

Household Pharmaceutical Waste: Regulatory and Management Issues



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PREFACE

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1.0 INTRODUCTION

1.1 Scope of This Report

Creating a convenient management program for unwanted residential pharmaceuticals will require navigating a complex set of regulations and safety issues. This report is intended to review briefly the issues regarding management of household pharmaceutical waste. Specifically, this report:

- Explains the relevant provisions of current law,
- Gives an overview of the current “reverse distribution” system for pharmaceuticals,
- Identifies safety and regulatory issues that need to be considered as the San Francisco Department of the Environment considers options for household pharmaceutical waste management, and
- Identifies the next steps in developing a program for managing household pharmaceutical waste safely by collection at pharmacies.

1.2 Information Sources

The information in this memorandum comes from the *California Health & Safety Code*; interviews with state and municipal government staff and healthcare industry professionals; technical reports and regulatory correspondence from Federal, state, and local agencies; information on state and municipal government internet sites; scientific journals; and the author’s experience with hazardous and medical waste related legislation, regulation, and management program operation.

2.0 IMPORTANCE OF SAFE HOUSEHOLD PHARMACEUTICAL WASTE MANAGEMENT

In 2002, the U.S. Geological Survey (USGS) released a nationwide reconnaissance of the occurrence of pharmaceuticals, hormones, and other organic wastewater contaminants in surface waters (Kolpin *et al.*, 2002). The USGS study revealed that pharmaceuticals and other personal care products are commonly found in the nation's surface waters. In the USGS study, nonprescription drugs were detected in more than 80% of tested streams; prescription antibiotics were found in nearly half of tested streams. Worldwide, dozens of pharmaceuticals have been detected in surface waters, wastewater treatment plant effluent, and sewage sludge (Heberer, 2002).

The importance of this finding to ecosystems exposed to these substances—and to people who rely on surface waters as a source of drinking water—remains unclear, though many published studies indicate cause for concern (Daughton, 2003a). For example:

- The occurrence of antibiotics in wastewater may be associated with the presence of antibiotic resistant bacteria in surface waters (Daughton and Ternes, 1999).
- Pharmaceuticals may have many subtle effects on both humans and aquatic life, such as disruption of normal endocrine system function (Daughton and Ternes, 1999).
- Lindane-based head lice and scabies treatments caused wastewater treatment plant lindane discharges to exceed surface water quality criteria designed to protect aquatic life (Heil, 2002).
- Antibiotics may also reduce the growth of aquatic plants (Brain *et al.*, 2004).
- Mixtures of pharmaceuticals, which commonly occur in surface waters where discharges from municipal wastewater treatment plants flow, may have cumulative effects on organisms (Richards *et al.*, 2004).

Given the biological activity of pharmaceuticals, public concern about these findings is growing.

To date, most studies of pharmaceuticals in surface water have focused on identification of the presence of pharmaceuticals in various environmental media. Research has not yet addressed the relative environmental importance of various potential sources of pharmaceuticals, such as dumping of residential pharmaceutical waste into the sewer system, sewer discharges from non-residential pharmaceutical use sites (*e.g.*, hospitals, doctor's offices, clinics, nursing homes), sewer discharges and runoff from veterinary uses, and sewer discharges from patients themselves in their urine and feces (Daughton, 2003b).

While water quality has generated great interest in pharmaceutical waste management, the original motivation for proper management of unwanted residential pharmaceuticals—human safety—remains relevant. Pharmaceuticals are one of the most common causes of poisonings in California (data from California Poison Control System, undated).

Pharmaceutical use is common—about three in five U.S. residents report having taken at least one over-the-counter drug product in the past six months. More than half (54 percent) report having taken a prescription drugs in the past six months (NCPIE, 2002). While drugs are widely marketed, information available to consumers about management of unwanted pharmaceuticals is limited, disjointed, and often conflicting.

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Recommendations for sewer disposal remain common, despite the well-publicized threat to water quality. Practical management options are few—household hazardous waste collection programs are the safest commonly available management strategy.

3.0 REGULATORY BACKGROUND

3.1 Medical Waste Management Laws

Household pharmaceutical waste is generally exempted from the California Medical Waste Management Act. California does not regulate management of ordinary household waste pharmaceuticals. No federal law regulates management of household medical waste.

One exception to the legal exemption for household pharmaceutical waste is that pharmaceuticals taken to homes and administered by a health practitioner (e.g., nurse, hospice care professional) may need to be managed as regulated medical waste (Kubo, 2004).

Management of regulated medical waste—including waste pharmaceuticals generated by businesses like hospitals and pharmacies—is regulated by the California Department of Health Services (DHS), in cooperation with local enforcement agencies. The California Medical Waste Management act requires regulated pharmaceuticals to be segregated from other medical waste and managed in accordance with a management method approved by DHS.¹ In San Francisco, the Department of Public Health is the local enforcement agency.

3.2 Hazardous Waste Management Laws

Like all household waste, household pharmaceutical waste is not regulated by U.S. EPA. The Federal Resource Conservation and Recovery Act (RCRA) exempts all household hazardous waste (HHW)—including pharmaceuticals—from regulation.

Some household pharmaceutical waste is regulated under the California Hazardous Waste Control Law. Any waste pharmaceutical meeting California criteria for classification as hazardous waste (toxicity, reactivity, corrosivity, ignitability, or exceeding threshold limit values) falls under the regulatory authority of the California Department of Toxic Substances Control (DTSC) (Beckman, 2004). No accurate reference list identifying which pharmaceuticals are California hazardous waste and which are not exists (Beckman, 2004; Smith, 2004). Examples of pharmaceuticals that would be hazardous waste include: any aqueous formulation containing 24% or more alcohol (ignitable); sanitizing or topical preparations containing solvents like rubbing alcohol (ignitable); nitroglycerin (reactive); lindane (toxic); vaccines, eye and ear drops with mercury or m-cresol preservatives (toxic or exceed threshold limit value).²

Hazardous waste laws only apply when a pharmaceutical is determined to be a waste. Both Federal and California law only regulate pharmaceuticals that have been determined to be “waste.” Pharmaceuticals that can be reprocessed, reused, or otherwise have financial value—or an unsorted group of unwanted pharmaceuticals, some of which may have future use—are not covered by hazardous waste regulations because they are materials awaiting classification, rather than waste. This exemption is the basis for the reverse distribution industry. U.S. EPA has authorized reverse distribution of pharmaceuticals without hazardous waste management permits. The U.S. EPA authorization specifically requires the returns industry not to be used as a

¹ Currently incineration is the only approved management method.

² Most HHW programs manage residential pharmaceuticals as California hazardous waste. Even if data were available to allow differentiation of California hazardous pharmaceuticals from non-hazardous pharmaceuticals, for HHW programs the cost of sorting would probably exceed the savings afforded by the sorting. This management approach prevents environmental impacts from the pharmaceuticals' bioactive properties, which are not fully accounted for California's waste classification requirements.

“waste management system” (U.S. EPA, 1981; U.S. EPA, 1991). Any items that are inherently “waste-like” (like a broken container or contaminated prescription) cannot be shipped as products to a reverse distributor.

Facilities that collect hazardous household pharmaceutical waste must obtain HHWCF permits. Either a household hazardous waste collection facility permit or a DTSC-issued variance from the requirement to obtain a permanent household hazardous waste collection facility permit would be needed to collect pharmaceuticals at a pharmacy or other convenient collection point (Beckman, 2004). DTSC works with the local Certified Unified Program Agency (CUPA) on permitting and inspection for facilities handling hazardous household waste. The CUPA for San Francisco is the Department of Public Health.

3.3 Other Laws

Certain Pharmaceuticals are regulated by the U.S. Drug Enforcement Administration (DEA). These are known as “controlled substances”. They are drugs that have a potential for abuse, such as narcotics or tranquilizers. Examples include codeine, Valium, anabolic steroids, Xanax, Ritalin, and Lomotil.

The DEA lists controlled substances in five schedules. Schedule I drugs have no medicinal use. Schedules II through V drugs may be given to patients by prescription. The DEA does not allow pharmacies or reverse distributors to accept returns of controlled substances³ that have been given to patients.

California Pharmacy Law does not relate to collection of unwanted residential pharmaceuticals. The California Board of Pharmacy (part of the California Department of Consumer Affairs) regulates pharmacists, pharmacies, and prescription drugs and devices to protect consumer health and safety. Neither Pharmacy law nor the Board of Pharmacy’s regulations have sections related to management of unwanted residential pharmaceuticals, as long as such drugs are kept segregated from the pharmacy’s own supplies and sent elsewhere for management.⁴

California Pharmacy Law prevents reuse of any unwanted residential pharmaceuticals. If there is any question as to the safety, identity, strength, quality or purity, the law requires that the pharmaceutical be destroyed. Since residents could store drugs improperly, mix or foul them accidentally, or even intentionally tamper with medications prior to taking them to a drop-off facility, the quality of returned medications would be questionable.

Prescription drug labels must be managed to prevent release of personal medical information. The Health Insurance Portability and Accountability Act (HIPAA) administered by the U.S. Department of Health and Human Services (DHHS) sets national standards to protect the privacy of personal health information. These standards require measures to ensure security of personal medical information, like that on prescription labels. The primary requirements are to secure personal information so that it cannot be viewed by others, and to ensure that labels will be obliterated or destroyed prior to or during prescription drug containers disposal.

³ Except the few listed on “Schedule V”, which include some codeine and lomotil products.

⁴ This conclusion could not be verified because a staff shortage has caused the Board of Pharmacy to restrict contacts with its staff. According to a Board of Pharmacy operator called June 15, 2004, staff can only be contacted directly by staff of other government agencies—and the only person who can be called about regulatory matters is the Assistant Executive Officer, Virginia Herold (916-445-5014 x 4005). Given the staff shortage, the Board of Pharmacy is unlikely to have resources to pursue any interest it has in pharmacist involvement in residential waste pharmaceutical collection.

While HIPAA technically covers only medical care providers (such as pharmacies), it also covers their “business associates.” Under HIPAA, “business associate” could be defined to include entities that collect waste from pharmacies.⁵ If an HHW program or its waste management contractor is defined as a “business associate,” then HIPAA requires the pharmacy to enter into a written agreement with the HHW program or the waste management contractor to protect private patient information. For example, if an HHW program’s waste management contractor picked up unwanted residential pharmaceuticals collected at a pharmacy, the waste management contractor may need to enter into a written agreement with the pharmacy to ensure protection of private patient information.⁶

⁵ LACSD found that even referrals to a HHW program may be covered. The business associate definition is not clear in the law and regulations covering this matter. LACSD is planning to work with the U.S. Department of Health and Human Services to clarify the status of HHW programs.

⁶ DHHS has sample language for the written agreement on its Internet site <http://www.hhs.gov/ocr/hipaa/contractprov.html>. While written agreements are only required for entities that are directly “business associates” of medical care providers, if a waste management firm or an HHW program enters into a written agreement with a pharmacy, it may need to amend its contracts with other entities to ensure that the commitment to protect patient privacy is fulfilled.

Table 1. Summary of the Most Important Laws Affecting Residential Pharmaceutical Waste Management

Law	Agency	Relevance
<i>Medical Waste Laws</i>		
California Medical Waste Management Act	Department of Health Services (DHS) and local enforcement agency	Exempts residential pharmaceutical waste.
<i>Hazardous Waste Laws</i>		
Resource Conservation and Recovery Act (RCRA)	U.S. EPA and California DTSC	Exempts residential pharmaceutical waste.
California Hazardous Waste Control Law	Department of Toxic Substances Control (DTSC) and local Certified Unified Program Agency	Requires management of some—but not all—waste pharmaceuticals as California hazardous waste.
<i>Other Laws</i>		
Controlled Substances Act	U.S. and California Drug Enforcement Administrations (DEAs) and local law enforcement	Generally exempts residential pharmaceutical waste, but creates limitations on management of certain “controlled” substances, to prevent drug abuse.
Health Insurance Portability and Accountability Act (HIPAA)	U.S. Department of Health and Human Services (DHHS)	Requires medical care providers and their “business associates” to implement procedures to protect patient personal information, such as that on prescription drug container labels.
California Pharmacy Law	California Board of Pharmacy	Requires destruction of collected unwanted residential pharmaceuticals. No apparent relevance for pharmacy collection programs as long as collected residential pharmaceuticals are kept segregated from the pharmacy’s own supplies and sent elsewhere for management.

Source: TDC Environmental.

4.0 REVERSE DISTRIBUTION OF PHARMACEUTICALS

Reverse distributors manage unwanted pharmaceuticals from pharmacies, hospitals, and clinics. Some collected pharmaceuticals are returned to manufacturers; others are packaged and sent off-site for disposal (Smith, 2004). This management service is carefully tracked both as a service to the pharmaceutical industry and to meet legal requirements for the collected controlled substances. The reverse distribution process is often viewed as a form of product stewardship, even though it only applies to drugs that are not dispensed to patients (Smith, 2004; Chapman, 2003). Neither reverse distributor services nor manufacturer product stewardship programs extend to unwanted residential pharmaceuticals.

Many pharmaceutical manufacturers offer credits for returned pharmaceuticals. These credits make the reverse distribution system work. Reverse distributors manage the returns process for pharmacies. This is a valued convenience, as sorting products and managing the various return credits is expensive for individual pharmacies. Reverse distributors package products, send them to manufacturers, and provide manufacturer credits to pharmacies. Products that cannot be returned to the manufacturer are sorted out for disposal. While manufacturers may process returned drugs for reuse, common understanding is that most—if not all—drugs returned to manufacturers are sent off-site for disposal (Smith, 2004).

Reverse distributors have relatively limited contact with the pharmaceuticals they handle. Generally, reverse distributors do not open drug containers for worker safety reasons. Reverse distributors do not process any pharmaceuticals for reuse (Smith, 2004).

As the reverse distribution system is currently structured, reverse distributors do not have hazardous or medical waste management or transfer station permits—they are simply treated as hazardous and medical waste generators under the law (Smith, 2004; Chapman, 2003). This is because unwanted pharmaceuticals that are sent to reverse distributors may have financial value—a value that is only determined by the sorting process at the reverse distributor. Pharmaceuticals sent to reverse distributors (and from reverse distributors to manufacturers) are treated as “products in commerce” because of this financial value, and thus are not subject to hazardous waste transportation and permitting requirements. For those pharmaceuticals that do not have financial value, reverse distributors become the waste generator.

Once prescribed and given to patients, pharmaceuticals cannot be reused. State and Federal law require pharmacists and pharmaceutical manufacturers to ensure that pharmaceuticals provided to patients are pure and safe. Once a drug has left the control of a pharmacy, its storage, handling, and condition are uncertain—and therefore it cannot be assured to be pure and safe. Because there is no viable reuse for unwanted residential pharmaceuticals, they are—by definition—waste.

In a nationwide survey of 27 reverse distributors, no companies were found that accept patient returns, unless the pharmaceutical is being returned as suspected defective product (Chapman, 2003). This finding is consistent with reverse distributor permitting—and with letters from U.S. EPA, which state that if reverse distributors handle waste, they will need to obtain appropriate permits (*i.e.*, permits for operating hazardous and medical waste transfer stations) (U.S. EPA, 1981; U.S. EPA, 1991).

5.0 HOUSEHOLD PHARMACEUTICAL WASTE MANAGEMENT: STRATEGIES AND ISSUES

5.1 Household Pharmaceutical Collection at Pharmacies

Nationally, most government efforts targeting household pharmaceutical waste involve collection events. One state (Maine) plans a residential mail-back program, but it is limited to controlled substances. In the U.S., only a few local governments have initiated programs to collect unwanted household pharmaceuticals at pharmacies. These nascent programs are described below.

Clark County (Washington). In late 2003, Clark County, Washington (population 380,000) established a program to safely dispose of unwanted or outdated medications (Clark County, 2003; Mansfield, 2004). The county-funded program is called the Unwanted Medications Return program. More than 80% of the County's pharmacies are participating in the program.⁷ Residents can drop off unwanted pharmaceuticals at participating pharmacies at no charge, if the medication is:

- Not a controlled substance;
- In the original container with the name of the medicine clearly marked;
- In a sealed container that does not leak; and
- In a container that has all patient information either removed or marked out.

Pharmacies put the collected pharmaceuticals into a shipping container, usually a container used to ship pharmaceuticals to the pharmacy. When the container is full, pharmacies notify the County and ship the materials to the County's hazardous waste vendor. The County pays for the shipments by allowing pharmacies to charge the shipment to the County FedEx account number.

Clark County tells residents to check with a doctor or pharmacist to determine if their drug is a controlled substance; if so, residents are told to take it to the County Sheriff's Department. The County Sheriff's Department accepts controlled substance returns at its reception counters. Each controlled substance is sealed in a heat-seal bag and stored in a container secured behind the reception desk until shipment off-site for disposal with drugs collected by the Sheriff as evidence in criminal cases.

Pharmacists can refuse any patient return, as long as they tell the patient why the return was refused. For example, pharmacists refuse leaking containers and controlled substances. When a product is refused, the pharmacist directs the resident to the County household hazardous waste program or to the Sheriff.

Alachua County (Florida). This spring, the Alachua County, Florida (population 220,000) Environmental Protection Department collected unwanted residential pharmaceuticals at 12 locations (pharmacies, clinics, and county facilities) (Alachua County, 2003). The temporary grant-funded collection program included prescription drugs, chemotherapy agents, and over-the-counter medications. Only products in pill, capsule, or liquid form were collected. No salves or ointments were accepted. At collection locations, residents were asked to empty their medications into a container and then take home the empty containers. The collection container held a dilute acid to render the drugs unusable.

Marin County. A residential pharmaceutical collection program is in development in Marin County, California (population 250,000) (Turner, 2004). Marin County

⁷ Clark County has 60 - 70 pharmacies.

Environmental Health is teaming with local household hazardous waste programs and water quality agencies to obtain funding for a small program. They envision the program to involve partnering with a few pharmacies to collect unwanted pharmaceuticals and perhaps conducting collection events at public facilities like fire stations.

Internationally, many examples of effective pharmaceutical management programs exist. For example:

- British Columbia (Canada). The law requires that pharmaceutical manufacturers take cradle-to-cradle responsibility for the safe management of their products. This responsibility is implemented through a medications return program, whereby consumers drop off unwanted pharmaceuticals at pharmacies.
- Prince Edward Island (Canada). The province has a voluntary program where residents drop unwanted medicines at pharmacies. Pharmacies transport the drugs to the solid waste management company, which pays for proper disposal.
- Australia. The Return Unwanted Medicines Project allows residents to drop off unwanted pharmaceuticals at pharmacies. The project, which is funded primarily by the government, receives support in the form of discounts and in-kind services from pharmacies and pharmaceutical wholesalers.
- European Union. Eleven European Union member nations have pharmaceutical take-back systems, all of which allow residents to drop unwanted pharmaceuticals at pharmacies. More than half of the European nation systems are operated by the pharmaceutical industry or by pharmacies; the rest are paid for municipalities (EFPIA, 2002).

These programs are made possible, in part, by the governments' structure for managing health care, which gives the government a great deal of leverage over companies in the pharmaceutical distribution system. The U.S. healthcare system is very different than the systems in these nations—our system provides government with few controls over pharmaceutical sales, limiting government's ability to pressure the private businesses in the pharmaceutical manufacturing and distribution system to act as product stewards.

5.2 Regional Pharmaceutical Waste Management Activities

San Francisco Bay Area (Water) Pollution Prevention Group (BAPPG). The BAPPG established a pharmaceuticals working group that includes wastewater agencies, household hazardous waste programs, and several state agencies (North, 2004). The goals of the BAPPG effort are:

- To develop a consistent, clear regional message regarding management of unwanted residential pharmaceuticals; and
- To develop and promote implementation of a long-term strategy for management of residential pharmaceuticals.

The BAPPG working group has agreed on a common regional message on residential pharmaceutical waste management (to direct residents not to use the sewer for disposal, but rather to contact their local household hazardous waste program). The next step will be to ask other entities in the Bay Area who provide information to the public about residential pharmaceutical waste management to join in providing this common message. The group is still considering possible long-term activities.

Los Angeles County Sanitation Districts (LACSD). In response to pressure from the public and the California Department of Health Services (which regulates wastewater

reuse), LACSD seeks to reduce pharmaceutical levels in its wastewater in order to improve the quality of the Districts' recycled water (Heil, 2004). LACSD has previously worked with some of the 1,000 pharmacies in its service area on efforts to reduce use of lindane-containing scabies and lice control products. This summer, LACSD plans to initiate a program to have pharmacies give out cards with waste disposal information when they give patients prescriptions. The cards are planned to have information discouraging sewer disposal and encouraging use of household hazardous waste programs. LACSD is currently working to address regulatory issues raised by pharmacists, including HIPAA "business associate" requirements⁸ and appropriate controlled substances handling procedures.

This spring, LACSD and other wastewater agencies in the Los Angeles area (City of Los Angeles and Orange County Sanitation District) met with area hospitals to discuss a proposal to prohibit discharges of pharmaceuticals (except nutrients, vitamins, etc.). The hospitals expressed great concern about the proposal. The main issue for hospitals is discharge of pharmaceutical-containing solutions such as IV bags and irrigation solutions used in operating rooms and trauma care. The wastewater agencies plan to continue work on the proposal this fall.

Washington State. In the Seattle area, government agencies have a regional pharmaceutical working group (the Pharmaceutical Workgroup of the Interagency Regulatory Analysis Committee) to examine regulations affecting the management of drug wastes (Chapman, 2004). To support the workgroup, the Local Hazardous Waste Management Program in King County conducted two surveys: a survey of reverse distributors (Chapman, 2003) and a survey of pharmaceutical waste management by businesses (Chapman, 2002). The waste management survey identifies the types of businesses that generate pharmaceutical waste, the volumes of that waste, and the fate of the waste (much of which is improperly disposed of in the sewer or improperly mixed with biohazardous medical waste⁹).

The Washington Department of Ecology is coordinating a recently formed informal agency working group to address residential pharmaceutical waste management. The group includes state and local government representatives from Washington, Idaho, and Oregon. The group plans to explore options for effective collection of pharmaceuticals, including the option of returning unwanted residential pharmaceuticals to pharmacies (Chapman, 2004).

5.3 Household Pharmaceutical Waste Management Issues

On the basis of the review of other programs and interviews with government and industry staff, a number of important issues were identified. These issues will need to be considered in the development of improved household pharmaceutical waste management programs.

- Convenience. Collection programs need to be easy to use if they are to compete with the toilet or the trash. All identified programs provide free disposal for residents.
- Safety. Unprescribed contact with some pharmaceuticals can pose safety hazards to pharmacy workers or residents (Smith, 2004). Some drugs are skin contact hazards; some have dusts that are inhalation hazards. Reactions among certain

⁸ LACSD plans to clarify whether a referral to an HHW program makes the HHW program a business associate of a pharmacy.

⁹ While legal requirements for disposal of pharmaceuticals differ in each state, like California, most states prohibit disposal of pharmaceuticals with infectious waste that is not otherwise hazardous. (Infectious waste is often treated in an autoclave to kill infectious organisms and then managed as ordinary solid waste).

substances are possible. Liquids may be hard to control. Spills could be difficult to clean up. While some programs address privacy and controlled substance requirements with procedures that involve opening drug containers, the safest approach is to keep containers closed.

- Privacy. Maintaining anonymity for residents may be important. For pharmacies, HIPAA compliance is essential. Procedurally, programs address privacy one of three ways: use of a secure “one way” container to hold waste; asking patients to remove or obliterate labels prior to putting them into the container (this may also remove the identification of the drug in the container), or asking patients or pharmacists to empty the medication into the waste container and send the patient home with the prescription container. Sorting and repacking of waste containers with personal information on them may require procedural controls to ensure privacy. If HIPAA “business associate” requirements are found to apply to entities handling collected residential pharmaceuticals, it may be necessary to have the waste handling contractors and/or San Francisco sign privacy agreements with pharmacies.¹⁰
- Disposal methods. At present, all waste pharmaceuticals that are collected through proper disposal channels are incinerated. There is no legal alternative. Sewer disposal may theoretically be legal for certain pharmaceuticals (those not classified as hazardous waste) (DHS, 2002), but both DHS and wastewater treatment plants recommend against sewer discharge of pharmaceuticals (McGurk, 2003; Tri-Tac, 2003). The industry professionals interviewed all believe that a destructive treatment like incineration is necessary for environmental safety. Although the volume of waste pharmaceuticals is small relative to the volumes of other wastes currently incinerated at hazardous and medical waste incinerators, pharmaceutical incineration contributes to unwanted air pollution emissions from incinerators. Other types of destructive treatment are theoretically possible; however, no alternative destructive treatment method is currently available commercially.
- Drug abuse. There is a real risk that collected prescription drugs could be taken for illegal re-issuance to customers or for recreational use. This risk is usually addressed with security measures or by rendering drugs unusable at the time of collection.
- Funding. There is no established funding source for residential pharmaceutical waste management.
- Pharmaceutical-like items. Residents may treat vitamins and homeopathic remedies like waste pharmaceuticals. Some of these substances may be regulated as hazardous waste due to the presence of metals or solvents. While collecting these may increase waste volumes, as long as they are managed along with residential pharmaceuticals, they should not pose regulatory or environmental problems.
- Identification of controlled substances. Controlled substances are not readily identifiable by consumers. Product labels do not indicate their regulatory status. To determine if a substance is controlled, the product ingredients need to be compared to the DEA schedules of controlled substances.
- Waste generator. Depending on what entity is the legal “generator” of the residential pharmaceutical waste, different rules apply for the waste management. If a pharmacy manages the waste, the waste would be regulated under the California

¹⁰ Such agreements are relatively simple. The U.S. Department of Health and Human Services Office of Civil Rights has an example on the Internet (www.hhs.gov/ocr/hipaa/contractprov.html).

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Medical Waste Management Act and could be regulated under RCRA. This would require collected pharmaceuticals to be sorted for proper disposal. Pharmacies normally do not handle these activities, which are managed for them by reverse distributors, who are typically the legal generator of pharmacies' wastes. If the waste is managed in conjunction with a municipal household hazardous waste program, then the legal generator is the government agency, avoiding new regulatory requirements for pharmacies.

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Improper management of unwanted residential pharmaceuticals poses hazards to both human health and the environment. Of the many possible strategies for managing residential pharmaceutical waste, the two most common are collection at pharmacies (international) and collection by household hazardous waste programs (U.S.).

Collecting unwanted residential pharmaceuticals at pharmacies is a practical concept for San Francisco. While collection at pharmacies will require certain regulatory and management issues to be addressed, its convenience for residents means it would probably be an effective waste pharmaceutical collection method. The regulatory issues that need to be addressed to establish a collection program at pharmacies include: California hazardous waste permitting, HIPAA, and DEA controlled substance requirements. Other issues that will need to be addressed in program design are safety in handling and storing unwanted pharmaceuticals, convenience, and security.

Because unwanted residential pharmaceuticals must be disposed of—and cannot be reused—the current “reverse distribution” system for pharmaceuticals is not equipped to manage them.

6.2 Recommended Next Steps

To establish a collection program at local pharmacies, the following steps are recommended:

1. Establish a pilot program. The purposes of the pilot program would be:
 - to work out the regulatory and management issues prior to widespread initiation of the collection program;
 - to obtain sufficient information to support legislative action that would simplify permitting requirements for a permanent program;
 - to determine the cost of the program to support actions to establish a stable, permanent funding mechanism for the program; and
 - to start collecting unwanted pharmaceuticals from San Francisco residents.

Starting the pilot program will involve the following steps:

- a) Identify which pharmacies will participate.
- b) Determine how pharmaceutical pickup and disposal will be handled. Under current law, residential waste pharmaceuticals need to be transported by a licensed hazardous waste hauler. Simply extending the City’s service contract for pickup of universal waste at satellite collection sites to cover the pharmacy program should be feasible and should meet both the City’s and participating pharmacies’ needs. Extending the City’s sharps collection service contract to cover the pharmacy program may also be possible if the contractor is a California-registered hazardous waste transporter.
- c) Work with pharmacies and regulatory agencies to develop the details of the collection program. The primary issue to be addressed will be the container for receiving and holding pharmaceuticals. This container will need to provide visual privacy, security, and secondary containment for the contents. It will also need to be designed to be convenient for the pharmacy to handle and secure. The issue

of controlled substances should be considered. Involving DTSC in this step is recommended, as it will likely smooth approval of the variance.

- d) Determine whether San Francisco's waste management contractor(s) are considered pharmacy "business associates" under HIPAA. It may be necessary for the household hazardous waste contractor or San Francisco to sign HIPAA business associate agreements with pharmacies that have concerns about HIPAA compliance.
- e) Obtain a variance from DTSC. The variance should allow residential pharmaceutical waste to be collected by pharmacies without the issuance of a permanent household hazardous waste collection facility permit for each pharmacy. The best approach for designing the variance application and the variance itself should be worked out with DTSC prior to filing the variance application. The logistics of the program should be fairly well developed prior to filing the formal paperwork requesting the variance.
- f) Develop the outreach campaign. Coordination with pharmacies is recommended to ensure that all participants are comfortable with the program. Working with partners like AARP is also recommended to maximize the effectiveness of the project.

After about six months, a program evaluation is recommended. This evaluation will provide the documentation needed to support legislative and funding activities, while offering the opportunity to identify needed program improvements prior to full program implementation.

2. Pursue legislation. Without a change in California law, DTSC has indicated that setting up a permanent program would require San Francisco to obtain a permanent household hazardous waste collection facility permit for each pharmacy that accepted unwanted residential pharmaceuticals. Several approaches to address this issue are possible.
 - Eliminate permit requirement for collection locations. California Health & Safety Code section 25218.8 could be amended to allow collection of pharmaceuticals at locations without hazardous waste collection facilities permits. This simple approach would probably be the most readily accepted legal change, as it would be unlikely to attract opposition.
 - Reclassify residential pharmaceutical waste. Residential waste pharmaceuticals could be legally re-classified as universal waste or as non-hazardous waste. While moving residential pharmaceuticals out of the hazardous waste regulatory structure would eliminate much of the cost and regulatory burden associated with their management, their reclassification—even into the simplified management category of universal waste—could engender opposition due to the inherent hazardous nature of many pharmaceuticals. One change that could provide cost savings¹¹ and might not provoke opposition would be to allow HHW programs to ship collected residential waste pharmaceuticals for management by the contractors that manage commercially generated non-RCRA waste

¹¹ All pharmaceuticals are currently disposed of by incineration. Medical incinerator destruction of pharmaceuticals by medical waste management firms is less expensive than hazardous waste incinerator destruction of household pharmaceuticals. Medical waste pharmaceuticals do not have to be lab-packed, so more can be disposed of in the same size container (and less volume of material is burned to destroy the same quantity of pharmaceutical waste). Shipping may also be less costly.

pharmaceuticals (which are managed as regulated medical waste pharmaceuticals under the California Medical Waste Management Act).

- Adopt product stewardship requirements. Cradle-to-cradle management of potentially hazardous products like pharmaceuticals has been suggested by many (*i.e.*, Daughton, 2003a; Daughton, 200b). There are many possible approaches to implementing a product stewardship management strategy for residential pharmaceuticals. For example, it might be possible to modify the reverse distribution system to accommodate management of residential pharmaceutical wastes. Alternatively, it might be possible to require pharmaceutical manufacturers or pharmacies to accept unwanted residential pharmaceuticals, similar to the requirement that automobile battery retailers accept unwanted batteries (*California Health & Safety Code* Section 25215). Since product stewardship approaches are relatively new in the U.S., it is likely that substantial effort would be required to develop a plan that would be generally acceptable to most affected parties (*i.e.*, pharmaceutical manufacturers and the healthcare industry). Without general acceptance by affected parties, a product stewardship plan would be unlikely to garner sufficient votes to pass the California Legislature.
- Waste management fees. California assesses fees on products like motor oil and electronics to fund the infrastructure to manage these products properly at the end of their life cycle. Local fees can be structured such that certain businesses fund the management of certain costly waste streams. While waste management fee proposals have generally been more successful than product stewardship proposals in the California Legislature, it is likely that substantial effort would be required to develop a fee structure that would be generally acceptable to enough affected parties to ensure passage in the legislature. Fees on pharmaceuticals would be particularly politically sensitive given the sharp increases in the cost of healthcare in recent years.

6.3 Other Recommendations

On the basis of this investigation, the following additional steps should be considered:

- Coordinate with and support other organizations seeking to improve management of residential waste pharmaceuticals. The Bay Area Pollution Prevention Group, Washington Department of Ecology, and Los Angeles County Sanitation Districts have active programs with interests common to those of San Francisco. San Francisco can increase its effectiveness by sharing information with others and teaming up to promote common interests.
- Consider supporting efforts to modify Federal legal requirements to simplify residential pharmaceutical waste management and to minimize surface water discharges of pharmaceuticals. For example, the DEA may consider allowing pharmacists to render controlled substances unusable simply by mixing them with rubbing alcohol. This would make them unusable, thereby eliminating the legal problems with collecting pharmaceuticals subject to drug abuse.
- Consider other drop-off locations for collecting pharmaceuticals, particularly senior centers. Since seniors generate a relatively large fraction of

- pharmaceutical waste (Daughton, 2003b), exploring opportunities to partner with Senior Centers and senior organizations like AARP¹² is recommended.
- Partner with others to promote proper pharmaceutical management. Possible partners include the American Medical Association, pharmacies, AARP, cancer care physicians, and Healthcare Without Harm. These partners can communicate a common message about proper pharmaceutical disposal and encourage participation in San Francisco-sponsored residential pharmaceutical waste management programs.
 - Consider possible actions to prevent improper pharmaceutical management by other entities that probably dispose of some pharmaceuticals improperly. Entities that may be directing staff to discharge unwanted pharmaceuticals to sewers include hospitals and medical care facilities, home medical care providers (e.g., hospice), and medical and veterinary offices (Chapman, 2002; North, 2004).

¹²The nation's largest membership organization for seniors, formerly known as the American Association of Retired Persons.

7.0 RESOURCES

Regulatory agency contacts:

- DTSC—William (Bill) Beckman, Hazardous Waste Management Program (DTSC staff member responsible for issuing variances of the type that would be appropriate in this case), (916) 324-8293.
- Local Hazardous Materials Unified Program Agency and Medical Waste Management Act Local Enforcement Agency—San Francisco Department of Public Health, Medical waste—Ed Halbach, (415) 252-3909.
- DHS—Steve Kubo, Medical Waste Management Program, (916) 449-5684

Other regional programs:

- Bay Area Pollution Prevention Group—Karin North, Palo Alto, (650) 494-7629
- Los Angeles County—Ann Heil, Los Angeles County Sanitation Districts, (562) 699-7411x2950
- Local Hazardous Waste Management Program, King County (Washington)—Alice Chapman, (206) 263-3058
- Washington Department of Ecology—Emma Johnson, (425) 649-7266

Municipalities that have organized programs to collect unwanted residential pharmaceuticals at commercial pharmacies:

- Marin County—Robert Turner, Environmental Health, (415) 499-7146
- Clark County (Washington)—Jim Mansfield, Solid Waste Program, Public Works Department, (360) 397-6118 x4016
- Alachua County (Florida)—Kurt Seaburg, Hazardous Waste Coordinator, (352) 334-0440

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