposed Rule & Regulation prohibits any "visible fee on consumers when covered drugs are purchased or returned." Drug producers must report on the total expenditures for their stewardship plan each year.

The proposed Rule & Regulation defines costs that drug producers and other stakeholders are responsible for. Drug producers are responsible for:

- Collection supplies for drop-off sites, prepaid, pre-addressed mailers, and any collection events;
- Transporting collected medicines, including law enforcement escort if required;
- Final disposal at approved high temperature incineration facilities;
- Program promotion and evaluation, as well as administrative costs; and
- Payment of fees to Public Health to reimburse costs of plan review and annual oversight.

The methodology for apportionment of costs among drug producers working together on a stewardship plan is not defined by the proposed Rule & Regulation and will be determined by the drug producers.

Collectors participate voluntarily and drug producers are not required to pay for staff time at drop-off sites. Collectors and drug producers may work out incentives or payment arrangements. Surveys of pharmacists and law enforcement agencies operating voluntary medicine return programs have found that required staff time to monitor the drop boxes is minimal, on average less than one hour of staff time per week.[18,19]

The Local Hazardous Waste Management Program, a ratepayer funded program, is responsible for costs of:

- Providing up to 400 secure drop boxes for the standard stewardship plan. Drug producers participating in the standard plan are responsible for any additional drop boxes or maintenance costs, and producers operating an approved independent plan must provide all drop boxes; and

- Assisting with program promotion (see description above).

Estimated costs of a county-wide secure medicine return system.

Costs to drug producers for providing a county-wide secure medicine return system would depend on their selections in stewardship plan design to meet the proposed Rule & Regulation's requirements and standards and on variable costs depending on the amount of medicines collected, the number of collection sites and methods utilized, and other factors.

Start-up expenses would include development of the stewardship plan, promotional materials and a website. For the standard stewardship plan, the start-up expense of purchasing secure drop boxes for drop-off sites would be supported by the Local Hazardous Waste Management Program which would ensure provision of up to 400 base-model boxes. Producers who are approved to operate an independent stewardship plan must purchase secure drop boxes for drop-off sites participating in their plan.

Ongoing variable expenses would include collection supplies for drop-off sites, prepaid mailers, transportation and disposal of collected medicines. These costs are dependent on the number of drop-off sites, the amount of medicines collected, and other collection methods utilized. Ongoing fixed expenses would include program promotion, evaluation, and administration. Depending on stewardship plan design, fixed expenses may also include warehouse rental for consolidation and secure storage of collected medicines prior to transport to final disposal.

Because costs of the secure medicine return system are dependent on stewardship plan design and the amount of medicines collected, annual costs can only be roughly estimated. Two estimates of annual operating costs of the standard stewardship plan based on requirements and standards of the proposed Rule & Regulation are provided below. Assumptions used for the number of drop-off sites and pounds of medicines collected per capita were selected to create a low and high estimate of plan expenses. These estimates are not meant to imply a direct relationship between number of drop-off sites and pounds of medicines collected, i.e. the lower number of drop-off sites could collect a larger amount of medicines per capita. Both estimates include substantial expenses that may not be required, such as law enforcement escort during transportation of all collected medicines and warehousing of drugs prior to final disposal.

> Estimate 1: approximately $600,000 annual operating expense to drug producers collectively. Assumes operation of 85 drop-off sites and collection of 50,000 pounds of medicines per year (0.0255 pounds per capita).
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> Estimate 2: approximately $1.3 million annual operating expense to drug producers collectively. Assumes operation of 400 drop-off sites and collection of 300,000 pounds of medicines per year (0.1533 pounds per capita).

Comparison of estimated costs of secure medicine return to annual medicines sales.

Analysis of the pharmaceutical industry finds over 53,000 prescription drugs and over 17,000 over-the-counter drugs approved for sale in the U.S. by the Food & Drug Administration.[20] Pharmaceutical sales in King County are estimated at more than $1.17 billion per year according to available industry information on prescription and non-prescription drug sales.

Estimated dollars spent on prescription drug sales in 2011[21]	$ 1,055,605,327
Estimated dollars spent on over-the-counter medicines in 2011[22]	$ 110,531,520
Estimated total dollars spent on medicines in 2011 in King County	$ 1,166,136,847

Drug producers whose products are sold for residential use in Washington state include at least 167 companies, based on a list of pharmaceutical manufacturers provided to Public Health by Cardinal Health, a large local distributor of prescription and non-prescription medicines.[23] Sixty-three of these manufacturers produce both prescription and nonprescription medicines; 78 produce prescription medicines only; and 26 manufacturers produce nonprescription medicines only. This list does not include store brands for nonprescription medicines, but includes manufacturers who make store branded over-the-counter medicines.

When compared to annual sales amounts, estimated annual operating costs of $600,000 to $1.3 million per year (see above) to drug producers collectively for providing the secure medicine return system would be less than or roughly equal to 0.10 percent of annual medicines sales. Or expressed per unit of medicines sold in the county, the costs to drug producers would be roughly 1.8 to 3.8 pennies per container of prescription or over-the-counter medicines sold.

Timing of stewardship plan submission, review and implementation.
The Rule & Regulation defines a detailed implementation schedule for drug producers to comply. No later than six months after the R&R is enacted, produces must state their intent to participate in the standard stewardship plan or to propose an independent stewardship plan. No later than nine months after the rule is enacted, drug producers must identify a plan operator as an official point of contact for the standard plan or any independent plan and must notify every retail pharmacy and law enforcement agency in the county of the opportunity to participate as a drop-off site. No later than 12 months after the rule is enacted, drug producers must submit a proposed stewardship plan for review.

Public Health must review and accept or reject a proposed stewardship plan within three months of its submission. If a plan is rejected, drug producers must submit a revised stewardship plan within two months. If a revised version of the standard stewardship plan is rejected again as insufficient, then Public Health has the option of requiring submission of another revised plan or imposing corrections to the plan in order to create an approved standard plan. If a revised version of any independent stewardship plan is rejected as insufficient, then those producers must return to participating in the standard stewardship plan.

No later than three months after a stewardship plan is approved, the plan must begin operations. Annually, drug producers shall submit a report on the activities and results of their stewardship plan. At least every four years, drug producers shall update their stewardship plan.

Next steps

The Board of Health Subcommittee on Secure Medicine Return is scheduled to meet after the initial public hearing and discussion with the full Board of Health to consider incorporation of changes to the draft proposed Rule & Regulation. It is expected that a proposed Rule & Regulation will be brought back to the Board of Health for consideration at a future meeting.

Attachments

1. Draft Proposed Rule & Regulation on Secure Medicine Return
2. Overview of Proposed Secure Medicine Return Rule & Regulation
3. Voluntary Medicine Take-Back Programs in King County
4. Stakeholder Presenters at Board of Health Subcommittee on Secure Medicine Return
5. Abuse and Preventable Poisonings from Medicines in the Home
6. Drug Abuse and Preventable Poisoning from Over-the-Counter Medicines
7. Schematic Overview of Product Stewardship Approach to Secure Medicine Return for King County
8. Summary of Retail Pharmacy & Law Enforcement Locations in King County

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[1] Centers for Disease Control and Prevention.(2012).CDC grand rounds: Prescription drug overdoses—a U.S.epidemic. Morbidity and mortality weekly report. Available online at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm, Accessed May 7, 2013.

[2] Los Angeles Times "Dying for relief | A Times Investigation: Legal drugs, deadly outcomes. Scott Glover, Lisa Girion. November 11, 2012. Available online at: http://www.latimes.com/news/science/prescription/la-me-prescription-deaths-20121111-html,0,2363903.htmlstory?main=true. Accessed May 7, 2013.

[3] King County Medical Examiner's Office (2011) Annual Report. Available online at: http://kingcounty,.gov/healthservices/health/examiner.aspx. And Center for Health Statistics, Washington State Department of Health (2009). Age-Adjusted Rates for External Causes for Residents, 1999-2008.

[4] King County Medical Examiner. 2011. Data coding and analysis by Caleb Banta-Green, Alcohol and Drug Abuse Institute, University of Washington.

[5] Washington Poison Center (2012). Top Ten for 2012. Available online at: http://www.wapc.org/about/statistics/2012-top-ten/

[6] Washington State Department of Health. (2013). "Poisoning and drug overdose." Washington State Injury and Violence Prevention Guide. Available online at: http://www.eastsidefire-rescue.org/InjuryGuide2013final.pdf

[7] Centers for Disease Control and Prevention. CDC WONDER Compressed Mortality File, Underlying Cause-of- Death. Centers for Disease Control and Prevention Website. Available online at: http://wonder.cdc.gov/mortSQL.html. Accessed February 15, 2012.

[8] Public Health – Seattle & King County. (2010). Child Death Review Case Study, King County Medical Examiner Office. Ronit Gourarie, Public Health - Seattle & King County.

[9] Substance Abuse and Mental Health Services Administration. 2011. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011. Available online at: http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm#2.16

[10] White House Office of National Drug Control Policy. (2013). "2013 National Drug Control Strategy" April 2013. Available online at: http://www.whitehouse.gov/ondcp/2013-national-drug-control-strategy. Accessed May 7, 2013.

[11] Smith, C. (2009). Personal correspondence from Charlotte Smith founder of PharmEcology, a company that assists the health care and pharmaceutical industry with managing pharmaceutical waste. PharmEcology is now owned by Waste Management.

[12] Washington State Department of Ecology. (2008) *Guide for Dangerous Pharmaceutical Waste Generators in Washington State*, Publication 07-04-025. Available online at: http://www.ecy.wa.gov/pubs/0704025.pdf . Accessed May 12, 2010.

[13] King County Waste Acceptance Rule, Department Code No.: PUT 7-1-5 (PR). Department/Issuing Agency: Department of Natural Resources and Parks, Solid Waste Division. Effective Date: June 20, 2005. Full policy available online at: http://www.kingcounty.gov/operations/policies/rules/utilities/put715pr.aspx .

[14] Seattle Municipal Code. Title 10 - HEALTH AND SAFETY. Chapter 10.76 - Hazardous Waste Management Coordination Committee. SMC 10.76.010 Findings and authority.

[15] Drug Disposal Guidances from Federal Agencies: (1) The White House Office of National Drug Control Policy encourages citizens to "take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal." The ONDCP recommends trash disposal only if no take-back program is available, in its Federal Guidelines for Proper Disposal of Prescription Drugs (October 2009), *see https://www.ncjrs.gov/pdffiles1/ondcp/prescrip_disposal.pdf* ; (2) The Drug Enforcement Administration states "Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold….Take-back programs are the best way to dispose of old drugs." – *materials for DEA National Prescription Drug Take-back Day, April 30, 2011;* (3) The Food and Drug Administration encourages the use of medicine take-back programs and currently advises that throwing specific drugs in the trash is so dangerous that they should be "flushed down the sink or toilet…when they cannot be disposed of through a drug take-back program." *See: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm;* and (4) The Environmental Protection Agency "encourages the public: to take advantage of pharmaceutical take-back programs or household hazardous waste collection programs that accept pharmaceuticals. If there are no take-back programs near you contact your state and local waste management authorities (the disposal of household waste is primarily regulated on the state and local levels) with

questions about discarding unused pharmaceuticals, whether or not these materials meet the definition of hazardous waste" *See: http://www.epa.gov/ppcp/faq.html#how* .

[16] Drug Enforcement Administration's Proposed Rule for the Disposal of Controlled Substances. Notice of Proposed Rulemaking: *Federal Register*, Vol. 77, No. 246, pp. 75784-75817 – Dec.21, 2012. Docket ID: DEA-2012-0008. Available online at: http://www.regulations.gov/#!docketDetail;D=DEA-2012-0008

[17] U.S. EPA Memorandum. Sept. 26, 2012. "Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-back Events, Mail-back, and Collection Programs" Available online at: http://www.epa.gov/osw/hazard/generation/pharmaceuticals/pharms-take-back-disposal.pdf. Accessed May 7, 2013.

[18] Washington Citizens for Resource Conservation. (2009). "Medicine Return Pilot Program. End of Pilot Pharmacy Evaluation. Surveys of Participating Group Health and Bartell Drugs Pharmacies" June 2009. Available online at: http://www.takebackyourmeds.org/pdf-files/medicine-return-pilot-findings

[19] Local Hazardous Waste Management Program in King County. (2010). "Survey of Law Enforcement Medicine Return Locations in King County." November, 2010. Available online at: http://www.takebackyourmeds.org/pdf-files/survey-of-law-enforcement-medicine-return-locations-in-king-county

[20] USFDA – National Drug Code Database. Available online at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm. Data downloaded on July 30, 2012; FDA - Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm; Physician's Desk Reference for Nonprescription Drugs. 2012. PDR Ed. 33. Online reference drug database, available online at: www.Drugs.com

[21] Data for prescription medicine sales were obtained from the Kaiser Family Foundation's statehealthfacts.org website, see 2011 Washington State data for prescriptions filled and sales dollars available online at: http://www.kff.org/state-category/health-costs/budgets/?state=WA. Available data is only for prescriptions filled at retail pharmacies, which includes chain pharmacies, independent pharmacies, food stores and mass merchandisers. Prescriptions filled by mail order are not reported. Analysis by Pembroke Consulting found that 17.5 percent of prescriptions were purchased through mail-order pharmacies in 2009, see http://www.drugchannels.net/2010/08/new-data-on-pharmacy-industry-market.html. Data for the U.S. and Washington State is taken directly from the Kaiser Family Foundation website. They report Washington State is 2.1 percent of U.S. for the total number of retail prescriptions filled at pharmacies, and 1.6 percent of U.S. for total retail sales for prescription medicines sold. King County figures were calculated on a per capita basis from the state data: King County's population is 28.8 percent of Washington's total population.

[22] Data for over-the-counter (OTC) medicines sales were obtained from the Consumer Healthcare Products Association's website, see http://www.chpa-info.org/pressroom/Retail_Sales.aspx for 2011 data. The data reported is total dollars spent on OTC medicines in the U.S., which includes personal care products that are regulated as OTC medicines such as toothpaste, sunscreen, and medicated shampoos. The 2011 data reported by CHPA does not include Wal-Mart's sales for OTC medicines.

[23] "Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health". Pharmaceuticals Project, Local Hazardous Waste Management Program in King County. November 12, 2012. Available online at: http://www.kingcounty.gov/healthservices/health/BOH/~/media/health/publichealth/documents/boh/MTB/DrugDefinitionsNov2012.ashx.

A RULE AND REGULATION relating to providing safe collection and disposal of unwanted drugs from residential sources through producer provided and funded product stewardship plans, and adding a new chapter to BOH Title 11; enacted pursuant to RCW 70.05.060, including the latest amendments or revisions thereto.

BE IT ADOPTED BY THE KING COUNTY BOARD OF HEALTH:

SECTION 1. **Findings.**

A. Residents of King County benefit from the authorized use of prescription and non-prescription (over-the-counter) medicines; however abuse, fatal overdoses, and poisonings from prescription and non-prescription medicines used in the home have emerged as an epidemic in recent years.

B. More people die from prescription medicines than from heroin and cocaine combined. Drug overdoses in King County have surpassed car crashes as a leading cause of preventable deaths, with the majority of overdoses involving prescription opiates.

C. Prescription and non-prescription medicines used in the home are the leading cause of poisonings reported to the Washington Poison Center, and preventable poisonings from medicines have been rising rapidly, especially among children and seniors.

D. Unused, expired, and leftover drugs that accumulate in homes increase risks of drug abuse, overdoses, and preventable poisonings. A system for the proper disposal of unneeded drugs is an element of a comprehensive strategy to prevent prescription drug

abuse.

E. Flushing medicines down toilets and sinks is an inappropriate disposal practice because wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Trash disposal of medicines is an undesirable disposal option because trash cans are not secure and mixed pharmaceutical wastes are household hazardous wastes that should not be disposed of in the solid waste stream.

F. Medicine take-back programs provide secure collection and environmentally sound destruction of unwanted medicines to protect public health.

G. Voluntary medicine take-back programs in the county are insufficient to protect the public, so local action is warranted to reduce risks of abuse, overdoses, and poisoning.

H. The board of health finds it in the interest of public health to establish a county-wide secure medicine return program providing equitable access for all of the county's residents that is financed and operated by drug producers selling medicines in or into King County for residential use.

I. The board of health approved the Local Hazardous Waste Management Program's plan, on April 15, 2010, which states support for product stewardship approaches for waste pharmaceuticals from residential sources. The plan states that product stewardship provides a means "to shift from a system focused on government-funded and ratepayer-financed waste disposal and diversion, to one that relies on producer responsibility in order to reduce public costs, increase accessibility to services, attain higher environmental benefits, and drive improvements in product design that promotes environmental sustainability."

J. Drug producers are well-positioned to efficiently develop and operate the medicine take-back system, working with other stakeholders such as pharmacies and law enforcement, within standards prescribed by the board to ensure safety and security of the system, and in compliance with pertinent federal and state laws, regulations, and guidelines.

K. The board of health encourages pharmacies, health care providers, health professionals, government agencies responsible for solid waste management, wastewater treatment, and health and community organizations in the county to inform residents through all their standard communication methods about safe storage of medicines and the use of collection services for unwanted medicines provided through the drug producers' stewardship program.

SECTION 2. Sections 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18 of this rule should constitute a new chapter on secure medicine return in BOH Title 11.

NEW SECTION. SECTION 3. **Citation.** This chapter may be cited and referred to, and shall be known as, the "King County Board of Health Secure Medicine Return Regulations."

NEW SECTION. SECTION 4. **Purpose and scope of chapter.**

A. This chapter is enacted as an exercise of the board of health powers of King County to protect and preserve the public health, safety, and welfare. Its provisions shall be liberally construed for the accomplishment of these purposes. This chapter governs the protection of human health and safety against the improper handling and disposal of leftover or expired medicines.

B. It is the specific intent of this chapter to place the obligation of complying with its requirements upon drug producers and other persons designated by this chapter within its scope, and any provision of or term used in this chapter is not intended to impose any duty whatsoever upon King County or any of its officers or employees, for whom the implementation or enforcement of this chapter shall be discretionary and not mandatory.

NEW SECTION. SECTION 5. **Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

A. "Collector" means a person that gathers unwanted covered drugs from covered entities for the purpose of collection, transportation and disposal.

B. 1. "Covered drug" includes all prescription and nonprescription drugs sold in any form and used by covered entities, including brand name and generic drugs.

2."Covered drug" does not include:

a. Vitamins or supplements;

b. Herbal-based remedies and homeopathic drugs, products, or remedies;

c. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal food, drug, and cosmetic act;

d. Drugs for which producers provide a pharmaceutical product stewardship or 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);

e. Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this chapter if the producer already provides a pharmaceutical product stewardship or take-back program;

f. Medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories; and

g. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

C. "Covered entities" means residents of King County, including individuals living in single and multiple family residences and other residential settings, and including other non-business sources of prescription and nonprescription drugs that are unused, unwanted, disposed of or abandoned by residents as identified by the director. "Covered entities" does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor’s offices, veterinarian clinics, pharmacies, or airport security and law enforcement drug seizures.

D. "Director" means the director of the Seattle-King County Department of Public Health or the director's duly authorized representative.

E. "Drug wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

F. "Drugs" means:

1. 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;

2. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

3. Substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or

4. Substances intended for use as a component of any substances specified in subsection F.1., F.2. or F.3 of this subsection, but not including medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories.

G. "Independent product stewardship plan" or "independent stewardship plan" means a plan other than the standard product stewardship plan for the collection, transportation, and disposal of unwanted covered drugs that may be proposed by a producer or group of producers; and, if approved, is financed, developed and implemented by the participating producer or group of producers, and operated by the participating producer or group of producers or a stewardship organization.

H. "Local hazardous waste management program" means the King County local hazardous waste management program identified in BOH chapter 2.08.080.

I. "Manufacture" means as defined in RCW 18.64.011(15) the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

J. "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices, as defined in RCW 18.64.011(16).

K. “Mail-back services” means a collection method for the return of unwanted covered drugs from covered entities utilizing prepaid and preaddressed mailing envelopes.

L. "Nonprescription drug" means any drugs that may be lawfully sold without a prescription.

M. "Person" means a firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.

N. "Pharmacy" means every place properly licensed by the state of Washington board of pharmacy where the practice of pharmacy is conducted as defined under RCW 18.64.011.

O. "Prescription drug" means any drugs, including controlled substances under chapter 69.50 RCW, that are required by an applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.

P. "Producer” means a manufacturer who is engaged in the manufacture of a covered drug sold in or into King County, including brand name or generic drugs. "Producer" does not include:

1. A retailer 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 6.C of this rule; or

2. A pharmacist who compounds a prescribed individual drug product for a consumer; or

3. A wholesaler who is not also a manufacturer.

Q. "Retail pharmacy" means a pharmacy properly licensed by the state of Washington board of pharmacy for retail sale and dispensing of drugs.

R. "Standard product stewardship plan" or "standard stewardship plan" means the plan for the collection, transportation, and disposal of unwanted covered drugs that is financed, developed, implemented and participated in by producers, operated by the participating producers or a stewardship organization, and approved as the standard product stewardship plan.

S. "Stewardship organization" means an organization designated by a producer or group of producers to act as an agent on behalf of each producer to develop and implement and operate the standard product stewardship plan or an independent product stewardship plan.

T. "Unwanted covered drug" 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.

NEW SECTION. SECTION 6. **Product stewardship plans – Participation.**

A. Each producer shall participate in the standard product stewardship plan approved by the director, except that a producer may individually, or with a group of producers, form and participate in an independent product stewardship plan if approved by the director.

B. The standard product stewardship plan and any independent product stewardship plan shall be approved by the director before collecting unwanted covered

drugs. Once approved, product stewardship plans must have prior written approval of the director for proposed changes as described under Section 15 of this rule.

C. By six months after this rule is adopted, each producer of covered drugs sold in or into King County shall notify the director in writing of the producer's intent to participate in the standard product stewardship plan or to form and participate in an independent product stewardship plan. A retailer whose store label appears on a covered drug or the drug's packaging must notify the director of intent to participate or provide written notification that the manufacturer from whom the retailer obtains the drug has provided its notice of intent to participate.

D. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall:

1. By nine months after this rule is adopted, identify in writing to the director a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the product stewardship plan.

2. By nine months after this rule is adopted, notify all retail pharmacies and law enforcement agencies in the county of the opportunity to participate as a drop-off site in accordance with the requirements of subsections 8.A. and 8.E. of this rule, and provide a process for forming an agreement between the plan and interested collectors; and annually thereafter, make the same notification to any non-participating or new retail pharmacies or law enforcement agencies in the county.

3. By one year after this rule is adopted, submit a proposed product stewardship plan as described in section 7 of this rule to the director for review;

4. Within three months after the director's approval of their stewardship plan, operate or participate in a product stewardship plan in accordance with this chapter;

5. At least every four years after each plan initiates operations, submit an updated plan to the director explaining any substantive changes to components of the stewardship plan required in section 7 of this rule, and accompanied by the review fee in accordance with section 18 of this rule. The director shall review updated stewardship plans using the process described in section 14 of this rule; and

6. Pay all administrative and operational costs and fees associated with their product stewardship plan as defined under Sections 11 and 18 of this rule.

E. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan may:

1. Enter into contracts and agreements with stewardship organizations, other service providers, or other entities as necessary, useful, or convenient to provide all or portions of their product stewardship plan;

2. Notify the director of any producer selling covered drugs in or into King County that is failing to participate in a product stewardship plan; and

3. Perform any other functions as may be necessary or proper to provide the product stewardship plan and to fulfill any or all of the purposes for which the plan is organized.

F. After the first full year of operation of the approved standard stewardship plan, a producer or group of producers participating in the standard stewardship plan may notify the director in writing of intent to form an independent product stewardship plan, and identify a plan operator, including the plan operator's telephone, mailing address and

email contact information, who is authorized to be the official point of contact for the proposed independent stewardship plan. Within three months of such notification, the producer or group of producers may submit a proposed independent product stewardship plan as described under section 7 of this rule to the director for review.

G. Submission dates and deadlines described in this section may be extended to a later date as approved in writing by the director.

H. After presenting official credentials and providing notice of an audit or inspection to determine compliance with this chapter or to investigate a complaint, the director may audit a producer's, group of producers', or stewardship organization's records related to a product stewardship plan or request that the producer, group of producers, or stewardship organization arrange for the director to inspect at reasonable times a product stewardship plan's or a collector's facilities, vehicles, and equipment used in carrying out the stewardship plan.

NEW SECTION. SECTION 7. **Product stewardship plans – Components.** The standard product stewardship plan or any independent product stewardship plan, which must be submitted and reviewed according to section 14 of this rule, shall include the following:

A. Contact information for all drug producers participating in the product stewardship plan;

B. A description of the proposed collection system to provide convenient ongoing collection service for all unwanted covered drugs from covered entities in compliance with the provisions and requirements in section 8 of this rule, including a list of all collection methods and participating collectors, a list of drop-off locations, a

description of how periodic collection events will be scheduled and located if applicable, a description of how mail-back services will be provided, and an example of the prepaid, preaddressed mailers to be utilized. The description shall include a list of retail pharmacies and law enforcement agencies contacted by the plan under subsection 6.D.2. of this rule, and a list of all collectors who offered to participate;

C. A description of the handling and disposal system, including identification of and contact information for collectors, transporters, and waste disposal facilities to be used by the product stewardship plan in accordance with sections 8 and 10 and other provisions of this rule;

D. A description of the policies and procedures to be followed by persons handling unwanted covered drugs collected pursuant to the product stewardship plan, including a description of how all collectors, transporters and waste disposal facilities utilized will ensure the collected, unwanted covered drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the product stewardship plan will operate under all applicable federal and state laws, rules and guidelines, including those of the United States drug enforcement administration, and how any pharmacy collection site will operate under applicable rules and guidelines of the state of Washington board of pharmacy;

E. A description of how patient information on drug packaging will be kept secure during collection, transportation, and recycling or disposal;

F. A description of the public education effort and promotion strategy required in section 9 of this rule, including a copy of standardized instructions for residents, signage developed for collectors, and required promotional materials;

G. A proposal on the short term and long term goals of the product stewardship plan for collection amounts, education and promotion; and

H. A description of how the product stewardship plan will voluntarily consider:

1. use of existing providers of waste pharmaceutical services;

2. separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and

3. recycling of drug packaging to the extent feasible.

NEW SECTION. SECTION 8. **Product stewardship plans – Collection of covered drugs.**

A. This chapter does not require any person to serve as a collector in a product stewardship plan. A person may offer to serve as a collector voluntarily, or may agree to serve as a collector in exchange for incentives or payment offered by a producer, group of producers or stewardship organization. Collectors may include law enforcement, pharmacies, mail-back services, or other entities, operating in accordance with state and federal laws and regulations for the handling of covered drugs, including those of the United States drug enforcement administration, and in compliance with this chapter. Any pharmacy collection site shall operate under applicable rules and guidelines of the state of Washington board of pharmacy.

B. The collection system shall be convenient on an ongoing, year-round basis to adequately serve the needs of covered entities and shall be designed in consideration of equitable opportunities for all King County residents for the safe and convenient return of unwanted covered drugs, in accordance with the requirements of this section.

C. The collection system for all unwanted covered drugs shall be safe and secure, including protection of patient information on drug packaging.

D. The service convenience goal for the standard stewardship plan and any independent stewardship plan is a system of drop-off sites distributed to provide reasonably convenient and equitable access for all residents in incorporated and unincorporated areas of the county.

1. In establishing and operating a product stewardship plan, a producer, group of producers or stewardship organization shall give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites. A product stewardship plan shall include, as collectors, any retail pharmacy or any law enforcement agency willing voluntarily to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter within three months of their offer to participate, unless the collector requests a longer time frame. A producer or group of producers establishing and operating a product stewardship plan may also accept other collectors willing to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this chapter.

2. The system of drop-off sites shall provide in every city, town, or unincorporated community service area with a pharmacy or law enforcement facility, one drop-off site and a minimum of at least one additional drop-off site for every thirty thousand residents, geographically distributed to provide reasonably convenient and equitable access.

3. If the service convenience goal in subsection D.2. cannot be achieved by the standard stewardship plan or any independent stewardship plan due to a lack of drop-off

sites at pharmacies, law enforcement agencies, or other qualified collectors in specific areas of the county, then those areas shall be served through periodic collection events or mail-back services, or a combination of these collection methods.

E. Drop-off sites shall accept covered drugs from covered entities during all hours that the retail pharmacy, law enforcement agency, or other collector is normally open for business with the public. Drop-off sites shall utilize secure drop boxes in compliance with all applicable requirements of the United States drug enforcement administration and the state of Washington board of pharmacy.

F. Mail-back services shall be made available to differentially-abled and home bound residents upon request through the stewardship plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to persons providing services to such residents; and may also be utilized as a collection method according to subsection D.3.

G. Periodic collection events, if utilized as a collection method according to subsection D.3., must be arranged with law enforcement personnel through voluntary agreements, and shall be conducted in compliance with U.S. drug enforcement administration protocols, any additional requirements of participating law enforcement agencies, and in compliance with this chapter.

NEW SECTION. SECTION 9. **Product stewardship plans – Promotion.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall:

1. Promote the use of their product stewardship plan so that collection options for covered drugs are widely understood by residents, pharmacists, retailers of covered

drugs, and health care practitioners including doctors and other prescribers, and promote the safe storage of covered drugs by residents prior to secure disposal through their stewardship plan;

2. Work with collectors participating in their product stewardship plan to develop clear, standardized instructions for residents on the use of drop boxes and a readily recognizable, consistent design of drop boxes. The local hazardous waste management program may provide guidance to producers and collectors on the development of the instructions and design;

3. Establish a toll-free telephone number and web site where collection options and current locations of drop-off sites will be publicized and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return unwanted covered drugs to the product stewardship plan. These materials must be provided to pharmacies, health care facilities, and other interested parties for dissemination to residents. Plain language and explanatory images should be utilized to make use of medicine collection services readily understandable by all residents, including individuals with limited English proficiency. A producer or group of producers participating in the standard stewardship plan or any independent stewardship plan shall coordinate these promotional activities to ensure that residents can easily identify, understand and access the collection services provided by any stewardship plan;

4. Annually evaluate the effectiveness of its outreach and product stewardship plan activities; and

5. Conduct a survey of residents of King County to determine the percentage of residents that are aware of the product stewardship plan and to what extent residents find

the plan convenient after the first full year of operation of the plan, and again after five and nine years of operation. Results of the survey shall be reported to the director and made available to the public on the stewardship plan's website.

B. The local hazardous waste management program shall:

1. Promote the use of product stewardship plans and the plans' toll-free telephone numbers and web sites through their standard educational methods;

2. Provide sample educational materials for use by pharmacies, law enforcement agencies, health care providers and local government agencies in the county;

3. Conduct educational outreach to targeted populations and groups as informed by survey results and other research indicators; and

4. Assume the costs of developing and providing promotional and educational materials under this subsection.

NEW SECTION. SECTION 10. **Product stewardship plans – Disposal of covered drugs.**

A. Covered drugs collected under a product stewardship plan must be disposed of at a properly permitted hazardous waste disposal facility as defined by the United States environmental protection agency under 40 CFR parts 264 and 265.

B. The director may grant approval for a producer or group of producers participating in the standard stewardship plan or an independent product stewardship plan to dispose of some or all collected covered drugs at a properly permitted large municipal waste combustor, as defined by the United States environmental protection agency under 40 CFR parts 60 and 62, if use of a hazardous waste disposal facility described under

subsection A is deemed not feasible for the stewardship plan based on cost, logistics, or other considerations.

C. A producer or group of producers participating in the standard stewardship plan or an independent product stewardship plan may petition the director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsections A. and B. of this section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:

1. Monitoring of any emissions or waste;

2. Worker health and safety;

3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

4. Overall impact to the environment and human health.

NEW SECTION. SECTION 11. **Product stewardship plans – Administrative and operational costs and fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay all administrative and operational costs related to their product stewardship plan, except as provided under this section. Administrative and operational costs related to the product stewardship plan include the following:

1. Collection and transportation supplies for each drop-off site;

2. Purchase of all secure drop boxes for drop-off sites in any independent stewardship plan;

3. Purchase of additional secure drop boxes needed for drop-off sites in the standard stewardship plan beyond the four hundred provided under subsection 11.B.

4. Ongoing maintenance or replacement of secure drop boxes, as requested by collectors.

5. Pre-paid, pre-addressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized;

6. Operating periodic collection events if utilized, including costs of law enforcement staff time if necessary;

7. Transportation of all collected pharmaceuticals to final disposal, including costs of law enforcement escort if necessary;

8. Environmentally sound disposal of all collected pharmaceuticals under section 10 of this rule; and

9. Program promotion under section 9 of this rule.

B. The local hazardous waste management program shall ensure the provision of up to four hundred secure drop boxes for retail pharmacies and law enforcement agencies willing to participate as drop-off sites for the standard stewardship plan. The local hazardous waste management program may purchase or provide a voucher toward the purchase, or may reimburse the standard stewardship plan for base-model drop boxes. Collectors who leave the standard stewardship plan for any reason are encouraged to donate the secure drop box to the standard stewardship plan. Producers participating in the standard stewardship plan shall retrieve drop boxes from collectors as requested.

C. No person or producer may impose a visible fee on consumers when covered drugs are purchased or returned.

D. Producers are not required to pay for costs of staff time at drop-off sites provided by collectors volunteering for a product stewardship plan.

NEW SECTION. SECTION 12. **Product stewardship plans – Reporting requirements.**

A. Within six months after the end of the first twelve month period of operation, and annually thereafter, the plan operator of the standard product stewardship plan and of any independent product stewardship plan shall submit a report to the director on behalf of participating producers describing their plan's activities during the previous reporting period to comply with this chapter. The report must include the following:

1. A list of producers participating in the product stewardship plan;

2. The amount, by weight, of unwanted covered drugs collected, including the amount by weight from each collection method used;

3. A list of drop-off locations, the number of mailers provided for differentially-abled and home bound residents, locations where mailers were provided, if applicable, dates and locations of collection events held, if applicable, transporters used, and the disposal facility or facilities used;

4. Whether any safety or security problems occurred during collection, transportation, or disposal of unwanted covered drugs during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security in the future;

5. A description of the public education, outreach, and evaluation activities implemented during the reporting period;

6. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;

7. A summary of the product stewardship plan goals, the degree of success in meeting those goals in the past year, and if any goals have not been met, what effort will be made to achieve such goals in the next year; and

8. The total expenditure of the stewardship plan during the reporting period.

B. The director shall make reports submitted under this section available to the public.

C. For the purposes of this section, "reporting period" means the period commencing January 1st and ending December 31st of the same calendar year, unless otherwise specified to the plan operator by the director.

NEW SECTION. SECTION 13. **Product stewardship plans – Lists of producers of covered drugs.** Beginning sixty days after this rule is adopted, each drug wholesaler that sells any covered drug in or into the county must provide a list of producers of covered drugs to the local hazardous waste management program in a form agreed upon with the director. Wholesalers must update the list by January 15th of each year.

NEW SECTION. SECTION 14. **Product stewardship plans – Review of proposed plans.**

A. By one year after this rule is adopted, a producer, group of producers, or stewardship organization participating in the standard stewardship plan or any independent stewardship plan shall submit its proposed product stewardship plan to the director for review, accompanied by the plan review fee in accordance with section 18 of

this rule. The director may upon request provide consultation and technical assistance about the requirements of this chapter to assist a producer, group of producers, or stewardship organization in developing its proposed plan.

B. The director shall review the proposed product stewardship plan and determine whether the proposed plan meets the requirements of section 7 and other applicable sections of this rule. In reviewing a proposed product stewardship plan, the director shall provide opportunity for written public comment and consider any comments received.

C. After the review under subsection B. of this section and within ninety days after receipt of the proposed product stewardship plan, the director shall either approve or reject the proposed product stewardship plan and, if rejected, provide reasons for rejection.

D. If the proposed product stewardship plan is rejected, a producer or group of producers must submit a revised product stewardship plan to the director within sixty days after receiving notice of the rejection. The director shall review and approve or reject a revised product stewardship plan as provided under subsections B. and C.

E. If the director rejects a revised product stewardship plan, or any subsequently revised plan, the producer or group of producers shall be deemed out of compliance with this chapter and is subject to the enforcement provisions contained in this chapter.

1. If the revised standard stewardship plan is rejected, the director may, in the director's sole discretion, require the submission of a further revised standard stewardship plan or develop and impose changes to some or all components of the rejected plan to constitute an approved standard stewardship plan. If the director imposes some or all of

the approved plan, the producers participating in and complying with the approved standard stewardship plan in accordance with this chapter shall not be considered out of compliance with this chapter.

2. If a revised independent stewardship plan is rejected, the producer or group of producers submitting the independent stewardship plan shall participate in the standard stewardship plan and shall not be eligible to propose an independent stewardship plan for six months after such rejection. Any producers whose revised independent stewardship plan is rejected shall not be considered out of compliance with this chapter if they participate in and comply with the standard stewardship plan.

F. In approving a proposed product stewardship plan, the director may exercise reasonable discretion to waive strict compliance with the requirements of this chapter that are applicable to producers in order to achieve the objectives of this chapter.

G. The director shall make all stewardship plans submitted under this section available to the public.

NEW SECTION. SECTION 15. **Product stewardship plans - Prior approval for change.**

A. Proposed changes to an approved product stewardship plan that substantively alter plan operations, including, but not limited to, changes to participating manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling covered drugs, education and promotion methods, or disposal facilities must have prior written approval of the director.

B. A producer or group of producers participating in the standard stewardship plan or any independent stewardship plan shall submit to the director any proposed

change to a product stewardship plan as described under subsection A. in writing at least thirty days before the change is scheduled to occur and accompanied by the review fee in accordance with section 18 of this rule.

C. The plan operator of an approved product stewardship plan shall notify the director at least fifteen days before implementing any changes to drop-off site locations, methods for scheduling and locating periodic collection events, or methods for distributing prepaid, preaddressed mailers that do not substantively alter achievement of the service convenience goal under subsection 8.D. of this rule, or other changes that do not substantively alter plan operations under subsection A.

NEW SECTION. SECTION 16. **Product stewardship plans – Enforcement – Penalty.**

A. The director shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer who is not participating in the standard product stewardship plan or an independent product stewardship plan as required under this chapter. The warning shall state that participation in a plan is required and warn of penalties for noncompliance.

B. A producer not participating in the standard product stewardship plan or an independent product stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty pursuant to subsections D. and E. of this section.

C. If the director determines that a product stewardship plan is not in compliance with this chapter or its plan approved pursuant to section 14 of this chapter, the director may send the producer or group of producers participating in the plan a written warning

stating the plan is not in compliance, providing notice of the compliance requirements and warning of penalties for noncompliance. The producer or group of producers has thirty days after receipt of the notice to achieve compliance. If the product stewardship plan is not in compliance after thirty days, the director may assess a penalty pursuant to subsections D. and E. of this section. This subsection does not preclude the director from suspending an approved plan if a violation of this chapter or an approved plan creates a condition that, in the director's judgment, constitutes an immediate hazard.

D. A violation of this chapter is subject to a civil penalty of up to $2,000 and may be assessed against a producer or group of producers. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate penalty, the director shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, the financial burden to the violator, and the size of the violator's business.

E. The director may utilize the provisions of BOH chapter 1.08 to assess civil penalties provided in this section. A producer or group of producers may appeal assessments imposed under this section as provided in BOH chapter 1.08. In addition to or as an alternative to utilizing the procedures set forth in BOH chapter 1.08, the director may assess or recover penalties accruing under this section by legal action filed in King County superior court.

NEW SECTION. SECTION 17. **Product stewardship plans – Administrative rules, performance standards, and report.**

A. The director may adopt rules necessary to implement, administer, and enforce this chapter.

B. The director may work with the plan operator to define goals for collection amounts, education, and promotion for a product stewardship plan.

C. The director shall report annually to the King County board of health concerning the status of the standard and independent product stewardship plans and recommendations for changes to this chapter.

NEW SECTION. SECTION 18. **Plan review and annual operating fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director plan review fees to be established under subsection D of this section for:

1. Review of a proposed product stewardship plan;

2. Resubmittal of a proposed stewardship plan;

3. Review of changes to an approved stewardship plan; or

4. Submittal of an updated stewardship plan at least every four years under subsection 6.D.5. of this rule.

5. Review of any petition for approval to use alternative final disposal technologies under Section 10.C. of this rule.

B. In addition to plan review fees, a producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director annual operating fees to be established under subsection D. of this section.

C. A plan operator or a stewardship organization may remit the fee on behalf of participating producers.

D. As soon as practicable, the director shall propose to the board of health a schedule of fees to be charged to a producer or group of producers to cover costs of administering and enforcing this chapter. Fees shall be calculated to recover actual costs.

SECTION 19. R&R 66, Section 1 (part), as amended, and BOH 2.08.080 are each hereby amended to read as follows:

Committee Established – Membership. The Local Hazardous Waste Management Program's Management Coordination Committee is hereby established. The Committee shall be composed of five members:

A. The director of the King County Department of Natural Resources – Solid Waste Division or his/her designee;

B. The director of City of Seattle Public Utilities or his/her designee;

C. A representative appointed by the ((~~Suburban~~)) Sound Cities Association;

D. The director of the King County Department of Natural Resources – Water and Land Resources Division or his/her designee; and

E. The director of the Seattle-King County Department of Public Health or his/her designee.

SECTION 20. R&R 66, Section 1 (part), as amended, and BOH 2.08.085 are each hereby amended to read as follows:

Powers of the committee.

A. 1. The committee shall be responsible for accepting and recommending a management plan and budget for:

a. the reduction of moderate risk waste generation, its entry into the solid waste stream, entry into the liquid waste (sewage) stream, into storm drainage or surface waters and evaporation into the air; and

b. the protection and enhancement of the public health and environmental quality in King County by the reduction of the threat posed by the production, use, storage and disposal of hazardous materials.

2. The management coordination committee will develop an annual plan and budget and reach agreement on it through consensus of the entire committee. Lacking a consensus, a majority and a minority report will be forwarded to the King County Board of Health.

B. The committee shall recommend contracts with the city of Seattle, suburban cities, sewer districts, or other governments or entities located entirely or partially within King County, and King County, to implement portions of the management plan, in consideration of sums collected under BOH 2.08.090.

C. The committee shall develop an annual plan and budget for implementation of the King County Board of Health Secure Medicine Return Regulations and reach agreement on it through consensus of the entire committee. Lacking a consensus, a majority and a minority report shall be forwarded to the King County Board of Health. The committee shall recommend contracts or interagency agreements to implement portions of the plan.

SECTION 21. **Severability.** If any provision of this rule or its application to any person or circumstance is held invalid, the remainder of the rule or the application of the provision to other persons or circumstances is not affected.

Overview of Proposed Secure Medicine Return Rule & Regulation. May 8, 2013

The King County Board of Health's Subcommittee on Secure Medicine Return has recommended a Rule and Regulation (R&R) establishing an industry-funded product stewardship model to collect and safely dispose of unwanted household medicines from residents of the county.

Overview of the proposed secure medicine return system

Residents will be encouraged to bring leftover, expired, and unneeded medicines to secure drop boxes in retail pharmacies or law enforcement offices throughout the county. These collection sites will participate voluntarily, and if a medicine drop-off site is not available in a specific area then periodic collection events or pre-paid return mailers will be provided. Pre-paid return mailers can be requested for residents who are home bound or disabled. Drop-off site locations and other collection services will be promoted to the community through a toll-free telephone line, a website, and print materials.

Collected medicines will be securely handled, transported and disposed of according to federal and state laws, including policies of the Drug Enforcement Administration and the Washington State Board of Pharmacy. The drugs will be destroyed at properly permitted high temperature incineration facilities.

Drug producers selling medicines for residential use in or into King County are required to finance and provide the secure medicine return system. Residents cannot be required to pay a fee for secure medicine return when they purchase medicines or return them. Public Health - Seattle & King County (Public Health) will oversee the drug producers' medicine return system to ensure safety and compliance with the R&R.

Medicines accepted for return

- Prescription and non-prescription (over-the-counter) medicines that residents use in their homes, or in other residential settings. Includes medicines in any form: pills, liquids, creams; and includes legally prescribed controlled substances, such as OxyContin, Vicodin, Valium, Ritalin, and stimulants.
- Current DEA regulations restrict return of controlled substances to law enforcement drop-off sites or collection events; however, new regulations the DEA is developing will authorize drug manufacturers, retail pharmacies and others to operate drop-off and mail-back programs.
- Not accepted for return: over-the-counter drugs that are regulated as cosmetics, e.g. toothpaste, sunscreen, medicated shampoos; vitamins and supplements; and pharmaceutical waste from businesses.

Operation of the system by drug producers

- The proposed R&R defines requirements and standards, but allows drug producers to develop their own stewardship plan for providing an efficient medicine return system.
- Every drug producer selling medicines for residential use in or into the county must participate in the "standard" stewardship plan. If a producer or group of producers prefers to form a different partnership, they may propose an "independent" plan. Both the standard plan and the independent plan must meet system requirements and standards, and be approved by Public Health before initiating operations.
- If multiple stewardship plans are approved, the plans must coordinate their promotional activities to ensure residents can easily understand and use the collection services of any plan.
- Timing of program implementation: drug producers must submit a proposed stewardship plan no later than 12 months after the R&R is enacted; and must begin operation of the stewardship plan no later than 3 months after plan approval by Public Health.

System requirements & standards

- The primary collection method will be secure drop boxes at retail pharmacies and law enforcement offices.
- The R&R defines a "service convenience goal" to ensure convenient and equitable access for all residents. Any retail pharmacy or law enforcement agency that volunteers to be a drop-off site must be included in the collection system to ensure as many drop-off sites as possible. Any areas lacking a minimum number of drop-off sites will be served through periodic collection events and/or through mail-back programs.

System requirements & standards (continued)

- Prepaid, preaddressed mailers can be requested for home bound or disabled residents.
- Collectors may offer to serve as a collector voluntarily, or may agree to serve in exchange for incentives or payment offered by the drug producers.
- Handling of all drugs must conform to all applicable federal and state laws and regulations, including those of the Drug Enforcement Administration and the Washington State Board of Pharmacy.
- Collected medicines must be disposed of at a properly permitted hazardous waste facility, unless permission is granted to use a large municipal waste combustion facility (e.g. Waste-to-Energy facilities) because of cost or logistical barriers. Use of alternative disposal technologies that provide superior environmental and human health protection may also be approved.

Promotion and evaluation requirements

Promotion: drug producers are required to promote safe storage of medicines and how to use the medicine return system to residents, pharmacists, retailers, and health professionals; provide materials to pharmacies, health care facilities, and others; and provide a website and a toll-free number. Drug producers must work with collectors to develop clear instructions on use of secure drop boxes and a readily recognizable, consistent drop box design.

Evaluation: drug producers must report annually on the pounds of medicines collected, annually evaluate the effectiveness of program promotion, and conduct a survey of residents to measure awareness and program convenience after the first program year, and again at years five and nine.

LHWMP will develop template educational materials for use by pharmacies, law enforcement, health care providers and local governments, and provide targeted education to key populations.

Costs responsibilities

Drug producers are responsible for:

- Costs of collection supplies for drop-off sites, prepaid mailers, and any collection events.
- Costs of transporting collected medicines (including law enforcement escort if required), and final disposal at approved high temperature incineration facilities.
- Costs of program promotion and evaluation, as well as administrative costs.
- Payment of fees to Public Health to reimburse costs of plan review and annual oversight.

Collectors participate voluntarily and provide in-kind staff time at drop-off sites.

The Local Hazardous Waste Management Program in King County is responsible for costs of:

- Providing up to 400 secure drop boxes for the standard stewardship plan. Drug producers participating in the standard plan are responsible for any additional drop boxes or maintenance costs, and producers operating an approved independent plan must provide all drop boxes.
- Assisting with program promotion (see description above).

Oversight and enforcement

- Public Health will oversee the program to ensure compliance and safety.
- Public Health oversight authority includes: review and approval of the stewardship plan(s) from drug producers, monitoring of plan operations, inspections as needed, review and approval of substantive changes to the approved stewardship plan(s), and review of annual reports.
- Drug producers who are not in compliance with the R&R are subject to written warnings and civil penalties of up to $2,000 per day.
- Public Health oversight costs will be recovered through plan review and annual operating fees from producers.

Voluntary Medicine Take-back Programs in King County

Law Enforcement Providing Medicine Take-back in King County

Medicines accepted: all prescription drugs, including controlled substances, and over-the-counter drugs.

Eleven police departments in King County offer ongoing medicine drop-off programs, currently funded by the police departments. LHWMP has provided financial assistance to some police units to purchase secure steel drop boxes (~$800 each). Most ongoing law enforcement programs have been disposing of collected medicines with their evidentiary drugs or through the semi-annual DEA National Prescription Drug Take-Back Events.

Ongoing Law Enforcement Medicine Take-Back Site	Examples of pounds collected, if recorded/reported to LHWMP (includes drugs collected through participation in DEA events where noted)
Auburn Police Department	105 pounds at 2 DEA events, ongoing collection not reported
Bothell Police Department	1,570 pounds, from January 2010 to April 2013
Burien Police Station	179 pounds, from April 2011 to December 2012
Issaquah Police Department	595 pounds, from January 2009 to October 2011.
Kenmore Police Department	Started September 2012.
Lake Forest Park Police Department	127 pounds, from July 2012 to May 2013
Maple Valley Police Department	242 pounds, from November 2010 to December 2012
North Bend Police Department	456 pounds, from March 2010 to December 2012
Sammamish Police Department	859 pounds in 2011 to December 2012
Snoqualmie Police Department	210 pounds, from September 2010 to January 2012
Woodinville Police Department	1,303 pounds, from July 2010 to December 2012

In addition, 22 police departments have participated in the DEA National Prescription Drug Take-back Events, one-day collections held semi-annually since fall 2010. The DEA plans to stop coordinating these take-back days once the new regulations for collection of controlled drugs are finalized.

Total Medicines Collected in King County at 5 Events = 10,333 Pounds, as reported by the DEA.

King County Police Departments Participating in DEA Prescription Take-Back Events	
Auburn Police Department	Kirkland Police Department
Bellevue Police Department (3 locations)	Medina Police Department
Black Diamond Police Department	Mercer Island Police Department
Bothell Police Department	Normandy Park Police Department
Burien Police Department	North Bend Police Department
Des Moines Police Department	Port of Seattle Police Department
Duvall - Carnation Police Department	Redmond Police Department
Federal Way Police Department	SeaTac Police Department
Issaquah Police Department	Seattle Police Department (5 locations)
Kent Police Department	Shoreline Police Department
King County Sheriff's Office (4 locations)	Snoqualmie Police Department

Pharmacies Providing Medicine Take-Back in King County

Medicines accepted: prescription drugs that are NOT controlled substances and over-the-counter drugs.

Bartell Drugs has offered medicine take-back at some of its stores in Western WA since March 2008. Currently Bartell Drugs has drug drop boxes at 12 of its 43 stores in King County. The program is financed by Bartell Drugs, with hazardous waste disposal costs paid by the LHWMP.

Examples of King County pounds collected:

In 2010, Bartell Drugs collected & disposed of ~ 5,924 pounds of drugs at a cost of ~ $10,756.
In 2011, Bartell Drugs collected & disposed of ~ 6,826 pounds of drugs at a cost of ~ $13,846.
In 2012, Bartell Drugs collected & disposed of ~ 7,480 pounds of drugs at a cost of ~ $15,173

12 Bartell Drugs Medicine Take-back Locations in King County

Bartell Drugs, Auburn
Bartell Drugs, Bellevue Village Pharmacy
Bartell Drugs, Bridle Trails Pharmacy
Bartell Drugs, Burien Pharmacy
Bartell Drugs, Factoria
Bartell Drugs, Fairwood Pharmacy
Bartell Drugs, Issaquah Pharmacy
Bartell Drugs, Magnolia Pharmacy
Bartell Drugs, Shoreline Pharmacy
Bartell Drugs, University Village Pharmacy
Bartell Drugs, Upper Queen Anne Pharmacy
Bartell Drugs, White Center Pharmacy

Group Health Cooperative has offered medicine take-back at all 25 of its clinical pharmacies in King, Kitsap, Pierce, Snohomish, Spokane, and Thurston counties since October 2006.
Group Health has 12 pharmacies in King County. The program is financed by Group Health.

Examples of King County pounds collected:

In 2010, Group Health collected & disposed of ~8,546 pounds of medicines at a cost of ~$22,310.
In 2011, Group Health collected & disposed of ~9,951 pounds of medicines at a cost of ~$38,452.
In 2012, Group Health collected & disposed of ~9,805 pounds of medicines at a cost of ~$37,888.

12 Group Health Medicine Take-Back Locations in King County:

Group Health Cooperative, Bellevue Medical Center Pharmacy
Group Health Cooperative, Burien Medical Center Pharmacy
Group Health Cooperative, Capitol Hill Campus Pharmacy
Group Health Cooperative, Downtown Seattle Medical Center
Group Health Cooperative, Factoria Medical Center Pharmacy
Group Health Cooperative, Federal Way Medical Center Pharmacy
Group Health Cooperative, Kent Medical Center Pharmacy
Group Health Cooperative, Northgate Medical Center Pharmacy
Group Health Cooperative, Northshore Medical Center Pharmacy
Group Health Cooperative, Rainier Medical Center
Group Health Cooperative, Redmond Medical Center Pharmacy
Group Health Cooperative, Renton Medical Center Pharmacy

For-Fee Mailers at Some Retail Pharmacies. At some drugstores - such as Walgreens, Rite Aid, Safeway - customers can purchase mailers for disposal of unwanted medicines. Costs of the mailers vary from $2.99 to more, and each 8”x11” mailer holds up to 12 prescription pill vials. Controlled substances cannot be returned in the mailers under current federal regulations. Mailers are sent to a

commercial waste incinerator. No information is available about how many residents are using these mailers.

Attachment 4
BOH Briefing No. 13-B11
Stakeholder Presenters at Board of Health Subcommittee on Secure Medicine Return

- Shirley Reitz, PharmD, Associate Director of Pharmacy Clinical Services, Group Health Cooperative
- Wing Lim "Billy" Chow, Pharmacy Professional Services Manager, Bartell Drugs
- North Bend Police Chief Mark Toner
- Cliff Webster, Jeff Gombosky, and Marjorie Powell, Senior Assistant General Counsel representing PhRMA (brand name drugs)
- Dave Mastin representing Mylan (a generic drug manufacturer)
- Members of the King County Take Back Your Meds Coalition:
    - Inga Manskopf, Prevention WINS Coordinator, Adolescent Medicine, Seattle Children's Hospital
    - Terri Helm-Remund, School Nurse Organization of Washington
    - Paula Matthysse, Eastside Community Network
- Joel Hadfield, Executive Director, Association of Northwest Pharmacies (independent pharmacies)
- Jenny Arnold, PharmD, Director of Pharmacy Practice Development, Washington State Pharmacy Association
- Bill Struyk, Western Region Director for State Government Affairs, representing Johnson & Johnson (a manufacturer of over-the-counter drugs)
- Chris Humberson, Executive Director, Washington State Board of Pharmacy
- Tim Fuller, Pharmacy Consultant for the Washington State Board of Pharmacy
- Steven Saxe, Director, Health Professions and Facilities, Washington State Dept. of Health (former acting Executive Director, Washington State Board of Pharmacy)
- Ginette Vanasse, Executive Director, Post-Consumer Pharmaceutical Stewardship Association (PCPSA), British Columbia

Attachment 5, BOH Briefing No. 13-B11

Abuse and Preventable Poisonings from Medicines in the Home

Prescription drug abuse is the fastest-growing drug problem in the country. Unwanted medicines left in the home endanger our children, seniors and pets. The following are alarming statistics on the problem of abuse and preventable poisoning from prescription and over-the-counter medicines found in the home.

- Drug overdoses in Washington have surpassed car crashes as the leading cause of accidental deaths. The majority of these overdoses involved prescription opiates.[1]

- Fatal poisonings increased 395% from 1990 to 2006 in Washington State; 85% of these deaths involved medicines.[2]

- 32% of child poisoning deaths in Washington were caused by someone else's prescription medication and 26% were caused by over-the-counter medications.[3]

- In 2006-2011 there were 1,360 drug overdose deaths in King County from prescription opiates (848) and sedatives (512). [4]

- The 209 overdose deaths in King County in 2010 are equivalent to a crash of a full Boeing 737.[5]

- In 2009 there were 3,855 emergency department visits in King County related to prescription opiates (2,960) and sedatives (895).[6]

- Emergency room visits in Seattle for non-medical use of prescription opiates went up 47% from 2004 to 2007.[7]

- 767 residents in King County were admitted for drug treatment for prescription opiates (701) and sedatives (66) as the primary drug at treatment admission in 2011.[8]

- 942 calls about prescription opioids were made to the Washington State Poison Center in 2010 from residents of King County.[9]

- 39% of heroin users said they got addicted to prescription painkillers before starting to use heroin in a 2010 study in King County.[10]

- Our medicine cabinets provide teens with easy access to drugs – 2010 national survey data shows over 70% of those who abused prescription pain relievers got them from friends or relatives, while approximately 5 percent got them from a drug dealer or over the Internet.[11]

- Medicines are consistently the top reason why people contact the Washington Poison Center, with kids and seniors at the greatest risk. The Washington Poison Center's 2011 "top Ten" substances causing poisonings of adults and children include: #1-Ibuprofen, #2-Benzodiazepines, #4-Antihistamines, excluding Benadryl, #5-SSRI Antidepressants, #6-Antibiotics, #8-Atypical antipsychotics, and #10-Acetaminophen.[12]

[1] Center for Health Statistics, Washington State Department of Health (2009). Age-Adjusted Rates for External Causes for Residents, 1999-2008. Available online at: http://www.doh.wa.gov/EHSPHL/CHS/chs-data/death/htmltables/e1.htm

[2] Washington State Department of Health. (2008). "Poisoning and drug overdose." Washington State Injury and Violence Prevention Guide. DOH Publication No: 530-090. Available online at: http://www.doh.wa.gov/hsqa/emstrauma/injury/pubs/icpg/DOH530090Poison.pdf

[3] Sabel, J. (2004). Washington State Childhood Injury Report – Poisoning Chapter. WA DOH. Available online at: http://www.childdeathreview.org/reports/WashingtonStateChildhoodInjuryReport.pdf

[4] King County Medical Examiner. 2011. Data coding and analysis by Caleb Banta-Green, Alcohol and Drug Abuse Institute, University of Washington.

[5] Banta-Green,C. et.al. (2010). Drug Abuse Trends in the Seattle/King County Area: 2010. Accessed online at: http://adai.washington.edu/pubs/cewg/CEWG_Seattle_June2011.pdf

[6] Drug Abuse Warning Network. 2009. Emergency Department Visiting in King County MSA in 2009. Data provided by Caleb Banta-Green, Alcohol and Drug Abuse Institute, University of Washington.

[7] Banta-Green, C. et al. (2007). The Use and Abuse of Prescription-Type Opiates in Washington State. Alcohol and Drug Abuse Institute, University of Washington. Available online at: http://depts.washington.edu/adai/pubs/arb/PrescriptionOpiates_March30_2007.pdf,

[8] Washington Division of Behavioral Health and Recovery. 2011. King County Residents, Drug Treatment Admission 2011 Primary Drug at Treatment Admission. Data obtained via Treatment Analyzer by Caleb Banta-Green, Alcohol and Drug Abuse Institute and, University of Washington.

[9] Banta-Green, Caleb, et al. 2011. Drug Abuse Trends in the Seattle/King County Area in 2010. Alcohol and Drug Abuse Institute, University of Washington. Available online at: http://adai.washington.edu/pubs/cewg/CEWG_Seattle_June2011.pdf

[10] Banta-Green,C. et.al. (2010). Drug Abuse Trends in the Seattle/King County Area: 2010. Accessed online at: http://adai.washington.edu/pubs/cewg/CEWG_Seattle_June2011.pdf

[11] Substance Abuse and Mental Health Services Administration. 2011. Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011. http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm#2.16

[12] Washington Poison Center. 2011. Top Ten for 2011. Available online at: http://www.wapc.org/about/statistics/top-ten-substance-exposures-for-2011/

Drug Abuse and Preventable Poisoning from Over-the-Counter Medicines

Drug Abuse

One of the most abused over-the-counter medicines by teens is cough syrup containing Dextromethorphan (DXM). DXM, a cough suppressant found in 310 FDA registered over-the-counter cough and cold medicines can produce euphoric, psychedelic, and dissociative effects similar to psychotropic drugs when taken in high doses.

- 10% of teens say they have taken non-prescription cough medicine to get high[1]
- 5,962 emergency department visits for nonmedical use of cough medicines involved patients aged 12 to 20 in 2004[2].
- In 2006, 3.1 million youth and young adults aged 12 to 25 said they had used an over-the-counter cough and cold medication to get high - with almost 1 million reporting they had done so in the past year[3]
- From 1999 to 2004, there was a seven-fold increase in cases related to the abuse of DXM reported to poison control centers nationwide. Most of these cases were among 15- and 16-year-olds.[4]
- Fewer than half of teens believe abusing cough medicine to get high is risky[4].

Although not as commonly reported as DXM, other over-the-counter medicines that are abused by teens include[5]:

- Caffeine stimulants like No-Doz, etc.
- Antihistamines like Benadryl containing dyphenhydramine
- Decongestants like Sudafed containing pseudoephedrine
- Weight loss supplements containing ma haung or ephedra
- Sleep aids containing doxylamine, like Unisom, etc.
- Motion sickness treatments with dimenhydrinates, like Dramamine

Preventable Poisonings

- In 2011, ibuprofen, acetaminophen, antihistamines and topical ointments such as hydrocortisone and triple antibiotics were the over-the-counter medicines reported most frequently to Washington Poison Control for poisonings of children under age 5[6].
- Of the estimated 71,224 emergency department visits made annually for medication overdoses by children under age 18, 82% involved children under age 5 and commonly available over-the-counter medications were implicated in 34% of visits. Acetaminophen, cold and cough products, NSAIDs and antihistamines were the most frequently reported[7].
- 26% of child poisoning deaths in Washington were caused by someone else's over-the-counter medications and 32% were caused by someone else's prescription medications[8].
- About 165 young kids — or roughly four school busloads of children — are seen in emergency rooms every day in the US after getting into medications (both over-the-counter and prescription)[9].
- Medication deaths (both over-the-counter and prescription) as a percentage of all child poisoning deaths have nearly doubled since 1970[10].

Drug Abuse and Preventable Poisoning from Over-the-Counter Medicines

Potential for Over-the-Counter Medication Adverse Events

FDA warning labels show many over-the-counter medicines are not safe to give young children *at any dose* – making them especially hazardous when accidentally ingested by a small child. Aspirin, cough and cold, antihistamines and bismuth subsalicylate (i.e. Pepto-Bismol) are just a few examples of common over-the-counters medicines that are particularly hazardous to young children.

For all consumers, many over-the-counter medicines carry warning labels about importance of not exceeding recommended dosages, cautions about drug interactions, and cautions about use by specific individuals that demonstrate the risks of improper use or unintentional overdoses from over-the-counter medications[11].

More, very potent, drugs are expected to switch from prescription to over-the-counter by 2016 according to the pharmaceutical industry. Prescription drugs used primarily for chronic therapy treatment such as hypertension, dermatology, lipid-lower, osteoporosis, arthritis and incontinence is expected to switch from prescription to nonprescription status.[12]

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[1] Partnership for a drug-free America. 2009. The Partnership Attitude Tracking Study (PATS) Teens 2008 Report. Released February 26, 2009. Available online at: http://www.drugfree.org/wp-content/uploads/2011/04/Full-Report-FINAL-PATS-Teens-2008_updated.pdf

[2] Drug Abuse Warning Network. 2006. Emergency Department Visits Involving Dextromethorphan. The DAWN Report. Available online at: http://www.samhsa.gov/data/2k6/TNDR32DXM/TNDR32DXM.htm

[3] Office of Applied Studies, Substance Abuse and Mental Health Services Administration **(**SAMHSA**).** 2008. National Survey on Drug Use and Health. Misuse of Over-the-Counter Cough and Cold Medications among Persons Aged 12 to 25. January 10, 2008. Available online at: http://www.samhsa.gov/data/2k8/cough/cough.htm.

[4] Office of National Drug Control Policy. 2008. Prescription for Danger, A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens. Available online at: http://www.theantidrug.com/pdfs/prescription_report.PDF

[5] Trobledteen101.com is a private company that provides a clearinghouse of information on parenting and treatment programs for troubled youth. Available online at: http://www.troubledteen101.com/articles50.html

[6] Washington Poison Control. 2011. Top 10 in 2011.

[7] Schillie, S.F., et al. 2009. Medication overdoses leading to emergency department visits among children. Am J Prev Med 2009. Available online at: http://www.ajpm-online.net/webfiles/images/journals/amepre/AMEPRE_2545.pdf

[8] Sabel, J. (2004). Washington State Childhood Injury Report – Poisoning Chapter. WA DOH. Available online at: http://www.doh.wa.gov/hsqa/emstrauma/injury/pubs/wscir/WSCIR_Poisoning.pdf

[9] Centers for Disease Control and Prevention. Put Your Medicines Up and Away and Out of Sight. Centers for Disease Control and Prevention Website. Available from: http://www.cdc.gov/features/medicationstorage/. Accessed February 9, 2012.

[10] Centers for Disease Control and Prevention. CDC WONDER Compressed Mortality File, Underlying Cause-of-Death. Centers for Disease Control and Prevention Website. Available from: http://wonder.cdc.gov/mortSQL.html . Accessed February 15, 2012.

[11] OTCsafety.org. http://otcsafety.org/en/ingredients/ A website on over-the-counter medicine safety from the Consumer Healthcare Products Association.

[12] The Pharma Letter. Accessed online August 13, 2012 at: http://www.thepharmaletter.com/file/107173/major-gloval-expansion-of-rx-to-otc-switch-forecase-by-2016.htm .

Schematic Overview of Product Stewardship Approach to Secure Medicine Return for King County

For prescription medicines (including controlled substances) and over-the-counter drugs from residential sources.

Funds Flow $

Medicines Flow

Producers Selling Covered Drugs in or into King County

Brand Name Drug Companies

Generic Drug Companies

Over-the-Counter Drug Companies

Prescription & Over-the-Counter Drug Sales

$

Drug Producers work together in the "Standard" stewardship plan, unless producer(s) opts to form "Independent" plan, that complies with the Rule & Regulation

Leftover & Expired Medicines

No fee

Medicine Drop-off Sites

Permitted Pharmaceutical Waste Disposal Vendors

Permitted Hazardous Waste Facility, unless permission granted to utilize a Permitted Large Municipal Waste Combustor (e.g. WTE)

$ $ $

Primary collection methods will be drop-off sites at retail pharmacies and law enforcement offices. Other collectors may also participate. Collection events and mail-back programs will serve areas of the county lacking a minimum number of drop-off sites.

Collectors participate voluntarily. All retail pharmacies & law enforcement that volunteer as drop-off sites must be included in the collection system.

Agency Oversight & Enforcement

$ for agency oversight (fees for plan review and annual oversight costs)

Private Sector

King County Board of Health

Government Sector

LHWMP

PHSKC (enforcement lead)

City and County Govt's in King County are encouraged to promote the secure medicine return program through existing communications methods.

Draft, May 2013 for Explanatory Purposes Only. Does not include all elements of proposed draft Board of Health Rule & Regulation.

Summary of Retail Pharmacy & Law Enforcement Locations in King County

Final 04/25/13

LHWMP staff have identified:

- 83 retail independent pharmacies (eg neighborhood pharmacies)
- 93 retail local chain pharmacies (eg Bartells, Fred Meyer, QFC, Top Food)
- 171 retail national chain pharmacies (eg Rite Aide, Safeway, Target, Walgreens, WalMart)
- 6 clinics/hospitals with co-located retail pharmacy
- 49 law enforcement offices (includes King County Sheriff Offices)

10 cities do not have a retail pharmacy within city or county boundaries: Beaux Arts Village, Black Diamond, Carnation, Clyde Hill, Hunts Point, Medina, Milton (part), Pacific, Skykomish, Yarrow Point.
5 cities do not have a law enforcement office in city or county boundaries: Beaux Arts Village, Carnation, Hunts Point, Milton (part), Yarrow Point.

	Number of Retail Pharmacies Within King County					Number of Law Enforcement Offices Within King County			
City	Independent	Local Chain	National Chain	Co-located at Clinics/ Hospitals	Total per City	Station	City Hall	Commmunity/ Storefront	Total Per City
Algona			1		1	1			1
Auburn (part)	3	3	6		12	2			2
Beaux Arts Village					0				0
Bellevue	5	9	12	1	27		1	2	3
Black Diamond					0	1			1
Bothell (part)		2	1		3	1			1
Burien	3	2	4		9	1	1		2
Carnation					0				0
Clyde Hill					0	1			1
Covington	1	1	4		6	1			1
Des Moines	1	2	2		5	1			1
Duvall	1		1		2	1			1
Enumclaw (part)	2	1	3		6	1			1
Federal Way	4	2	11		17	1		1	2
Hunts Point					0				0
Issaquah		4	6		10		1		1
Kenmore	2		2		4		1		1
Kent	7	4	12		23	1			1
Kirkland	3	7	8		18		1		1
Lake Forest Park			2		2	1			1
Maple Valley		2	1		3	2			2
Medina					0	1			1
Mercer Island	2		4		6		1		1
Milton (part)					0				0
Newcastle		1	1		2		1		1
Normandy Park	1				1	1			1
North Bend		1	1		2	1			1
Pacific (part)					0	1			1
Redmond	2	5	5		12	1			1
Renton	2	5	12	2	21	1		1	2
Sammamish		1	2		3	1			1
SeaTac			1		1	1			1
Seattle	40	34	54	3	131	6		2	8
Shoreline		5	8		13	1			1
Skykomish					0	1			1
Snoqualmie	2				2	1			1
Tukwila	1	1	3		5	1			1
Vashon Island	1				1	1			1
Woodinville		1	4		5	1			1
Yarrow Point					0				0
TOTAL	83	93	171	6	353	36	7	6	49
	Independent	Local Chain	National Chain	Co-located at Clinics/ Hospitals	Total per City	Station	City Hall	Commmunity/ Storefront	Total Per City