

Disposal of Medications from Residential Consumers

Issues, barriers, and opportunities

Compiled by:

Pharmaceuticals from Households:
A Return Mechanism (PH:ARM) Pilot Team

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Purpose of this Document

This document frames the issue of unwanted medicines disposal for decision makers and stakeholders. Our goals are:

- To clarify and explore frequently raised issues.
- To establish a common framework of understanding, thus allowing the development of effective policy recommendations and programs for proper drug disposal.

This document briefly provides:

- A background of scientific evidence and the regulatory framework related to waste consumer pharmaceuticals;
- A discussion of the current barriers to implementing an efficient and effective collection program;
- An overview of necessary components for successful medicine returns programs.

Pharmaceuticals Background

Why prevent improper disposal of waste residential medicines?

Poisoning and abuse remain the most acute human health concerns related to left-over and unwanted medicines in people's homes.

Poisoning

Disposal to the household trash or improper storage may contribute to the risk of accidental poisonings. According to the Washington State Department of Health, nine children die each year from poisoning, 465 are hospitalized, and 3,490 visit the doctor.¹ Of 24 child poisoning deaths from 1999 to 2001, 16 were due to medications², or approximately 5 per year. Unintentional poisoning³ death rates in Washington increased 345% between 1990 and 2004, from 2.3 to 10.2 per 100,000 people.⁴

Nationwide, medications are the most common poison exposure category. The Centers for Disease Control⁵ reported that:

- 71.2% of poisoning suicides were caused by drugs—both legal and illegal (2003).
- Most nonfatal, poison-related suicide attempts involved prescription drugs (2003).
- Drugs caused 94.3% of the unintentional and undetermined poisoning deaths (2003).
- Poisonings led to \$26 billion in medical expenses and made up 6% of the economic costs of all injuries in the United States (2000).

Abuse

Rising drug abuse is a serious concern which may be related to improper storage or disposal of unwanted medications in people's homes:

- The number of Americans who abuse controlled prescription drugs

has nearly doubled from 7.8 million in 1992 to 15.1 million in 2003. Prescription drug abuse among teens has more than tripled during that time⁶

- One in 10 teens reports having abused Over-The-Counter cough medicines to get high.⁷
- In 2006 abuse of prescription pain killers ranked second—only behind marijuana—as the Nation's most prevalent illegal drug problem. Much of this abuse appears to be fueled by the relative ease of access to prescription drugs⁸.

Assistant Surgeon General Eric Broderick, D.D.S., M.P.H., the Substance Abuse and Mental Health Services Administration Acting Deputy Administrator, stated that:

“...70 to 80 percent of those 12 years or older said they got their drugs from a friend or relative... Parents and other caregivers should ***store their prescription drugs carefully and dispose of any unused drugs*** before they can fall into the wrong hands.”⁹

Are pharmaceuticals present in the environment?

Due to new assessment tools, pharmaceuticals are now being detected in water and soil by scientists worldwide. A 2002 U.S. Geological Survey (USGS) study found Organic Wastewater Contaminants (OWCs), including many pharmaceutical and personal care product contaminants, in 80 percent of 139 streams sampled in 30 states.¹⁰

A 1999 summary of research from the EPA's National Exposure Research Laboratory cites that “Excluding the antibiotics and steroids, over 50 distinct pharmaceuticals and personal care products or metabolites (from more than 10 broad classes of therapeutic agents or personal care products) have been identified in sewage treatment effluent or in environmental samples (mainly surface and ground waters); representative classes include analgesics/anti-inflammatories, antineoplastics, antiseptics, beta-blocker (antihypertensives), 2-sympathomimetics (bronchodilators), lipid regulators and bioactive metabolites, musks (synthetic nitro and polycyclics; also reduced metabolites of nitro musks), anti-psychotics, sun screen agents, and X-ray contrast media.¹¹

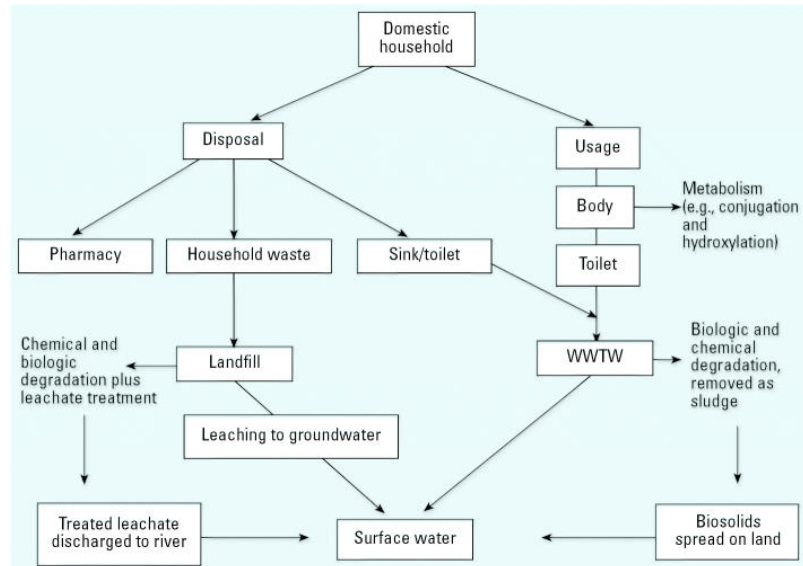
In Washington state, a screening analysis conducted in tertiary wastewater treatment plant effluents and nearby wells and creeks in the Sequim-Dungeness area of northwest Washington detected 16 organic wastewater contaminants (OWCs) in the effluent samples. In the Sequim study, 9 of 11 samples (82%) contained pharmaceutical drugs. Significantly, the Washington state analysis was limited to only 24 chemicals, whereas the USGS study tested for 95 chemicals.¹²

How do pharmaceuticals enter the

Pharmaceuticals and OWCs have been found primarily in effluent and surface water, and emerging research indicates the presence of pharmaceutical chemicals in biosolids and soil.¹³

environment?

Residential, commercial, and agricultural pharmaceuticals can follow various pathways to the environment, described in the illustration below.¹⁴



- 1) Excretion: A large percentage of a drug or its metabolites can be excreted following human and livestock consumption.¹⁵ The portion of the substances that is excreted follows sewage, septic or surface runoff pathways to wastewater or into sludge (biosolids). Topical medicine products are eventually washed off and can enter the wastewater system.
- 2) Direct Disposal: Unused pharmaceuticals are typically disposed of to the septic tank, sewer or landfill. About one third (33%) of the pharmaceuticals prescribed in Germany and one quarter (25%) in Austria are disposed of in household waste or down the drain.¹⁶
- 3) Reclaimed Water and Land Application: Pharmaceuticals contained in wastewater sludge can be applied to agricultural land as fertilizer, which could leach into groundwater¹⁷. A USGS study showed that soils samples from land irrigated with reclaimed water contained 19 different pharmaceuticals¹⁸.

Problems:

When discharged to the sewer, pharmaceuticals end up at wastewater treatment plants that offer primary, secondary or tertiary treatment levels. Most conventional wastewater treatment cannot effectively eliminate all pharmaceutical compounds.¹⁹ Some treatment technologies are available for organic wastewater contaminants²⁰, but thus far they have been cost and space prohibitive in large waste water applications.²¹ Pharmaceuticals discharged to septic tanks may also enter the environment when pumped material is disposed or from seepage into groundwater or soil.

Landfill leachate may also contain pharmaceutical contaminants. Often this leachate is sent to the same wastewater treatment systems that receive residential wastewater. Traces of pharmaceuticals have been detected in landfill leachate²², so disposal of pharmaceuticals at engineered landfills may merely postpone pollution of surface water and ground water.²³ In Germany, barbiturate use peaked more than 3 decades ago, yet drugs are still being detected in surface water and groundwater in Germany at several micrograms per liter. No barbiturate was degraded biotically or abiotically. Researchers suggested the source of barbiturates as old landfills or contaminated sites, rather than excretion via WWTPs.²⁴

Why is there concern about pharmaceuticals in the environment?

“A particularly troublesome environmental pollution scenario is one resulting in continual but unnoticed biochemical effects on organisms — effects that accumulate so slowly that major change is not detectable until their cumulative level finally cascades to irreversible change. One possible example fitting this scenario, starting with subtle, unnoticed effects and culminating with outward change, could be manifested by the continual exposure of aquatic organisms to the complex spectrum of pharmaceuticals that can persist in the treated effluent from sewage facilities.²⁵”

The emerging concern about pharmaceutical pollution is the *widespread detection and number* of low-level Organic Wastewater Contaminants (OWCs) found in the 2002 US Geological Survey study samples. An average of seven OWCs and as many as 38 OWCs were found in individual water samples. Most pharmaceuticals degrade in the environment, but have a quality of pseudo-persistence due to the continual release of the contaminants via use, excretion, and disposal.

Little is known about the potential interactive effects (such as synergistic or antagonistic toxicity) that may occur from complex mixtures of OWCs in the environment.²⁶ However, researchers are starting to suspect that hormones and medicines in the water may be responsible for effects on wildlife including:

- Endocrine disruption among male fish exposed to municipal wastewater, including feminization, sluggish activity or reduced appetite.²⁷
- Antibiotic resistant bacteria in surface waters based on the occurrence of antibiotics in wastewater.²⁸
- Antibiotics may reduce the growth of aquatic plants.²⁹

A recent study by the University of Minnesota demonstrated that corn, potato and lettuce can uptake antibiotics into their leaves and plant tissue from animal manure applied to soil. Concentrations in plant tissue also increased as the amount of antibiotics present in the manure increased. From 9 to 13 million kg of antibiotics are used in livestock

operations in the US annually.³⁰

How common is prescription use in Washington state, the U.S. and the world?

Pharmaceutical use in the general population is common and growing, meaning that more often than not, households are dealing with leftover drugs. The average prescription rate in Washington was 9 prescriptions per capita per year in 2006, totaling 56.8 million retail prescriptions in Washington state.³¹ The national average was 11 per capita per year for 2006, totaling 3.3 billion retail prescriptions.³² From 1994 to 2004, the number of prescriptions purchased increased 68% (from 2.1 billion to 3.5 billion), as the U.S. population grew only 12% over the same period³³.

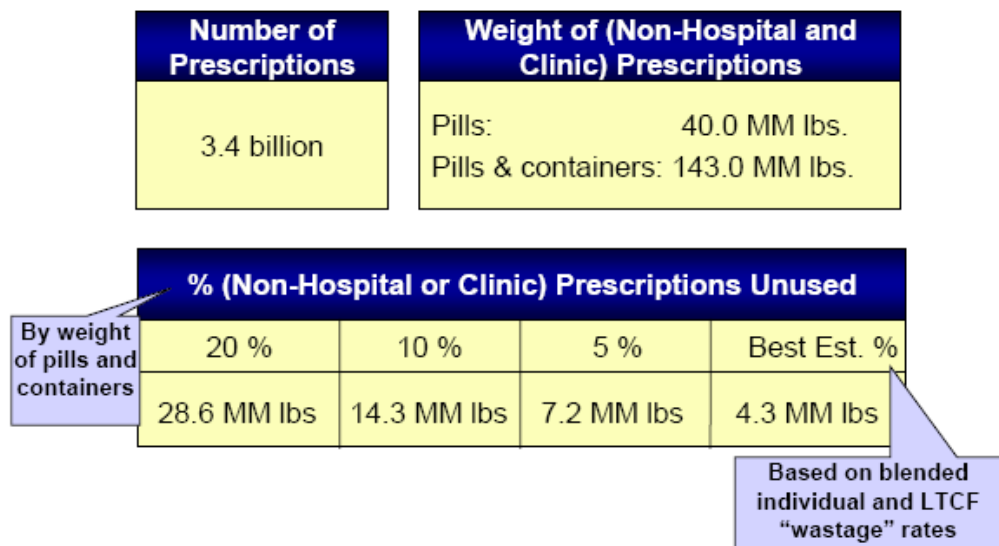
This trend is also in evidence on a global basis. Worldwide, the pharmaceutical industry is forecasted to more than double to \$1.3 trillion by 2020.³⁴

What is the total quantity of waste pharmaceuticals?

There are a variety of estimations of the volume of waste pharmaceuticals being stored or disposed of by consumers. A recent study completed by the EPA estimated that 17.9 metric tons of medicine is disposed of annually to the sewage system by the deceased population alone.³⁵

The following illustration used in a 2005 presentation by PhRMA, the U.S. brand owner pharmaceutical manufacturer association. The total weight of unused pharmaceuticals in the U.S. is estimated based on four different estimates of total unused prescriptions³⁶.

The quantity of unused medicines depends on the assumptions used.



One study of older adults (65 and older) conducted in 1999 approximates the value of wasted medications to be 2.3% of the total medications

prescribed. If the subjects in this research are representative of the elderly population in the U.S., the value of wasted medications could top one billion dollars each year³⁷.

PhRMA, estimates 3% of product sold is wasted nationwide³⁸. This figure contrasts the estimated 25-33% waste rate noted in studies from Germany and Austria of pharmaceuticals disposed of either to a landfill/incineration or into the wastewater system³⁹.

PhRMA reported that sales of 23 active ingredients (representing a typical sampling of drugs) totaled approximately 22 million lbs.⁴⁰ If the 25% wastage rate from Germany and Austria is accurate, 5.5 million pounds of pharmaceuticals are disposed per year nationwide from sale of these 23 active ingredients.

How do consumers currently dispose of waste medication?

A survey completed in 1996 showed that 63% of the U.S. population disposed of medication in the past.⁴¹ The following table from a study done in the Eastern U.S. estimates the fate of unused pharmaceuticals by source prior to disposal.⁴² About two thirds of unused pharmaceuticals are generated by individuals. Another third originates at long term care facilities.

Unused medicines management practices vary depending on who holds the unused medicine.

Pharmacies	Hospitals																
<ul style="list-style-type: none"> • Most unused medicines returned for credit 	<ul style="list-style-type: none"> • Use their pharmacies to return for credit • Unreturnables: <ul style="list-style-type: none"> - Ordinary IV → drain - Chemo IV → HW - Pills → Medical Waste 																
Long Term Care Facilities	Individuals																
<ul style="list-style-type: none"> • Source of 34% (1.5 MM lbs) of unused medicines • 4% to 10% wastage • Typical disposal practice is flushing down the drain 	<ul style="list-style-type: none"> • Source of 66% (2.8 MM lbs) of unused medicines <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="background-color: #000080; color: white;">Pittsburgh</th> <th style="background-color: #000080; color: white;">Ontario</th> </tr> </thead> <tbody> <tr> <td style="background-color: #ffff00;">Trash</td> <td style="background-color: #ffff00;">54%</td> <td style="background-color: #ffff00;">31%</td> </tr> <tr> <td style="background-color: #ffff00;">Drain</td> <td style="background-color: #ffff00;">35%</td> <td style="background-color: #ffff00;">46%</td> </tr> <tr> <td style="background-color: #ffff00;">Keep</td> <td style="background-color: #ffff00;">7%</td> <td style="background-color: #ffff00;"></td> </tr> <tr> <td style="background-color: #ffff00;">Pharmacy</td> <td style="background-color: #ffff00;"></td> <td style="background-color: #ffff00;">17%</td> </tr> </tbody> </table>			Pittsburgh	Ontario	Trash	54%	31%	Drain	35%	46%	Keep	7%		Pharmacy		17%
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A June 2005 survey completed in King County and Seattle showed that

- 36.5 % of residents typically disposed of pharmaceuticals to the trash.
- 29.4% of residents typically disposed of pharmaceuticals to the sink or toilet.⁴³

SoundStats conducted a telephone survey of King County residents in

January 2006, on current disposal practices for unwanted or expired medicines. The survey found that only a third of King County residents are actively using or planning to use the medicines they have in their households in the next six months.⁴⁴

What's the difference between over-the-counter drugs, prescription drugs, and controlled substances?

Over-the-counter (OTC) drugs are products that consumers can buy without a prescription. Prescription (or legend) drugs require a prescription from a doctor, and are dispensed by a pharmacist. Some legend drugs are called 'scheduled drugs' or 'controlled substances,' and are categorized into Schedules I-V by the US Drug Enforcement Administration (DEA) according to their beneficial use and addiction potential. Many of these controlled substances are legally prescribed to patients, commonly for pain control, such as codeine. Schedule I drugs are illegal.

Are pharmaceuticals considered hazardous waste? Aren't they a beneficial consumer product?

Many pharmaceuticals have ingredients with characteristics that cause them to 'designate' as hazardous waste when disposed. To designate means to either be a federally-regulated (under RCRA – Resource Conservation and Recovery Act) or state-regulated hazardous waste (under the Dangerous Waste Regulations WAC 173-303). Federally-regulated hazardous wastes include lists of certain discarded chemical products or manufacturing/industrial processes or wastes with hazardous characteristics (ignitability, corrosivity, reactivity or toxicity). Washington State has additional criteria for toxicity and persistence that make other pharmaceuticals 'designate.'

Hazardous waste regulations apply to pharmaceuticals as soon as a business makes a decision that they are waste and no longer a product. It is important to note that **pharmaceutical waste generated by households is exempt** from the state Dangerous Waste and the federal RCRA rules.⁴⁵ However, local jurisdictions responsible for municipal waste management may disallow household hazardous waste from regular solid waste, septic, or sewer disposal routes⁴⁶, as in the case of Snohomish County, Kitsap County, and the City of Seattle. Many cities and counties have goals to prevent and remove pharmaceuticals from both wastewater and solid waste streams.

A study from 1996 showed that, for medications that are not returnable: 15% were incinerated; 17% were directed to hazardous waste handlers; and 68% were disposed to solid waste or the toilet⁴⁷.

Why the Current System Needs Modification

Can hazardous waste disposal companies accept waste

Yes, though these companies need special permits to do so. Currently, hazardous waste transporters pick up hazardous waste and deliver it to sites permitted for hazardous waste treatment, storage, and disposal (TSDFs).⁴⁸ Medicine waste can be handled by these businesses with the

pharmaceuticals from consumers?

following two conditions:

- 1) Handling pharmaceuticals or waste pharmaceuticals requires a license from the Washington Board of Pharmacy.
- 2) Disposal service companies cannot accept any end-user controlled substances returned to a pharmacy take-back program without federal permission (such as a waiver to DEA regulations).

Can pharmaceuticals be collected at municipal household hazardous waste facilities or events?

Municipal household hazardous waste facilities and events are not licensed by the Washington State Board of Pharmacy, or the DEA, to handle medications. Such facilities do not have capability to take the necessary precautions or the desire to handle a material that would make them a potential target of drug seekers (by the public or the site staff).

In addition, there are limited numbers of household hazardous waste (HHW) facilities, typically one per county, which makes them generally inconvenient. In comparison, there are numerous pharmacies (1,300+ statewide) found in any given community. Many consumers would not think of taking waste pharmaceuticals to a hazardous waste facility—but are naturally inclined to take waste pharmaceuticals back to their convenient local pharmacy. In a SoundStats survey completed in 2006, 2% reported they considered a municipal waste facility convenient, and 5% said they considered a special collection event convenient.⁴⁹

Can waste consumer medications currently be returned through pharmacies?

Yes and no. There are two distinct barriers to the return of a consumer's medications to a pharmacy:

- 1) Federal DEA rules do not currently allow for the return of end-user controlled substances to a pharmacy.
- 2) Federal Resource Conservation and Recovery Act (RCRA) rules do not allow the take-back of **waste** household pharmaceuticals through a pharmacy's pharmaceutical take-back provider (called a reverse distributor, see next section) because reverse distributors are not permitted to accept waste without the applicable regulatory controls for waste management, according to a 1991 EPA memo.⁵⁰

The first barrier cannot be eliminated *unless* the DEA grants a local program waiver or changes the Controlled Substances Act (which is the reason for the detailed waiver request made by the PH:ARM team in March 2007).

The second barrier can be eliminated if the reverse distributor meets one or more of the following conditions: they can be classified as an exempt "take-back" location (for Washington State household hazardous waste only)⁵¹, a hazardous waste transporter (subject to a 10-day storage limit), or a solid waste transporter (a 'G-certificate' issued by the Utilities and Transportation Commission in Washington). The Washington UTC generally issues one G-permit for a single territory of service.

Can the pharmacy's waste and waste medications from consumers be put into the same disposal system?

Household waste, if combined with business waste, would lose its exemption from Federal RCRA hazardous waste rules. Though small quantity generators (SQGs) have streamlined compliance requirements compared to regulated generators,⁵² they are not exempt from the requirements to designate and count their hazardous waste. In some situations, adding an additional quantity of pharmaceutical waste may place a pharmacy above the Small Quantity Generator⁵³ volume limit for hazardous waste and extremely hazardous waste, such as epinephrine.

Therefore, segregating patient & consumer returns and business waste is critical to remain in compliance with environmental laws.

Alternatively, the US EPA is looking to develop universal waste rules which would eliminate counting and designation requirements, allowing business and household waste to commingle. That rule change will take several years.

Reverse Distributors

What is a reverse distributor (RD)?

A reverse distributor (RD) is a business that manages certain pharmaceuticals typically shipped from a licensed pharmacy. The RD then makes the determination of whether the pharmaceutical is "product" or "waste", thereby becoming the generator of the waste (rather than the original business generator). The RD may accept expired or unusable product, but only product that has not already been designated as waste.

If the product has been designated as business 'hazardous waste,' Federal RCRA rules require the waste to be handled by a hazardous waste treatment, storage or disposal facility.⁵⁴ Business waste must be designated by type of hazardous waste and counted by the original business generator. RD's provide some credit (for business waste only) when a valued product is ultimately returned to the manufacturer.

Can a reverse distributor collect controlled substance waste for destruction?

DEA regulations permit the collection of *a pharmacy's* controlled substances (CS) by a licensed reverse distributor (RD) for the return of the pharmaceuticals to the manufacturer or for destruction. RDs are still required to keep detailed records of all controlled substances that change hands on Forms 222 and 41. However, RDs cannot currently accept controlled substances from end-users without a DEA waiver from regulations, even if all accounting procedures are in place.⁵⁵

The DEA allowed RDs in Kentucky to take-back controlled substance pharmaceuticals from long term care facilities. A similar proposal was also made by Washington state in 2005 to do the same, but the DEA has

stated that expansion of the Kentucky program will not be considered.

Medicine Return Programs

What are the reasons to collect waste household medicines?

- Pharmaceuticals present both a public safety and environmental hazard if no secure disposal option exists.
- Data generated by the collection program can be used in educational efforts to reduce waste in both pharmaceutical use and prescription writing.
- A collection system decreases the environmental pollution from solid waste landfills and waste water treatment discharge.
- Separate collection helps communicate the environmental impact of this waste stream to the responsible parties: consumers, retailers, and manufacturers.
- A simple collection system can be modeled after other take-back programs for light bulbs, computers, thermometers, batteries, and oil.

What is the expected quantity of waste medicines that could be collected in a pharmacy-based take-back program?

The EPA Workshop on Pharmaceuticals in the Environment held in 1995 looked at the results of other consumer product take-back programs to attempt to gauge what the capability of a drug take back program could be. They determined that in general the success rate was under 20% of total products sold with exceptions being lead acid and rechargeable batteries⁵⁶. There were 53.8 million retail prescriptions sold in Washington state in 2006.⁵⁷ If the take-back program follows the success rates of some of the other products, the eventual yield could be 10% (5.38 million prescriptions per year) to 20% (10.8 million prescriptions per year). That is an equivalent of 63,000 lbs to 127,000 lbs annually in Washington State, using a conversion rate of 0.0118 lbs of pill weight per prescription.⁵⁸

A pharmacy-based take-back program launched in October 1996 in British Columbia, Canada serves a population of 4 million with 800+ pharmacies and collected **44,092 lbs** of waste medicine in 2006.⁵⁹

Extrapolating the B.C. collection data to Washington state, with a population of 6.2 million, a statewide program based on the BC program could collect **66,000 lbs** per year for proper disposal.

Current collection volumes from the PH:ARM pilot at Group Health Cooperative between October, 2006 and September 2007 showed sites collecting an average of 1.5 lbs per pharmacy per day. If the average collection rate continues, a statewide program could collect **600,000+ lbs** of medications per year (6 days a week at 1,300 pharmacies), excluding long term care facilities.

In addition, there appears to be a ramp-up effect as visitors to

pharmacies develop awareness of the program and begin to bring in medications. The latest screening collected 1.5 lbs per day, or three times more than the collection rates at the beginning of the program which only yielded 0.5 lb per day. Time will be needed to determine whether the higher rates will continue or whether they will level off.

Medicine Collected Per Day Per Pharmacy (WA Group Health)

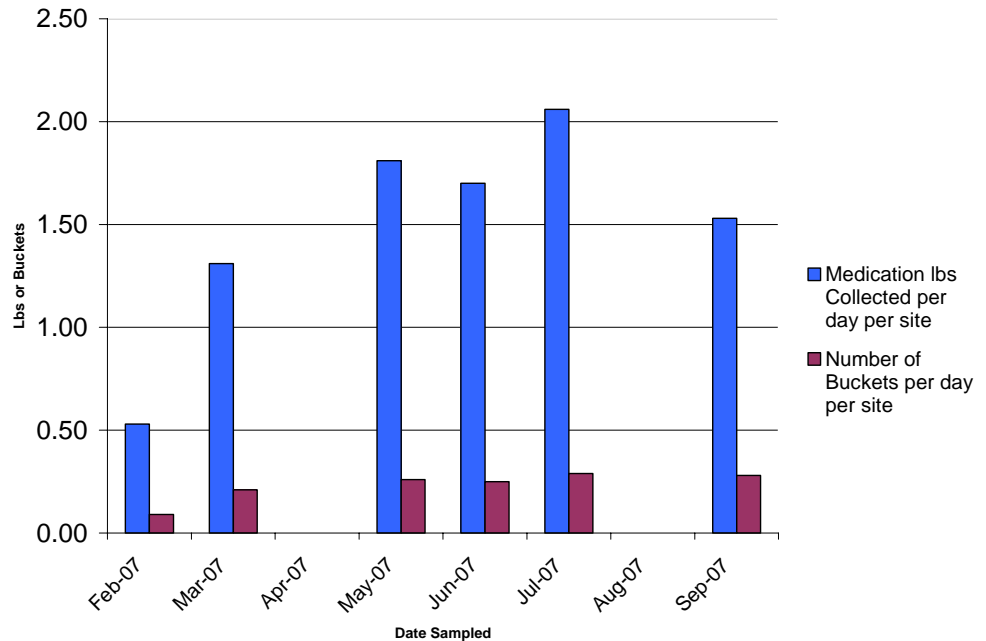


Figure 1 PH:ARM Pilot Program Generation Rates measured February 2007 to September 2007. Collection began October 2006.

What is the anticipated composition of medications collected in a pharmacy take-back program?

Though there are thousands of drugs on the market, fifty of the best selling drugs in 2001 accounted for 44.4% of total outpatient retail drug sales, and should be indicative of the variety of waste returned. The remaining 9,482 drugs accounted for 55.6% of total sales.⁶⁰

Based on data from other collection programs,⁶¹ PH:ARM estimated the general composition of the collected pharmaceutical waste (by weight) to be:

- Inhalers 0-1%
- Chemotherapy drugs 0-0.1%
- High toxicity drugs (Epinephrine) 0-0.5%
- Inert packaging 10-20%
- Lindane (zero to trace)
- Low toxicity drugs (includes antibiotics) 50-75%
- Preparations with alcohol (e.g. cough syrup) 0-2%
- Thimerosal (zero to trace)
- Vitamins (1-5%)

Could a law enforcement-based collection program work?

The DEA has suggested police and sheriff offices as potential collection locations. While these agencies can offer a high level of security, law enforcement locations are generally inconvenient and intimidating for the general public to dispose of medications. In the SoundStats survey, 4% considered a law enforcement location to be convenient.⁶²

While some sheriff offices (e.g. Clark County) are willing to act as collection locations, many police organizations, including the Washington Association of Sheriffs and Police Chiefs, support non-police officer dependent types of collection due to the cost, storage, or inventory requirements of providing this service.

Could a periodic community collection program work?

Periodic collection sends an inconsistent message to the community about proper behavior regarding storage and disposal, and could lead to increased home poisoning incidents (by requiring longer term storage of unused medications). Additionally it is difficult to create lasting, beneficial behavior change in a population that lacks on-going access to services.

A program based on periodic collection events also may artificially create ‘a crisis of scarcity,’ thereby encouraging a flood of medications coming in at once. This increases overhead and management costs.⁶³ Finally, the inconvenience to customers reduces overall participation in the program.

Could a mail-back program work?

A mail-back program may work well because of the rise in internet sales of pharmaceuticals and the high convenience level of this approach. This may also be an expensive approach, as the Oregon stakeholder group estimated a cost \$3.40 per 0.5 lb mailer.⁶⁴ Another barrier is the current US postal code regarding mailing controlled substances. There are also restrictions on air transport of certain hazardous materials by the US Department of Transportation.

Maine is currently working on a mail-back program for controlled substances (resulting from 2004 legislation), but implementation of a program has thus far been halted by the Federal DEA and the Controlled Substances Act.

According to US Mail Publication 52⁶⁵:

483.1 Controlled Substances

If the distribution of a controlled substance is unlawful under 21 USC 801 or any implementing regulation in 21 CFR 1300, then the mailing of the substance is also unlawful under 18 USC 1716.

Controlled substances and drugs that contain controlled substances are

acceptable in the domestic mail only under the following conditions:

- a. For mailable controlled substances, generally both the sender and addressee must meet either of the following conditions:
 - (1) Be registered with the Drug Enforcement Administration (DEA).
 - (2) Be exempted from DEA registration, such as military, civil defense, and law enforcement personnel, in performing official duties.
- b. For prescription medicines containing mailable narcotic drugs (controlled substances), only a pharmacist or medical practitioner, etc., who dispenses the medicine may mail such substances to the patients under their care.

483.6 Return of Prescription Drugs

Mailers may use merchandise return service to return prescription drugs for purposes of drug recalls; voluntary manufacturer withdrawals; and dispensing errors such as incorrect drug, dosage, or strength, as permitted by 21 CFR 1307.12 or other applicable law. The mailpiece must be addressed to the manufacturer or its registered agent. Manufacturers or their registered agents must furnish mailing containers to their customers for the purpose of mailing back the identified drugs. Manufacturers or their registered agents must use merchandise return service (see DMM 507.9.0) with First-Class Mail or Priority Mail for these mail pieces. Manufacturers or their agents continue to be responsible for maintaining records in compliance with any regulation of the Drug Enforcement Administration and/or the Food and Drug Administration.

What are the key elements of PH:ARM's proposed take-back program?

- Waste household medicines will be as easy to return as they are to purchase (for example, via a pharmacy, or via mail back).
- Collection of waste medicine is offered on an on-going basis at statewide pharmacies.
- Unwanted over-the-counter (OTC), prescription and controlled substances from consumers would be collected in the same system (because consumers don't distinguish among these categories).
- Collection and consolidation of waste consumer pharmaceuticals will use existing business infrastructure, such as wholesaler/distributor supply chains, reducing costs for handling, permitting, and transportation.
- The pharmacies offering a collection program will not take official possession of the drugs. The pharmacies will only provide collection sites and assist in the security for the pharmaceuticals.
- Waste medicines are thrown away by the consumer, so the material would be considered 'household' waste, and not generated

- by the pharmacy.
- No specific inventory of the pharmaceutical waste placed inside the waste collection containers would be required because it is household hazardous waste. Volumes collected will be tracked as part of the program.
- All waste collected will be considered irretrievable by the consumer after disposing of the medication.
- Shipping of waste containers from pharmacies to central consolidation locations and to the site of ultimate destruction will be documented. New technology, such as embedded radio frequency tags could facilitate and expedite this tracking.
- Collection at pharmacies, if done in a cost-effective manner, should not impact the retail price of consumer medicines.

Why is a pharmacy-based pharmaceutical return program a preferred collection model?

The 2006 SoundStats Survey found that three-quarters (74%) of King County respondents said they would be willing to properly dispose of their unused or expired medicines by returning them to a convenient location. Local pharmacies were chosen as the most convenient location to dispose of unused or expired medicines by 84% of the respondents. Four in five (80%) respondents stated that they are likely to return their unused or expired medicines to their local pharmacy if a secure drop box was set up there for this purpose.⁶⁶

Reasons to pursue pharmacy locations as take-back sites include:

- Collecting this waste through conveniently located pharmacies is anticipated to maximize collection of residential consumer pharmaceutical waste.
- Local retailers and clinics are already interested and willing to participate when regulations allow them (if easy, inexpensive, and low risk).⁶⁷
- It capitalizes on the level of trust already present in the pharmaceutical industry, and presents an opportunity for the industry to promote individual and community health.
- It is an opportunity for pharmacies to provide additional customer service.
- It links environmental consciousness and community service with the pharmaceutical industry in the mind of the customer.
- It allows for a secure, low-cost and efficient return mechanism that uses existing business infrastructure.
- The diversion risk is minimized because collection is located at a site that already handles pharmaceuticals, with professional staff familiar with the risks and hazards of pharmaceuticals, and the ethic and security measures in place to prevent diversion.
- Costs of the program are born by the producers and users of the product, rather than by all taxpayers.
- It increases public safety.

What do the secure collection boxes being piloted in pharmacy locations look like?

A prototype of a secure drop-box for collection in a pharmacy is shown below. The double-locked and bolted container would be within eyesight of the pharmacist counter. The consumer would deposit medications in their original packaging.

One design is a steel container with a 5 gallon bucket or a 14 cubic inch box inside. A new prototype is in development.

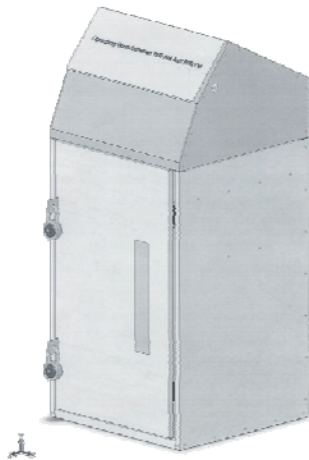


Figure 1. Group Health Collection Container (Steel Outer Drop Box)

Once pharmaceuticals are collected, why is the supply chain the preferred consolidation service provider?

- Distributors are already servicing pharmacies regularly.
- Distributors are permitted to handle medications.
- Oversight of wholesalers by Board of Pharmacy already exists.
- Interactions between established business systems are the most efficient.
- There are a few large wholesalers in the state that service all pharmacies, making consolidation efficient.
- It offers a secure physical location for consolidation.
- It promotes producer and supply chain responsibility.
- Other programs use a similar take-back model effectively, such as in Canada and Australia.⁶⁸

What kinds of problem items can enter collection programs and how can it be prevented?

The most common problem items are used syringes, lancets, and IV needles. Packaged, unused syringes are not a safety concern. It is important to offer collection of used needles in a different system at a nearby location, along with visual information. The program is evaluating methods to safely remove these items if inadvertently collected. A few used syringes and lancets have been found thus far in the PH:ARM pilot program, and they have been safely removed.

Some consumers may deposit mercury thermometers into the collection

program. Mercury should not be incinerated, so it is important to inform consumers that they shouldn't put thermometers into the container. A few mercury thermometers have been found in the PH:ARM program, and we are evaluating procedures to safely remove these items if inadvertently collected. The pharmacist should also have information for the customer about where to take thermometers for proper disposal.

Several electronic glucose meters have been found in collection buckets. Electronic devices should not be incinerated due to heavy metal content. Screening procedures remove these items when inadvertently collected.

Medicated aerosol cans have flammable propellants which are classified in a different Department of Transportation class as the rest of the waste medications. DOT prohibits transport of these two material classes in the same container. Screening procedures remove aerosols, and proper signage must be in place to inform the public. The small number of *inhalers* received and the small amount of pressurized gas (typically non-flammable gas) in each inhaler allows for their acceptance into the collection system.

Pharmacists trying to dispose of their business waste properly may want to use the convenience of the household collection units. Because there is not an easy, inexpensive, or accessible pharmaceutical waste management option for small clinics, this is likely unavoidable. However, business waste is usually identifiable because it is different in appearance from individually prescribed medication. Screening procedures are needed to remove identifiable business waste and educate the business generator who is improperly using the system.

Will patient confidentiality requirements affect collection of waste household pharmaceuticals?

No. If patients are concerned, they can mark out patient information. However, waste containers will be disposed of in a way that destroys all patient information.

Collecting Controlled Substances

Can pharmaceutical collection programs currently collect waste controlled substances (CS) from consumers?

Several states have requested permission, and the DEA has denied these requests. The denial is based on DEA regulations which:

- Permit the possession of controlled substances only by an entity that is either registered with the DEA or is specifically exempted from registration (i.e., end users in possession of a controlled substance issued via a prescription, or law enforcement).
- Do not permit a registrant to take possession of controlled substances from a non-registrant. Therefore a pharmacy,

hospital, physician or wholesaler would not be permitted to take possession of a controlled substance from a patient.

Why should we collect controlled substances from end-users in the same system?

- There is **no** legal or safe disposal option available for unused controlled substances from households. Even disposal to the trash is technically in violation of DEA regulations because the waste hauler is “taking possession” of the drugs contained in the household trash.
- Controlled substances are typically a small, but ubiquitous, percentage of total wasted pharmaceuticals from households (estimates of 10-15%).⁶⁹
- Consumers cannot distinguish between prescription and controlled substances.
- A collection program offers much more security than the current routes of disposal into unlocked dumpsters or unattended home storage.
- Leftover controlled substances from home care environments present potential for abuse/suicide.

Is there any possible way to collect controlled pharmaceuticals from households?

Currently the only legal way to collect controlled substances is at exempt agencies (such as sheriff offices) because DEA allows them to take possession of a controlled substance (through drug arrests, etc.). If law enforcement agencies were to accept household-generated controlled substances, the agency would have to manage and dispose of the drug as they would other controlled substance seized as evidence.⁷⁰ The resources required for the handling and disposal of this waste has made law enforcement reluctant to be involved with the collection of household waste.

Can individual states allow for disposal of controlled substances?

DEA regulations (21 CFR 1307.21) permit the DEA to allow the Special Agent in Charge (SAC) for DEA regions (in our case, Washington, Alaska, Idaho, and Oregon) to authorize the destruction of controlled substances held in the possession of non-registrants (end-users), after the non-registrant appropriately accounts for and lists the substances to be destroyed. CFR 1307.31(d) also states that the section “*shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State*”. **Thus State law may take precedence in governing the destruction of controlled substances within the State.** Further legal interpretation and guidance regarding this section may be desired.

How can the DEA grant permission to pilot take-back of controlled substances?

In Washington’s case, the DEA was asked in March 2007 to provide a “limited waiver of enforcement” to allow for the collection and transfer of the controlled substance household waste to a permitted entity for destruction. Such licensure or waiver would then permit our pilot partners, under established procedures, to collect and consolidate waste medicines, and would allow a hauler to take the waste from the

consolidation point to the final disposal location.

At the most recent updating of this document, DEA has responded that since their regulations are silent on the take-back of controlled substances, they are “studying the issue..., and the Office of Diversion Control is in the early stages of drafting regulations to address the issue in detail. The PH:ARM team can weigh in during Federal Register public comment period.”⁷¹

Programs for Long Term Care Residents and Hospice

What is the definition of a nursing home, boarding home, or assisted living facility?

Nursing homes and boarding homes may be called assisted living facilities, managed residential care facilities, or long-term care facilities.

A nursing home facility provides 24 hour supervised nursing care, personal care, therapy, nutrition management, organized activities, social services, room, board, and laundry.

A boarding home is a facility in a community setting licensed to care for seven or more residents. The home provides housing, meal services, and assumes general responsibility for the safety and well-being of the resident. Boarding homes can range in size from 7 beds to 150 beds. Some facilities provide intermittent nursing services.

Managed residential care facilities (including skilled nursing facilities) are businesses but also temporary or permanent households. The EPA Resource Conservation and Recovery Act (RCRA) and Ecology WAC 173-303 Dangerous Waste Rules determine that pharmaceuticals that are prescribed to patients but ‘wasted’ in home health care settings are household waste, rather than business waste. EPA region X and the Washington State Department of Ecology are still resolving whether pharmaceutical waste from a business-residential healthcare setting is “household” waste.

Unwanted controlled substances prescribed to patients at managed care residential facilities have been commonly disposed through the sewer per Board of Pharmacy regulations, 246-865-060 Washington Administrative Code (WAC). Non-controlled ‘household’ waste pharmaceuticals from managed care residential facilities are sometimes disposed through a pharmaceutical waste service provider, but typically disposed via the sewer, garbage, or medical waste system. Medical waste is not equivalent to hazardous waste disposal for chemicals.

What quantity of pharmaceuticals do managed residential care facilities generate?

According to a National Health Policy Newsbrief from 2002, routine medication orders in nursing homes increased by 14 percent from 1997 to 2000. The percentage of nursing home residents using nine or more prescription medications per day also rose from 18 percent in 1997 to 27 percent in 2000.⁷²

What is the total quantity of waste pharmaceuticals from Long Term Care Facilities?

A 2005 pharmaceuticals workshop for the EPA stated that long term care facilities account for a third of unused medications, with households accounting for the remaining two-thirds (non-hospital/non-pharmacy).⁷³ Two state specific studies cite the following⁷⁴;

- A Massachusetts study referenced in the table below determined 6.7% of total medications prescribed ended up wasted.
- The value of unused drugs in *long term care facilities* may be as high as \$378 million, or between 4 and 10 percent of the total dispensed costs.⁷⁵
- More than 90 percent of the wasted medication is due to change in prescription, death, or transfer of the resident.⁷⁶ These discontinued drugs are often disposed of into the toilet.⁷⁷

**% Medication Destroyed by Reason
(Long Term Care Facility Study from Massachusetts) ⁷⁸**

Medication changed 6.3%
Medication discontinued 34.2%
Medication decreased 3.4%
Medication increased 2.0%
Medication expired 1.9%
Patient died 35.5%
Patient hospitalized 6.8%
Patient transferred 7.3%
Other 2.6%

A 2003 King County survey estimated that managed residential care facilities in Washington generate 7,200 lbs annually statewide, or 8 lbs/facility/year.⁷⁹

How would medications be collected from nursing homes?

- The system would allow for safe management of all types of waste pharmaceutical products, including controlled substances.
- Nursing home staff would have a secure return container located in the “med room” for depositing waste household medications on behalf of patients in their care. In assisted living situations, a container could be located in the clinic area for patients to deposit their own medications.
- This return container would be able to accommodate both bingo cards (blister packaging) and individual vials of medication.
- The nursing home staff would not have to inventory most of the material deposited into the container.
- The nursing home staff would still account for controlled substances disposed (as they currently do) according to current State and Federal regulations.
- Depositing medications into the container would be considered irretrievable destruction.
- Nursing home staff would not have access to the contents once material was deposited.
- The waste medications would be collected on a schedule by a licensed pharmaceutical waste hauler for final, environmentally-responsible disposal.

How does hospice care take responsibility for household medication disposal?

Hospice agencies provide symptom and pain management to terminally ill individuals and emotional, spiritual, and bereavement support to the individual and family, in the home or places of permanent or temporary residence.

Hospice agencies are licensed by the state to provide care within the minimum health and safety standards established by statute and rule. Hospice services may also include the provision of home health and home care services. The Department of Health enforces the standards by periodically conducting unannounced surveys of these agencies. The rules state that:

A pharmacist must provide sufficient on-site consultation to ensure that medications are ordered, prepared, disposed, secured, stored, accounted for and administered in accordance with the policies of the center and chapter 246-865 WAC;

Schedule II - IV controlled substances must be:

- (a) Kept in a separate keyed storage unit; and
- (b) When heat sensitive, be kept in a locked refrigeration unit;

Schedule II - IV controlled substances no longer needed by the patient must be disposed in compliance with chapter 246-865 WAC.

The Washington state pilot hopes DEA will allow hospice care providers to use secure collection containers or a mail-back program.

Financing a Collection System

What are the costs of a pharmacy take-back collection program?

The current B.C. program estimates the total aggregated costs associated with management of waste consumer medications at \$5.27 per lb (US Dollar).

A full scale program at 1,300 pharmacies could collect over 470 lbs⁸⁰ annually per participating pharmacy. Using the Canadian \$5.27/lb rate, the program would cost approximately \$2,500/yr per location. If 1,300 pharmacies in Washington participated in the program, collection and disposal costs could total \$1 million to \$3 million.

PH:ARM is currently spending \$5.00 per lb to collect, manage, and dispose of collected waste pharmaceuticals. This does not include purchase of reusable supplies, such as secure drop box (\$600 each) or the wheeled tote (\$100 each).

Mail-back programs have an additional postal cost. It would take 940 mailers to mail 470 lbs of material collected at each pharmacy annually (assuming each mailer is 0.5 lbs). Oregon estimates the purchase and shipment of the mailer at \$3.40 per piece⁸¹, thus 470 lbs of drug waste shipped through the mail will cost \$3,200. Thus, full participation of 1,300 Washington pharmacies would require \$4 million in single-use mailer costs alone. Disposal costs are additional.

How does the cost of a medicine return program compare to the value of medicines sold in Washington State?

\$3.1 billion was spent in Washington to purchase 53.6 million prescriptions in 2006.⁸² \$15.4 billion was spent on over-the-counter medication and/or personal care products nationwide, excluding Wal-Mart.⁸³ Thus, approximately \$51 per capita is spent on OTC drugs, totaling \$327 million in Washington State. Washingtonians spend \$3.4 billion annually on the retail purchase of prescription and OTC medications.

In comparison, the cost of a hypothetical Washington take-back program collecting 1.5 lbs per day⁸⁴ per pharmacy could range from \$1 million to \$3 million. That is 0.03 to 0.09 percent of the purchase price of prescriptions and OTCs sold in Washington, or \$0.02 to \$0.05 per prescription (not including the number of OTC sales).

Why should manufacturers operate and finance a pharmaceutical disposal program?

Increasingly, products with potential negative impacts on society and the environment are being collected at their end-of-life through programs managed and/or funded by the manufacturers of those products. This approach is being used for rechargeable batteries and cell phones in the US, and for electronics and mercury-containing devices in several states, Europe and Asia. There are many successful and cost-effective examples of manufacturer stewardship for pharmaceuticals, including British Columbia, Australia (partially manufacturer-funded), Prince Edward Island, France, Italy, and several other European countries.

Manufacturers (and by extension, consumers) are the most equitable funders of product take-back programs; such management costs should not be borne by taxpayers or garbage utility ratepayers.

By managing their products at end-of-life, manufactures get significant information with which to inform product redesign. In the case of pharmaceuticals, such data can help inform prescribing practices, patient compliance practices, and possibly drug formulation. Efforts in Sweden are already underway to inform prescribing practices with data about a medicine's potential Persistent, Bioaccumulative, or Toxic qualities.

Transportation Requirements

Who can transport household generated pharmaceutical waste?

Any company that is managing pharmaceutical waste needs to possess a wholesaler/ manufacturer license from a Board of Pharmacy where their facility is located.⁸⁵

A company that is managing controlled substances must have a DEA registration number for each designated location at which controlled substances 're-packaged' or handled. DEA registration numbers are federally issued and allow for the transfer of controlled substances from one DEA registrant to another. A DEA registration number does not currently allow for patient returns.

Any firm that is handling household-exempt hazardous waste must either have a solid waste G permit (issued by the Washington State Utilities and Transportation Commission, or UTC)⁸⁶, EPA Identification number for a transporter (issued by the Washington State Department of Ecology)⁸⁷, or be classified as a product take-back center (defined in the 173-350-360 WAC ; exempt from solid waste handling permitting). These transporters must also have common carrier permit from the UTC.⁸⁸

What are the shipping requirements enforced by the Federal Department

The U.S. Department of Transportation has the responsibility to enforce rules related to the transport of hazardous materials for commerce that may pose unreasonable risks to health and safety, and to promulgate regulations for the safe transportation of these hazardous materials.

of Transportation?

Household hazardous waste that is pharmaceutical waste may be shipped as medicine, solid/ liquid, toxic, n.o.s. (not otherwise specified), division of 6.1⁸⁹ or ORM-D Consumer Commodity (if in the original consumer package) defined in 49 CFR 171.8. ORM-D includes medications. The quantity limit for ORM-D is 66 lbs, or less than 55 gallons. Inner packaging units should not exceed 250 ml (8 ounces) net capacity for liquids or 250 g (8.8 ounces) net capacity for solids. *Unpackaged* medicine, solid/liquid, toxic, n.o.s. has a quantity limit for shipping of 11 lbs (solid) or 5 Liters (liquid).

Two material types that are not compatible for shipping are flammable aerosols and solutions with greater than 24% alcohol.

- 1) Aerosols with flammable propellants cannot be combined in the same container as poisons. Inhalers are not included in this flammable category because the product is shipped as DOT class 2.2 aerosol non-flammable gas.⁹⁰
- 2) Typical over-the-counter cough syrup concentrations of alcohol are less than 24% alcohol. However, even if the medicine has a content of >24% alcohol, they are not subject to DOT if inner packages are less than 0.5 liter (0.1 gallon).⁹¹

DOT regulations state that packaging and containers marked or labeled for biomedical waste may contain no other wastes.⁹² This is a potential barrier to proper management of residential pharmaceutical waste because it requires waste screening to remove used sharps or lancets.

Labels

Shipping labels are not required for ORM-D (if 49 CFR 173.156 is met) but are required for medicine, solid/liquid, toxic, n.o.s. However, ORM-D packages must be marked as such.

Shipping Papers

DOT laws state that a carrier may not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49CFR172.200, 172.201, 172.202, and 172.203.⁹³

- Shipping documentation is not required for ORM-D except when the material is offered or intended for transportation by air.⁹⁴
- Hazardous waste manifests are only required for hazardous waste, which is defined by 40 CFR 261. A manifest is not required for household-exempt hazardous materials.

What are the responsibilities of transporters?

EPA hazardous waste transporters are responsible for receiving the proper paperwork from the generator, ensuring delivery to the specified receiving facility (or specified alternate facility), and retaining records. Hazardous waste transporters cannot store the material for more than 10 days at a registered transfer station.

Solid waste transporters who are offering a service for hire must obtain a G-permit from the Utilities and Transportation Commission and ensure delivery to a facility that meets the performance standards of 173-350-040 WAC (Washington Administrative Code). Issuance of a G-permit depends on proof of public convenience and necessity. Typically the UTC only grants one G-permit per ‘territory.’

Product take-back centers,⁹⁵ defined in 173-350-100 WAC, must prevent releases to the environment, exposure of the public, and ensure delivery to a facility that meets the performance standards of 173-350-040 WAC. They must notify the health department of any failure to comply with 173-350-360 (3) (b, e, f) WAC. Product take-back centers must ensure that they are taking household hazardous waste back which is comparable to the type sold or distributed at that location.

Companies that transport non-household goods for compensation within the state of Washington must also have a common carrier permit from the Washington UTC.

Disposal Options

What is the best available final disposal treatment for collected waste medications?

Most other countries with medicine take-back programs use incineration for final disposal. The World Health Organization recommends high temperature incineration for cytotoxic medications (toxic to cells, or chemotherapy drugs) and recommends that no more than 5% of the fuel fed into the incinerator be pharmaceuticals.⁹⁶ Without direct evidence of harmful air emissions from incineration of medications, it is best to act with precaution and dispose of hazardous medicines in the most protective way possible.

Reasons for concern about landfill disposal:

- Groundwater or to surface water contamination from landfill leachate containing pharmaceuticals.
- Vinyl chloride leaching from Polyvinyl Chloride (PVC) medicine containers (PVC is present in some blister packaging and IV bags).
- Security and ultimate destruction at the disposal location.
- Scavenging from trash receptacles or at the disposal location.

Reasons for concern about incineration:

- The quantity and severity of air pollution from medicines burned in solid, medical, or hazardous waste incinerators is unknown.
- Emissions monitoring for solid waste and medical waste facilities does not occur on a daily basis.
- Ash residue from solid and/or hazardous waste incinerators may contain pollutants from medicine if they are non-organic chemicals.
- The variations in temperature and burn time at which pharmaceuticals are destroyed are not consistent at solid waste

and medical waste incinerators, because the feed stock (garbage in) determines the temperature.

- Carcinogenic dioxin can form when containers containing Polyvinyl Chloride are burned.
- Transportation costs, handling efficiency, and environmental impacts of shipping to and from disposal site must be considered. No commercial hazardous waste incinerators are located west of Utah.

General concerns about the final disposal location include:

- Community impacts and compliance issues at the disposal location.
- Regulatory oversight at in-state and out-of-state facilities may vary. (Occasionally, out-of-country facilities may be used for disposal.)

What are the waste acceptance policies of hazardous waste (RCRA) and municipal solid waste (MSW) incinerators?

RCRA incinerators must comply with their permit conditions issued by the delegated authority. Usually, this is the state where the facility is located. All hazardous waste facilities are required to confirm knowledge about a dangerous waste before storing, treating, or disposing of it. This information is provided on a document called a **profile** (supplied by the generator) or is developed through detailed chemical analysis at the facility. The owner or operator of a hazardous waste facility must develop and follow a written waste analysis plan that describes the procedures that will be used to comply.

The profile is a form supplied by the final disposal company which contains information about the waste. The information is derived from material safety data sheets (MSDS), chemical analysis, or other types of research. The profile is approved by the final disposal company before shipment of the waste commences.

In Washington, county health departments have permit authority over solid waste incinerators. Regulations adopted locally can be found in 173-350-240 WAC. These facilities must ensure that dangerous waste is not disposed at the solid waste incinerator (business-generated hazardous waste) and that only fuels approved in writing by the agency with jurisdiction over the facility for air quality regulation are combusted.

Where can household pharmaceutical waste legally be disposed?

Regulations in Washington state legally allow for the disposal of household-generated hazardous material as solid waste. Whether this is appropriate depends on the facility, quantity and quality of waste, evidence of safety, and the control technology. Local county or city regulations may prohibit certain types of material, such as electronics or all hazardous waste (regardless of the household origin), into their solid waste systems.

Disposal facilities can accept household pharmaceuticals, if they OR the

transporter possesses a license from the state Board of Pharmacy.

If a DEA witness is required, the facility or transporter must hold a DEA reverse distributor license.

What are the alternatives to incineration?

Environmentally-preferred alternatives to incineration that need additional research include:

- Waste prevention efforts
- Transformation and stabilization of pharmaceutical waste for disposal to a hazardous waste landfill.
- Alkaline hydrolysis (not commercially available at this time).
- Pyrolysis-type chemical reactions or plasma arc (not commercially available at this time).

If controlled substances are included in the collection of pharmaceutical waste, the Drug Enforcement Administration requires destruction beyond reclamation of this material.

Can collected waste pharmaceutical material be reused?

Collected waste pharmaceuticals from households are not yet able to be reused or redirected from a final disposal program per FDA regulations.

Donations to other countries must be initiated by the receiving organizations. Waste or expired medications should NEVER be given to charitable organizations as a method of disposal.

Reprocessing of collected waste pharmaceuticals could be a potential solution in the future, but needs major technical and regulatory change to become a realistic option.

Can pharmaceutical products become more environmentally friendly?

Research is just beginning in this area. One notable effort is the Stockholm County Council which developed a scoring system for different medications, taking into account environmental persistence (P), bio-accumulation (B) and toxicity (T). They have published this information in a brochure called "Environmentally Classified Pharmaceuticals." ⁹⁷ The information is meant to provide doctors tools to prescribe similarly effective drugs that have fewer environmental impacts.

Other ways to 'green' pharmaceuticals is to reassess appropriate expiration dates, design more targeted drug interactions, and create metabolites that quickly break down under conventional wastewater treatment.

Support for the PH:ARM Approach

Organizations that Support a DEA Waiver

U.S. Senators Murray and Cantwell
Washington State Governor, Christine Gregoire
Washington State Attorney General, Rob McKenna
King County Executive, Ron Sims
Washington State Department of Health Secretary, Mary Selecky
Environmental Protection Agency, Region X Director, Office of Air, Waste & Toxics, Rick Albright and Region X Regional Administrator, Elin Miller
City of Renton Mayor, Kathy Keolker
Washington Association of Sheriffs and Police Chiefs Executive Director, Donald Pierce
Seattle Office of Sustainability and Environment Director, Steve Nicholas
Group Health Cooperative Pharmacy Clinical Services Associate Director, Shirley Reitz
Bartell Drug Company Assistant Vice President, Dan Connelly
Washington Board of Pharmacy Executive Director, Steven Saxe
Washington State Pharmacy Association CEO, Rod Shafer
Washington State Board of Health Chair, Treuman Katz
King County Wastewater Treatment Division Director, Don Theiler
Seattle-King County Public Health Director and Health Officer, David Fleming
People for Puget Sound Executive Director, Kathy Fletcher
Washington Poison Control Medical Director, William O. Robertson
Washington State Department of Ecology Program Managers, Cullen Stephenson and Darin Rice
University of Washington Industrial Hygienist, William Rowe and Research Scientist, Caleb Banta-Green
Ritchie Law Firm Attorney and Pharmacist, Craig Ritchie
Pacific Northwest Pollution Prevention Resource Center Executive Director, Chris Wiley
Snohomish County Corrections Nurse Practitioner, Sandra Needham
Puget Sound Action Team Director, Brad Ack

Team Members of PH:ARM

Washington State Department of Ecology, Emma Johnson
Local Hazardous Waste Management Program in King County, Cheri Grasso and Alice Chapman
Washington Citizens for Resource Conservation, Eva Dale and Suellen Mele
Washington State Board of Pharmacy, Stan Jeppesen
Northwest Product Stewardship Council, David Stitzhal
Snohomish County Solid Waste Management Division, Sego Jackson
Public Health – Seattle & King County, Will Perry
Bartell Drug Company, Dan Connelly
Group Health Cooperative, Shirley Reitz, Bob Willott, and Walter Sidles
Pacific NW Pollution Prevention Resource Center (PPRC), Cathy Buller
DSHS, Aging and Disability Services, Todd Henry

Funding Organizations of PH:ARM Project

Russell Family Foundation
King County Waterworks
Group Health Community Foundation
Puget Sound Action Team
Washington State Department of Ecology
Snohomish County Solid Waste Division
King County Department of Natural Resources Solid Waste Division
Seattle Biotech Legacy Foundation
Seattle Public Utilities

Sample Media Covering PH:ARM Project

- 2/1/2007, Curing the problem of discarding pills, *Seattle Post-Intelligencer* Feature. http://seattlepi.nwsource.com/health/301869_hcenter01.html
- 3/2/2007, New way to dump old meds, *The Herald* (Everett)
Lead story.
<http://www.heraldnet.com/article/20070302/NEWS01/703020764&SearchID=73291847693648>
- 3/2/2007, Drug take-back program protects streams and fish, KING-TV (NBC)
http://www.king5.com/topstories/stories/NW_030207HEBgrouphealthEL.1240fe18.html
- 3/5/2007, Group Health creates pilot program for disposing old medication, KUOW radio Feature. <http://www.kuow.org/defaultProgram.asp?ID=12367>
- 3/18/2007, Don't flush drugs down the toilet, *The News Tribune* (Tacoma)
Feature. <http://www.thenewstribune.com/soundlife/story/6420862p-5723303c.html>
- 4/19/07 –Good for us; bad for fish? *Wenatchee World*
- 4/22/2007, Pharmacy disposal sites established, *The Spokesman-Review*
Feature. <http://www.spokesmanreview.com/local/story.asp?ID=185907>
- 4/22/2007, Close the lid on old medicine, *USA Today*
http://www.usatoday.com/news/health/painter/2007-04-22-old-medicine_N.htm?csp=34
- 5/5/07 The Environmental Side Effects of Old Medicines, Eco-Consumer Article, *The Seattle Times*. <http://archives.seattletimes.nwsource.com/cgi-bin/texis.cgi/web/vortex/display?slug=ecoconsumer05&date=20070505&query=medications>
- 5/19/07 American Society of Health-System Pharmacists Saving the Environment One Prescription at a Time *Members Devise a Unique, Safe Disposal System for Consumers*
- 5/28/07 Program Accepts Old Medicines, *The Olympian*.
<http://www.theolympian.com/environment/story/117172.html>

¹ Washington State Childhood Injury Report, November 2004, p. 38
www.doh.wa.gov/hsqa/emstrauma/injury/pubs/wscir/WSCIR_Poisoning.pdf

² Washington State Department of Health injury tables 2003

³ Poisoning includes accidental overdose of drug, wrong drug given or taken in error, and drug taken inadvertently; accidents in the use of drugs; and the damaging physiologic effects of ingestion, inhalation, or other exposure to a broad range of chemicals, including pesticides, heavy metals, gases/vapors, drugs, and a variety of common household substances, such as bleach and ammonia.

⁴ Unintentional Poisoning/Drug Overdose Deaths in Washington State, June 12, 2007, Washington Department of Health

⁵ Poisoning in the US: Fact Sheet. Centers for Disease Control, last modified Feb 7, 2007.

www.cdc.gov/ncipc/factsheets/poisoning.htm

⁶ The National Center on Addiction and Substance Abuse (CASA). Under the Counter. The Diversion and Abuse of Controlled Prescription Drugs in the U.S. July 2005

www.casacolumbia.org/supportcasa/item.asp?CID=12&PID=138

⁷ Consumer Healthcare Products Association, Stopping Cough Medicine Abuse, www.chpa-info.org/ChpaPortal/ForConsumers/Cough_Med_Abuse/Stop_Cough_Med_Abuse.htm

⁸ News and Public Affairs, Office of National Drug Control Policy, WHAT EVERY AMERICAN CAN DO TO PREVENT MISUSE OF PRESCRIPTION DRUGS, August 29, 2007,

<http://www.whitehousedrugpolicy.gov/news/press07/022007.html>

⁹ SAMHSA press release, issued October 27, 2006. <http://www.samhsa.gov/>

¹⁰ Kolpin, D.W., Furlong, E.T., Meyer, M.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., and Buxton, H.T., 2002, [Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000--A national reconnaissance](#): Environmental Science and Technology, v. 36, no. 6, p. 1202-1211.

¹¹ USEPA, Pharmaceuticals & Personal Care Products in the Environment: An Emerging Concern? 1999 research abstract, <http://www.epa.gov/nerl/research/1999/html/g8-14.html>

¹² Johnson, A., B. Carey, and S. Golding, November 2004, [Results of a Screening Analysis for Pharmaceuticals in Wastewater Treatment Plant Effluents, Wells, and Creeks in the Sequim-Dungeness Area](#): Environmental Assessment Program, Washington State Department of Ecology, Publication Number 04-03-051

¹³ Study finds chemicals in biosolids. SUSAN GORDON; The News Tribune updated: September 18th, 2006. (note: Scientific assessment of the fate of pharmaceuticals in air has not been published.)

¹⁴ J. P. Bound, N. Voulvoulis. "Household Disposal of Pharmaceuticals as a Pathway for Aquatic Contamination in the United Kingdom." Environmental Health Perspectives 2005 <http://www.ehponline.org/docs/2005/8315/abstract.html> Accessed November 7, 2007

¹⁵ Kelly A. Reynolds, MSPH, Ph.D., "Pharmaceuticals in Drinking Water Supplies" [Water Purification and Conditioning Magazine](#), June 2003: Volume 45, Number 6.

¹⁶ Kummerer, K., 2004, Pharmaceuticals in the Environment-scope of the book and introduction, in Kummerer, K (ed), Pharmaceuticals in the environment: Sources, fate, effects, and risks, Second Edition, Springer-Verlag, Berlin, Heidelberg, New York, p. 1-11.

¹⁷ Richard T. Williams, Editor, Human Pharmaceuticals: *Assessing the impacts on aquatic ecosystems*, 2005,

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¹⁸ USGS, Kinney, C.A., Furlong, E.T., Werner, S.L., and Cahill, J.D., 2006, Toxic Substances Hydrology Program, "The 19 Pharmaceuticals in the Study of Pharmaceuticals in Soil Irrigated with Reclaimed Water", http://toxics.usgs.gov/highlights/pharm_soils/listing.html

¹⁹ Wastewater effluent tested in the Sequim-Dungeness 2004 study occurred at a tertiary treatment plant, yet pharmaceuticals were still present.

²⁰ Treatment of effluent waste water with the aid of advanced oxidation techniques such as ozone treatment and UV/hydrogen peroxide treatment was studied at laboratory scale for ibuprofen, gemfibrozil, naproxen, ketoprofen, diclofenac, atenolol, trimethoprim, metoprolol, sulphamethoxazole, propranolol, carbamazepine, ofloxacin and lomefloxacin. With the exception of sulphamethoxazole and propranolol all substances studied were eliminated by over 70% with ozone treatment. With UV/hydrogen peroxide treatment all substances were eliminated (gemfibrozil not included in the measurements) by 90–100%. "Environmental Effects of Pharmaceuticals, Cosmetics, and Hygiene Products," Report from the Swedish Medical Products Agency, August 2004

www.noharm.org/details.cfm?type=document&id=1026

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- ²¹ Ozone treatment works well at removing organics, but is very energy intensive. UV works well on a small scale, but not on a large scale. Hydrogen Peroxide is more expensive than chlorination, and more space intensive. These technologies usually work better in combination than alone. Conversations with John Smith, King County Wastewater Treatment Division, August 2, 2005
- ²² K. Barnes, S. Christenson et.al. Spring 2004 "Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill" [Ground Water Monitoring and Remediation](#) 24, No.2 pages 119-126
- ²³ German poster shows that degradation is limited in landfill. C. Schneider, B. Kuch, M. Braun, J. W. Metzger, Institute of Sanitary Engineering, Water Quality and Solid Waste Management (ISWA), University of Stuttgart, Germany. Pharmaceuticals in landfill leachates and receiving WWTP influents. 2004 www.iswa.uni-stuttgart.de/ch/poster/setac04_pharmaceuticals_in_landfill_leachates.pdf
- ²⁴ Peschka, M.; Eubeler, J. P.; Knepper, T. P., Occurrence and Fate of Barbiturates in the Aquatic Environment *Environ. Sci. Technol.*; (Article); 2006; ASAP Article [10.1021/es052567r](https://doi.org/10.1021/es052567r)
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- ²⁸ Daughton, C. G., Ternes, T. A., "Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?" *Environmental Health Perspectives*, Vol. 107, Supplement 6, pp. 907-938, 1999.
- ²⁹ Brain, R. A.; Johnson, D. J.; Richards, S. M.; Sanderson, H.; Sibley, P. K.; Solomon, K. R., "Effects of 25 pharmaceutical compounds to *Lemna gibba* using a seven-day static-renewal test," *Environmental Toxicology and Chemistry*, Vol. 23, No. 2, pp. 371-82, 2004 as quoted in HOUSEHOLD PHARMACEUTICAL WASTE: Regulatory and Management Issues *for the San Francisco Department of the Environment* <http://www.tdcenvironmental.com/HouseholdPharmWasteMgtIssuesFinal.pdf>
- ³⁰ Soil Science Society of America, July 13, 2007 www.sciencedaily.com/releases/2007/07/070711134530.htm
- ³¹ This figure excludes prescriptions filled by mail order. Mail order is approximately 6.8% of total prescriptions filled. Henry J. Kaiser Family Foundation. <http://statehealthfacts.org>
- ³² *ibid.*, Henry J. Kaiser Family Foundation.
- ³³ Pennsylvania State Representative Tim Murphy, Rx: Health Care FYI #31, http://murphy.house.gov/UploadedFiles/HealthCareFYI_31.pdf, Accessed 10/31/07
- ³⁴ Price Waterhouse Cooper, New Pharma Thought Leadership Released Pharma 2020: The Vision – Which path will you take? August 29, 2007 [http://www.pwc.com/extweb/pwcpublications.nsf/docid/91BF330647FFA402852572F2005ECC22/\\$File/hi ghlights-pharma2020.pdf](http://www.pwc.com/extweb/pwcpublications.nsf/docid/91BF330647FFA402852572F2005ECC22/$File/hi ghlights-pharma2020.pdf)
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- ³⁸ Department of Toxic Substance Control Pharmaceuticals Webinar, Broadcast May 22, 2007. 3% waste was quoted by Mary Buzby, PhD, Merck & Co., representing Pharmaceutical Research and Manufacturers Association (PhRMA). www.dtsc.ca.gov/AssessingRisk/PPCP/index.cfm
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⁴⁰ Draft report by Tischler/Kocurek, October 2006, Potential Releases of Unused Medicines in Subtitle D Landfill Leachate

⁴¹ Christian Daughton, US EPA, May 2003 “Cradle to Cradle Stewardship of Drugs while Minimizing their Environmental Disposition while Promoting Human Health, Green Pharmacy Mini-Monograph Part II” Environmental Health Perspectives. Volume 111, Number 5

http://findarticles.com/p/articles/mi_m0CYP/is_5_111/ai_103563596 p781

⁴² Pharmaceutical Research and Manufacturers of America (PhRMA), U.S. Environmental Protection Agency Workshop on Pharmaceuticals in the Environment, August, 2005, “Pharmaceuticals in the Environment”, PowerPoint Presentation, http://es.epa.gov/ncer/publications/meetings/8-23-2005/Buzby_300_d2.pdf, Accessed 10/31/07

⁴³ June 2005, DNR Behavior Survey, available through King County Local Hazardous Waste Management Program.

⁴⁴ SoundStats Survey of King County households (2006, WCRC)

www.wastenotwashington.org/Pharmsurvey.pdf

⁴⁵ 40 CFR Section 261.4(b) (1) and WAC 173-303-071(3)(c) state that waste generated at a household is excluded from regulation as a hazardous waste.

⁴⁶ Seattle-King County Public Health Title 13.04.058 prohibits disposal of hazardous waste to septic tanks. Seattle Municipal Code 21.36.025 prohibits HHW and SQG hazardous wastes from being disposed in any commercial or residential garbage container. Snohomish Health District Solid Waste Code Chapter 3.1 XXI G 1 prohibits disposal of hazardous waste to sewer, septic, or solid waste routes. Kitsap County Code 2004-2 (6)(d)(i) states that household hazardous waste shall not be deposited in the general municipal solid waste collection system, a public sewer system, a storm drain, an on-site sewage system, in surface or ground water, or onto or under the surface of the ground.

⁴⁷ Kuspis DA, Krenzelok EP. What happens to expired medications? *Veterinary and Human Toxicology*. 1996;38(1):48-49. Cited on Facts on Pharmaceuticals and the Environment THE JOURNAL OF ECOLOGICALLY SUSTAINABLE MEDICINE • SPRING/SUMMER 2007, <http://www.teleosis.org/pdf/symbiosis/Facts4.2.pdf>, Accessed 10/31/07

⁴⁸ Hazardous waste recycling facilities may operate under more streamlined regulations or certain exemptions. Permits are issued by the state where the TSDF is located or by the EPA if the State doesn't have federally delegated permitting authority. A manifest is used to track the waste generated by businesses from the point of generation to the final disposal.

⁴⁹ SoundStats Survey of King County households (2006, WCRC)

www.wastenotwashington.org/Pharmsurvey.pdf

⁵⁰ RCRA online, document 11606. www.epa.gov/rcraonline/

⁵¹ See WAC 173-350-360 (3)

⁵² Small Quantity Generators may transport their own hazardous waste to a hazardous waste disposal facility or vendor without a manifest. The land disposal restriction (disposal to permitted landfills) for hazardous waste does not apply to Small Quantity Generators. Small Quantity Generator requirements focus on determining which wastes are hazardous and ensuring disposal at a safe location.

⁵³ A Small Quantity Generator, or Conditionally Exempt Small Quantity Generator, generates less than 220 lbs per month of designating hazardous waste, or less than 2.2 lbs per month of extremely hazardous waste.

⁵⁴ Some RD's (Kellcor, Inc. and Strong Environmental, www.strongenvironmental.com) and some hazardous waste vendors (Philips) are willing to “take back” household medication waste (non-controlled medications) for a fee. The fee is usually based on weight. This is partially not allowed

under Federal and State law (Board of Pharmacy licensing rules and EPA), but has been overlooked by enforcement regulators.

⁵⁵ DEA-1: DEA Interim final rule: FR Doc 03-17578, Fed. Register July 11,2003(vol 68,No. 133), [docket No. DEA0108] Rin 1117-AA19, Definition and Registration of Reverse Distributors. 21 CFR parts 1300, 1301,1304,1305, 1307.

⁵⁶ Pharmaceutical Research and Manufacturers of America (PhRMA), U.S. Environmental Protection Agency Workshop on Pharmaceuticals in the Environment, August, 2005, “Pharmaceuticals in the Environment”, PowerPoint Presentation, http://es.epa.gov/ncer/publications/meetings/8-23-2005/Buzby_300_d2.pdf, Accessed 10/31/07

⁵⁷ Henry J. Kaiser Family Foundation. <http://statehealthfacts.org>, Accessed 10/31/07

⁵⁸ Pharmaceutical Research and Manufacturers of America (PhRMA), U.S. Environmental Protection Agency Workshop on Pharmaceuticals in the Environment, August, 2005, “Pharmaceuticals in the Environment”, PowerPoint Presentation, http://es.epa.gov/ncer/publications/meetings/8-23-2005/Buzby_300_d2.pdf, Accessed 10/31/07

⁵⁹ Conversations with BC Residuals Management Group, Paul Iverson, July 7, 2005

⁶⁰ Prescription Drug Expenditures in 2001. National Institute for Health Care Management, Revised May 6, 2002 <http://www.nihcm.org/~nihcmor/pdf/spending2001.pdf>

⁶¹ Data was analyzed by Alice Chapman, King County, who gathered information from the Northeast Recycling Council pilot project and California.

⁶² SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

⁶³ Evidenced in Washington State Household Hazardous Waste collection events, which have costs several times that of a permanent facility per pound collected. Washington electronic waste take-back events have been often overwhelmed by the amount of material collected due to the appearance of scarcity of service.

⁶⁴ Oregon Drug Take Back Group, Final Draft Report, July 1, 2007

⁶⁵ U.S. Postal Code 48. http://pe.usps.gov/text/pub52/pub52c4_008.html#NL508_52

⁶⁶ SoundStats Survey of King County households (2006, WCRC) www.wastenotwashington.org/Pharmsurvey.pdf

⁶⁷ Includes Costco, Group Health Cooperative, and Bartell Drug Company.

⁶⁸ The Australian program is called the Return Unwanted Medications program. www.returnmed.com.au/

⁶⁹ Alan Jones, hospital waste consultant and Stan Jeppesen, Washington Board of Pharmacy, estimates

⁷⁰ Reference: DEA,2: DEA letter to Mr. Phil Bobel, Manager, Environmental Compliance, City of Palo Alto, California

⁷¹ Eric J. Akers, DEA Congressional Affairs Section Chief. Letter to Honorable Senator Patty Murray, October 25, 2007.

⁷² National Health Policy Forum, Issue BriefNo.784 Prescription Drugs in Nursing Homes: Managing Costs and Quality in a Complex Environment / November 12, 2002, http://www.avalerehealth.net/research/docs/IB784_RxDrugsNursHomes_11-12-021.pdf

⁷³ Pharmaceutical Research and Manufacturers of America (PhRMA), U.S. Environmental Protection Agency Workshop on Pharmaceuticals in the Environment, August, 2005, “Pharmaceuticals in the Environment”, PowerPoint Presentation, http://es.epa.gov/ncer/publications/meetings/8-23-2005/Buzby_300_d2.pdf, Accessed 10/31/07

⁷⁴ Pennsylvania State Representative Tim Murphy, Rx: Health Care FYI #10, http://murphy.house.gov/UploadedFiles/HealthCareFYI_10a.pdf, Accessed 10/31/07

⁷⁵ OSU. Prescription Medicines and Nursing Homes: A Problem . . . A Solution. Health and Medicine Issue Paper. Tulsa, OK:Oklahoma State University College of Osteopathic Medicine. 2000. cited in http://murphy.house.gov/UploadedFiles/HealthCareFYI_10a.pdf, Accessed 10/31/07

⁷⁶ AMA. Report 2 of the Council on Scientific Affairs (I-97) Full Text: Recycling of Nursing Home Drugs. Chicago: American Medical Association. March 2001., cited in http://murphy.house.gov/UploadedFiles/HealthCareFYI_10a.pdf, Accessed 10/31/07

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- ⁷⁸ Robert P. Paone et al, Medication Destruction and Waste Measurement and Management in Long-term Care Facilities, Published by the American Society of Consultant Pharmacists, 1996, <http://www.ascp.com/publications/tcp/1996/jan/mdwm.html> Accessed 10/30/07
- ⁷⁹ King County Pharmaceutical Waste Survey, April 2003, publication number SQG-RR-6 www.govlink.org/hazwaste/publications/PharmaceuticalWasteSurvey.pdf
- ⁸⁰ Based on average Pilot medicine return rates at Group Health Cooperative of 1.50 pounds per day *312 days a year.
- ⁸¹ Oregon Drug Take Back Group, Final Draft Report, July 1, 2007
- ⁸² Kaiser Family Foundation, StateHealthFacts.Org, Washington: Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2005, <http://statehealthfacts.org/cgi-bin/healthfacts.cgi?action=profile&area=Washington&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs&topic=Total+Sales+for+Retail+Rx+Drugs>, 2/27/07
- ⁸³ Consumer Healthcare Products Association. OTC Retail Sales -- 1964-2006. www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCRetailSales.htm
- ⁸⁴ July and September 2007 screening results are 2 lbs per day to 1.5 lbs per day at Group Health Cooperative. This is per open day, not per calendar day.
- ⁸⁵ Washington State Department of Health, Board of Pharmacy, <https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/forms.htm#firms>
- ⁸⁶ Washington State Utilities and Transportation Commission. www.wutc.wa.gov
- ⁸⁷ How to obtain a RCRA Site ID number. Washington State Department of Ecology, www.ecy.wa.gov/pubs/9112j.pdf
- ⁸⁸ Washington Utilities and Transportation Commission <http://www.wutc.wa.gov/commoncarriers>
- ⁸⁹ US Department of Transportation. <http://www.myregs.com/dotrspa/>
- ⁹⁰ 49CFR 173.306 Limited quantities of compressed gases.(i) Aerosols with a capacity of less than 50 mL. Aerosols, as defined in §171.8 of this subchapter, with a capacity not exceeding 50 mL and with a pressure not exceeding 970 kPa (141 psig) at 55 °C (131 °F), containing no hazardous materials other than a Division 2.2 gas, are not subject to the requirements of this subchapter.
- ⁹¹ 49CFR 173.150 Limited quantities of flammable liquids and combustible liquids are excepted from labeling requirements, unless offered for transportation or transported by aircraft, with strong inner packaging not over 0.5 L.net capacity each, packed in strong outer packaging.
- ⁹² WAC 480-70-451. (5) Packaging and containers marked or labeled as containing biomedical waste may not be used to ship or transport waste that does not meet the definition of biomedical waste.
- ⁹³ 49CFR 177.817(a)
- ⁹⁴ 49CFR 172.200(b)(3)
- ⁹⁵ “Product Take-Back Center” means a retail outlet or distributor that accepts household hazardous waste of comparable types as the products offered for sale or distributed at that outlet. This definition could be extended to reverse distributors accepting household hazardous waste.
- ⁹⁶ World Health Organization “Guidelines for Safe Disposal of Pharmaceuticals in and after Emergencies” 1999 WHO/EDM/PAR/99.2 p.23
- ⁹⁷ Janus Info website, http://www.janusinfo.org/imcms/servlet/GetDoc?meta_id=7236