Discussion Paper on Pharmaceutical Disposal to Sewer Systems

White Paper prepared by the
Emerging Contaminants Workgroup[1,2]
of the Santa Clara Basin Watershed Management Initiative

February 2005

Emerging Contaminants Workgroup
The Emerging Contaminants Workgroup was chartered at the request of the Santa Clara Basin Watershed Management Initiative (WMI) in 2001 to provide a forum to discuss issues related to endocrine disrupting compounds and recycled water. The workgroup has since broadened its scope to include all emerging contaminants of concern, not just those having endocrine disrupting effects. The workgroup is open to all interested parties and the participants include scientists, engineers, staff and managers from government and non-government organizations.

The current purpose of the group is to collect and review information based on the best available science on emerging contaminants of concern in and around the San Francisco Bay. The Workgroup has been successful in developing communication pieces for different audiences, including white papers for local government and non-governmental organizations' staff, and fact sheets for the general public.

Audience and Purpose of White Papers
The white papers are produced for regional and local government, as well as participating non-government organization staff, and are designed to provide a starting point for discussion regarding emerging contaminants found in and around the San Francisco Bay. The papers provide an overview of research, current programs when applicable, and potential pollution prevention solutions that will allow the interested parties to consider possible action items or next steps.

EXECUTIVE SUMMARY

This white paper has been prepared to initiate a regional dialogue regarding pharmaceutical disposal to the sewer system. It provides an overview of research on pharmaceuticals in the environment and potential actions for consideration during that regional dialogue. These potential actions specifically address the issue of surplus pharmaceutical disposal to the sanitary sewer and ways to avoid their entry into the sewer system. Municipal agencies and non-governmental organizations are encouraged to review this document and consider participating in regional activities to reduce improper disposal of these pollutants, to the extent practical, given individual financial and regulatory constraints. It is recognized that the potential actions are interim ones as suitable long-term solutions are sought.

Pharmaceutical residuals from humans and animals, personal care products, and their metabolites are continually introduced to the aquatic environment as complex mixtures via a number of routes: discharge of treated domestic wastewater, treated industrial wastewater, commercial animal feeding operations, and surface application of manure.[3] Potential public health and environmental effects from these compounds are being studied worldwide. There is increasing concern that the pharmaceuticals detected in surface waters could cause adverse environmental effects, including endocrine disruption in aquatic life and/ or increased antibiotic resistance.

The two largest sources of pharmaceuticals entering the sewer systems are believed to be from hospitals and residents. Pharmaceuticals enter the sanitary sewer primarily through: (1) excretion of partially

[1] For more information, contact the Workgroup Chair, Karin North, Karin.north@cityofpaloalto.org
[2] This document was peer-reviewed by Bobbye Smith, U.S. EPA Regional Science Liaison; Dr. Christian Daughton, Chief, Environmental Chemistry Branch, National Exposure Research Laboratory, U.S. EPA; and Charlotte Smith, PharmEcology.
[3] Daughton, C.G. and Ternes, T.A. (1999) Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change. *Environmental Health Perspectives*, Vol 107, Supplement 6: 907-938 [available: http://epa.gov/nerlesd1/chemistry/ppcp/images/errata.pdf

metabolized pharmaceuticals by the human body and (2) the disposal of unused or expired medications down the drain or toilet.

In general, the regional dialogue must consider a two-pronged pollution prevention message for the disposal of unwanted medications:

- Unwanted medications should not be disposed down household drains or toilets
- Dispose of unwanted or expired medication with hazardous wastes

While this paper presents potential public messages and outreach mechanisms, it is recognized that significant financial constraints at the household hazardous waste (HHW) facilities throughout the Bay Area may make it difficult for public agencies to fully advocate the use of the HHW programs. As will be described in this paper, efforts have been initiated to address this issue.

Table 1 presents possible regional or local programs that could be implemented, including anticipated challenges, next steps, and identified lead agencies. While the Bay Area Pollution Prevention Group (BAPPG) has already begun reviewing regional opportunities, individual agencies are encouraged to review the strategies presented and consider piloting programs that they believe to be appropriate for their jurisdictions. Agencies are encouraged to communicate with other agencies about project successes and failures, in order to optimize subsequent actions.

Table 1: Summary of potential actions to control disposal of pharmaceutical wastes

Potential Actions	Anticipated Challenges	Next Steps	Lead Agency
Hospital Pharmaceutical Disposal			
Regional hospital training	Obtaining participation from hospital EH&S staff	Bay Area Pollution Prevention Group (BAPPG) is planning to fund a regional training event	BAPPG (task chaired by City of Palo Alto)
Regional training of POTW staff	Budget and staff constraints of individual agencies	Create powerpoint and factsheet for agency staff; Conduct trainings at BAPPG meetings and CWEA conferences	BAPPG (task chaired by City of Palo Alto)
Training of local hospital staff by industrial waste inspectors	Agency budget and staff constraints; lack of current mandate	Provide training to hospitals	Individual wastewater agencies, as feasible
Residential Unused or Expired Pharmaceuticals			
Discourage disposal in toilets or sinks	Funding; prioritization amongst other clean water messages	NGOs encouraged to educate residents on this topic	NGOs, regional media campaigns
Encourage disposal at Household Hazardous Waste events	Funding for Household Hazardous Waste programs prior to region-wide campaign	BAPPG is investigating on a regional scale. Local HHW and POTWs are encouraged to communicate about local funding constraints	BAPPG and local municipal agencies
Take-back programs at pharmacies	Buy-in from pharmacists, HMO pharmacies, and drug store chains/ businesses, funding	BAPPG is investigating. Local pilot programs encouraged.	BAPPG
Take-back events at local senior centers	Coordinate with HHW programs or haulers	Educate seniors and provide take-back options	Local pilot programs encouraged
Take-back events or programs with Fire or Police Department	Buy-in from fire or police department Funding	Local agencies may wish to collaborate with Fire/ Police to pilot a take-back event.	Local pilot programs encouraged.
Legislation to require a take-back program and provide funding for (or execution of) program	Time and funds to research different approaches; Conduct a cost-benefit assessment	BAPPG is investigating.	BAPPG

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Acknowledgments

Listed below are the authors of the white paper:

- Jessie Denver, City of San Jose
- Mary Ellen Dick, City of San Jose
- Lorrie Gervin, City of Sunnyvale
- Stephanie Hughes, City of Palo Alto
- Kristy McCumby Hyland, City of Sunnyvale
- Karin Didriksen North, City of Palo Alto
- Luisa Valiela, Environmental Protection Agency
- Andria Ventura, Clean Water Action

1. Pharmaceuticals in the Environment

During the past decade there have been growing questions about potential adverse effects from the environmental release of pharmaceutically active compounds. Small concentrations of hormones, antidepressants, antibiotics, and chemicals from personal care products have been found in various waterways nationwide, including the San Francisco Bay, according to reports from the U.S. Geological Survey (USGS)[4] and the San Francisco Estuary Institute[5].

Pharmaceuticals do not typically persist in the environment; continual input into the aquatic environment keeps the concentrations relatively constant.[6] While they may not cause acute toxicity in aquatic organisms, they may interfere with endocrine systems, particularly when exposure occurs during developmentally sensitive times such as before birth. There are several well-documented cases of endocrine disrupting effects on fish and wildlife.[7]

Pharmaceuticals enter surface waterways from various sources:

- Plants that treat household, industrial, and businesses waste water (wastewater treatment plants)
- Industrial dischargers
- Commercial animal feeding operations
- Surface application of manure and biosolids[8]

Because of the large number of pharmaceuticals and the high cost of testing, relatively little data is available on the presence of pharmaceutical products in natural water bodies. The most recent extensive study of pharmaceuticals in surface waters was performed by the USGS in 1999 and 2000.[9] This nationwide reconnaissance study surveyed 139 streams throughout the United States in locations that were thought to be susceptible to contamination from agriculture or urban activities. The USGS analyzed water samples from waterways for 95 organic chemicals usually found in wastewater from the sources listed above. In 80% of the samples analyzed, one or more of the pharmaceuticals were detected, albeit at very low concentrations. Examples of medications found included:

- Acetaminophen was found in 24% of samples analyzed
- Steroids and hormones were also commonly found, with 17-ethynyl estradiol (a hormone used in birth control pills) found in 16% of samples analyzed
- Diltiazem (blood pressure medication) was found in over 13% of samples analyzed.
- Codeine was found in 11% of samples analyzed
- Antibiotics and antimicrobials such as erythromycin, lincomycin, sulfamethoxazole, and trimethoprim were found in over 10% of samples analyzed

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[4] Kolpin, Dana et al. (2002) Pharmaceuticals, hormones and other organic wastewater contaminants in U.S. Streams, 1999-2000: A National Reconnaissance, *Environmental Science and Technology* v. 36: 1202-1211.

[5] Oros, Daniel and David, Nicole (2002). Identification and Evaluation of Unidentified Organic Contaminants in the San Francisco Estuary, *San Francisco Estuary Regional Monitoring Program for Trace Substances*, SFEI Contribution 45

[6] Daughton, C.G. and Ternes, T.A. (1999) Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change. *Environmental Health Perspectives*, Vol 107, Supplement 6: 907-938 [available: http://epa.gov/nerlesd1/chemistry/ppcp/images/errata.pdf

[7] http://www.ourstolenfuture.org

[8] Origins and Fate of PPCPs in the Environment, by the US Environmental Protection Agency, Office of Research and Development, http://www.epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf.

[9] Reference info…. http://pubs.acs.org/hotartcl/est/es011055j_rev.html

- Ibuprofen was found in 10% of samples analyzed

2. Sources and Fate of Pharmaceuticals at Wastewater Treatment Plants

Wastewater treatment plants are designed to remove conventional pollutants such as suspended solids and biodegradable organic material, but they are not designed to remove low concentrations of synthetic pollutants such as pharmaceuticals. Limited testing suggests that certain types of treatment substantially remove some pharmaceuticals. Removal efficiencies of pharmaceuticals appear to be chemical-specific, especially since many synthetic compounds are designed to be resistant to biological degradation. There appears to be no single wastewater treatment technology that will remove all of these compounds.

Pharmaceuticals enter the sanitary sewer from two sources: (1) excretion of partially metabolized pharmaceuticals by the human body and (2) disposal of unused or expired medications down the sewer. The two largest sources of pharmaceuticals entering the sewer systems are from hospitals and residents. Therefore, one way to reduce the level of pharmaceuticals in surface water is to educate hospitals and residents that unused or expired pharmaceuticals should not be disposed of down the sewer.

3. Current Disposal Practices and Pollution Prevention Messages

A. Medical Facilities

Medical facilities are the largest bulk users of medications. These facilities include hospitals, skilled nursing facilities, and veterinary hospitals. Many hospitals currently dispose of excess material in syringes and IV bags into drains, where they pass into sewer systems.

In September 2003, Tri-TAC[10] created a memo regarding the practice of disposing pharmaceuticals into the sanitary sewer at hospitals[11]. A summary of their guidelines is presented in Table 2.

In addition to the disposal guidance, Tri-TAC highly recommends that medical facilities adopt a best management practice of disposing excess syringe material into a pharmaceutical waste container prior to administration of injections. For instance, following communication with the City of Palo Alto's Environmental Compliance Division, Stanford Hospital successfully added a pharmaceutical waste container to their nursing carts, so that excess medication (solid and liquid) is discarded into the waste container rather than down the drain.

[10] Tri-TAC is a statewide technical advisory group which includes representatives from California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities

[11] Tri-TAC Memo to POTW Pretreatment Coordinators and Managers, September 23, 2003, A copy may be found on-line at http://www.ciwmb.ca.gov/WPIE/HealthCare/TriTACMemAtt.pdf

Table 2. Tri-TAC's Guidelines for Pharmaceutical Disposal at Hospitals and Clinics

Wastes that are generally acceptable for sewering:
• IV bags containing *only* saline solution, lactate, nutrients such as glucose (e.g., D5W), added salts such as potassium, vitamins, and/or other electrolytes.
Wastes not acceptable for sewering:
• Any hazardous wastes, both California-only hazardous wastes and federal hazardous wastes regulated under RCRA (see Appendix for Medical Waste regulation summary).
Wastes not recommended for sewering:[12]:
• Solutions in IV bags containing biologically active materials such as antibiotics, painkillers, and chemotherapy agents. • Liquid pharmaceutical wastes, including controlled substances • Solid pharmaceutical waste, including controlled substances

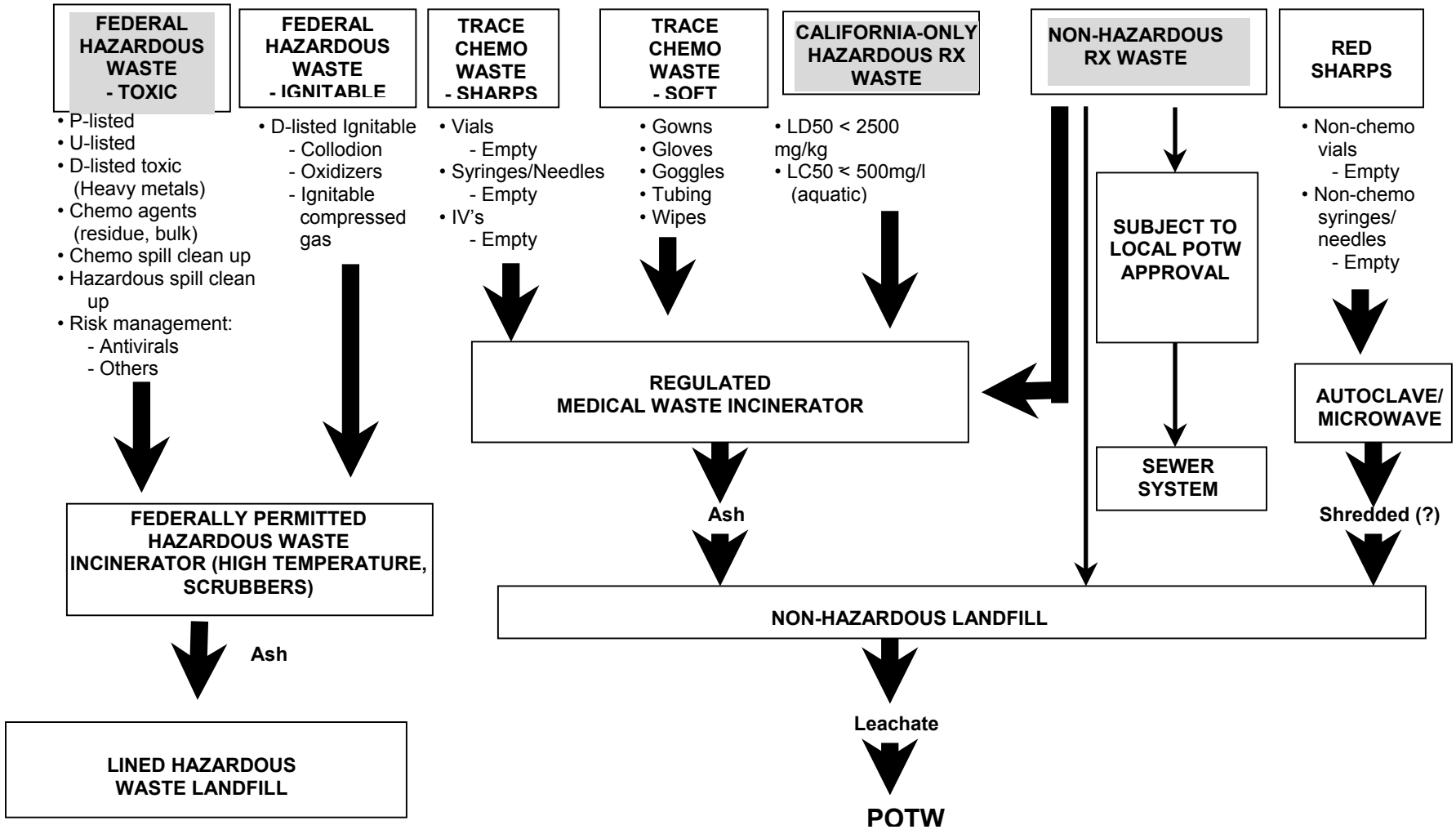
There are educational tools for medical facilities regarding proper pharmaceutical waste disposal. One such tool, developed by PharmEcology[13], is presented in Table 3. This table provides a complete model for proper disposal of medical wastes in California. The prescription drug wastes are primarily in the first, fifth, and sixth columns, indicated by the gray shading of the boxes. Notice that the sixth column indicates "non-hazardous prescription waste" and recommends that a hospital contact the local POTW for disposal approval. Under this model, only if and when approved, may it may go into the sewer. If the POTW disapproves of sewering the waste, the medical facility is directed to include it with regulated medical wastes for incineration.

Some agencies, such as Orange County, East Bay MUD, and the City of Los Angeles, have begun actively working towards improved policies and practices at their local hospitals. King County, Washington has a zero discharge policy for pharmaceutical waste written into their hospital permits.

[12] Tri-TAC notes these are of particular importance for POTWs engaged in water recycling or discharge to surface waters

[13] http://www.pharmecology.com; PharmEcology, founded by a registered pharmacist, is available to conduct regional or statewide seminars.

Table 3. Recommended Disposal Routes for California Pharmaceutical Waste Streams[14]



[14] Copyright © 2003 by PharmEcology™ Associates, LLC used with permission. At present incineration of pharmaceutical waste is currently the only legal disposal mechanism in California.

Unfortunately, California hospitals have received conflicting messages about pharmaceutical disposal. This makes outreach to this audience particularly important to address. In fact, the Tri-TAC memo described above was actually a response to a document issued by the California Department of Health Services (DHS).

In October 2002, DHS issued a memo to hospitals regarding disposal of pharmaceutical wastes.[15] DHS specifically indicated that if a pharmaceutical does not meet the criteria to be either a California or RCRA hazardous waste, it may be "sewered" (disposal to sanitary sewer) or put in with regular trash. The memo included another memo created by Kaiser discussing fish toxicity information and presenting that as the sole rationale for whether or not to dispose pharmaceuticals in the sewer system.

Following the Tri-TAC memo, DHS issued a revised memo to hospitals referring readers to their local sewage treatment plant for guidance before any sewer disposal.[16] However, anecdotal evidence suggests that hospitals continue to use the initial DHS memo (and the Kaiser attachment) as their primary guidance. Outreach to the medical community is needed to improve awareness of the Tri-TAC and revised DHS message.

B. Residents

Traditionally, doctors and health care specialists recommended flushing unwanted medications down the drain to reduce accidental poisonings and abuse by those for whom the medications were not intended. This is still a common method for disposal of pharmaceuticals by residents, in the absence of convenient alternatives.

According to DHS, once a resident is prescribed a medication, that medication is no longer regulated under the Medical Waste Management Act and/or the Federal Drug Enforcement Administration (DEA). Subsequently, most pharmaceutical wastes generated by households are not classified as medical wastes and may be handled by household hazardous waste collection programs. Furthermore, because the Department of Toxic Substances Control does not regulate residential pharmaceuticals[17] (even pharmaceuticals that are classified as hazardous), agencies could choose to conduct collection events at community sites without the burden of hazardous waste collection permits.

Unfortunately, household hazardous waste programs face funding difficulties. A dialogue was initiated in mid-2004 amongst staff of wastewater treatment agencies and household hazardous waste facilities. The group concluded that if wastewater treatment plants advertise HHW programs as disposal options for waste medications, then adequate funding must be found for the HHW programs to perform this task. Based on those initial discussions, an HHW representative spoke at the December 2004 meeting of the Bay Area Clean Water Agencies. This is an on-going challenge that warrants additional regional discussion.

In addition to the normal residential use of pharmaceuticals, there is a significant quantity of medications used for end of life care (hospice care). Residents under hospice care typically have many medications, which include controlled substances that are regulated by the DEA. Local hospice staff typically ensures that all medications are properly disposed of by flushing them

[15] http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/PDFs/MangtPharmsMW_101502.pdf
[16] http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/PDFs/pharms_out_sewers_%20v3_090503.pdf
[17] http://www.cwea.org/p3s/documents/DTSCLtr200411.pdf

down the drain[18]. Staff members often conduct the disposal themselves, and log the disposal in their record books.

It is important to work closely with the DEA to develop appropriate take-back and disposal programs for highly regulated controlled substances, especially if outreach is expanded to include hospice activities. The laws for residential pharmaceutical disposal are not clear and concise; therefore, further investigation is required to ensure that take-back programs can legally collect and dispose of controlled substances.

Some jurisdictions in California and other areas are currently working on improving appropriate disposal of residential pharmaceutical waste materials. Table 4 presents a list of such programs as of December 2004.

Table 4. Sample Programs to Improve Residential Disposal of Pharmaceuticals

Agency	Program	Status
City of Santa Rosa	Advertising HHW disposal messages	Utility bill stuffer in July 2004
Clarke County, Washington	Take-back program at pharmacies, with mail-back to HHW agency Controlled substances collected at Sheriffs office	Initiated in December 2003
Marin County Health Department	Pilot take-back at pharmacies, in conjunction with "sharps" collection program	Pharmacies lined up; advertising anticipated in 2005.
Regional Water Quality Control Plant, Palo Alto	1. Advertising HHW disposal messages 2. Pilot take-back at senior centers and/or local police offices	1. Utility bill inserts initiated in 2003. 2. Pilot scheduled for January 18-20, 2005
San Mateo County	Advertising HHW disposal messages	On-going
State of Maine	Residential mail-back program	Initiated by 2004 legislation; awaiting funding.

Based on these programs developed elsewhere, the Workgroup compiled a summary of potential actions for residents (Table 5) and a list of outreach methods to be considered (Table 6).

4. Conclusions and Recommended Next Steps

This report provides background information and sample messages and outreach mechanisms for significant but controllable sources of pharmaceutical compounds in wastewater. This information is intended to provide a starting point for dialogue amongst municipal staff and department managers/directors of POTWs, water utilities, HHW programs, outreach programs, non-governmental organizations, and other related programs that have oversight responsibility, interest or concern about the issue.

[18] Based on personal communication with Palo Alto staff

A. Regional Collaborations

Consortiums such as the Bay Area Pollution Prevention Group, and Bay Area Clean Water Agencies are appropriate forums for discussion of this topic and agreement on actions to be taken. Coordinating on a regional basis will likely provide for greater efficiency and effectiveness in taking action, as well as identifying any potential problems with such actions. Larger POTWs could pool their resources and offer a training/conference for hospital environmental health and safety staff regarding the proper disposal of pharmaceuticals as a future training event.

The recommended topics for regional discussion include:

- Regional training(s) for hospital staff (BAPPG to lead)
- Trainings for industrial waste inspectors and pollution prevention leads (BAPPG to lead)
- Strategies to identify and reduce further funding obstacles to using HHW for residential disposal of pharmaceutical wastes (need further discussions with BAWCA)
- Opportunities for take-back programs at pharmacies (BAPPG investigating)
- Opportunities for legislation to require and fund take-back programs (BAPPG investigating)

B. Opportunities for Local Activities

While it is recognized that agencies have multiple pollution prevention priorities competing for fewer and fewer resources, there may be cases in which individual agencies have the resources to pursue actions within their own community.

Regarding hospital outreach, agencies are encouraged to participate in regional trainings and provide follow-up with local hospitals and clinics regarding appropriate disposal. Agencies that do not currently permit hospitals may wish to consider doing so. Agencies may wish to include zero pharmaceutical waste policies in such permits.

Regarding residential disposal of pharmaceuticals, agencies are encouraged to consider promoting and supporting disposal practices similar to those outlined in Table 5. Sample outreach methods are provided in Table 6. When considering and planning such programs, agencies are strongly encouraged to coordinate efforts with others, to ensure that implementation is as effective and efficient as possible.

Table 5. Potential Disposal Actions for Santa Clara County Residents.

Suggested Actions	Details
Encourage household hazardous waste collection event use	• Encourage/facilitate residents disposing of unwanted or expired medications through local household hazardous waste program (Santa Clara County Household Hazardous Waste Program (www.hhw.org, 408.299.7300). • Most cities participating in the program have a maximum budget and number of residents that can participate. The County and the participating cities need to review any encouragement, marketing or advertising. • Palo Alto residents can use their city's monthly household hazardous waste collection program (www.cityofpaloalto.org/hazwaste, 650.496.6980). • Encourage residents to bring in all of their household hazardous waste items when returning unused or expired medication. Privacy issues related to information from the pill container need to be addressed and included in outreach. • Resolve funding issues between household hazardous waste programs and wastewater agencies.
Continue to work with Department of Health Service, Hospice and Solid Waste Management staff	• Develop a policy that enables hospice staff to remove medication from the patient's home • Ensure that medication is disposed of properly at a household hazardous waste event, through a certified contractor, or with law enforcement personnel.
Provide local pharmaceutical collection events at senior centers.	• Privacy issues related to information from the pill container need to be addressed and included in outreach. • Ensure that medications are incinerated.
Encourage uniform pharmacy take-back programs that ensure that medications are disposed of properly. Not down the sanitary sewer.	• Work with legislature to sponsor required take back legislation. • Pharmacists are not currently required to take back unused or expired medications. (A phone survey of local pharmacies indicated a vast difference of responses to such requests, even within a single store chain. Some pharmacists may take back medications, however, because there are no regulations or industry standards for the handling of expired medications, many residents will be declined or their medication will be disposed of as garbage or down the sewer.)
Contact poison control regarding the proper disposal of waste pharmaceuticals	• Revise poison control information to ensure that it is telling people to dispose of unused mediations through a household hazardous waste event, not down the sanitary sewer.
Educate people who prescribe medication regarding the proper disposal of pharmaceuticals.	• Encourage medical facilities to educate their patients regarding the proper disposal of unused or expired medications. • Encourage pharmacies and pharmaceutical companies to help with the education of patients regarding proper disposal of medications.

Table 6. Potential Outreach Events

Potential events	Target Audiences	Potential Issues	Agencies to contact	Regulatory Agencies	Other comments
HHW drop off events	Residents	• Controlled substances • Liability • Increased expense for household hazardous waste programs	HHW Staff; POTW staff; Police, Sheriff and Fire Departments; City representatives responsible for funding HHW events	DEA	• Pilot in Santa Clara County • Currently there is no a uniform Bay wide message
Take back events or disposal process for hospice caregivers	Hospice caregivers, Doctors, Residents, Pharmacists	• Controlled substances • Working within hospice's current rules and regulations	Hospice, DEA, DHS, Police, Sheriff and Fire Representatives; City representatives	DEA, Federal Hospice	Current Pathways hospice ensures that medication is out of the home by flushing unused medications down the sanitary sewer
Take back events at local senior centers	Seniors, Residents	Need to comply with privacy laws	HHW; POTW; Fire Stations; City representatives	DEA	
Pilot a pharmacy take-back program	Pharmacists, Residents, Doctors	• Develop regulations • Currently pharmacists are not required to take-back medications • Need pharmacists to agree • Logistics of container and comply with privacy laws	National Pharmacy Program; DTSC; POTW; Police; Health Insurance/ Blue Shield; Kaiser State Legislators	DEA	• Flyers notifying of proper disposal could be handed out to customers when the prescription is picked up. • Campaign posters posted at the pharmacies. • Pharmacist could advise the customer on proper disposal during the consulting session for new prescriptions.

5. Frequently Asked Questions

1. If there is not conclusive information about the impact of pharmaceuticals on water quality human or environmental health, why should cities and agencies support this?

Wastewater treatment plants are designed to remove conventional pollutants such as suspended solids and biodegradable organic material, not other pollutants such as pharmaceuticals. There is increasing concern that the pharmaceuticals detected in surface waters could cause adverse environmental effects, including endocrine disruption in aquatic life and/ or increased antibiotic resistance. While environmental effects in the San Francisco Bay estuary system are uncertain, it appears to be prudent for agencies to initiate the dialogue and consider the relatively cost-effective pollution prevention measures contained in this white paper.

2. When does a medication become a hazardous waste?

Not all medical wastes are hazardous wastes. Characteristics that make a waste a hazardous waste include ignitability, corrosivity (having a pH less than 2 or greater than 12.5), reactivity (including nitroglycerin, which is generally exempt from federal hazardous waste regulations but not California hazardous waste regulations), and toxicity. Listed hazardous wastes include epinephrine, nitroglycerin, and certain chemotherapy agents. California does not allow hazardous wastes to be sewered (California Code of Regulations, Sections 66261.3 and 66261.4).

3. What are the medical waste disposal requirements for hospitals and pharmaceutical companies?

Disposal of medical wastes in California is regulated by the Medical Waste Management Act (MWMA), codified in the Health and Safety Code (HSC), Sections 117600 to 118360, and administered by the Department of Health Services. Under the MWMA, there are three types of waste pharmaceuticals; none of which can be sewered:

a) RCRA-hazardous waste pharmaceuticals. If a waste pharmaceutical is a RCRA-hazardous waste, it must be managed as a hazardous waste.
b) Radioactive wastes. These are regulated under the Radiation Control Law. See the HSC starting with Section 114960.
c) Medical wastes. California law requires that all waste pharmaceuticals that are not RCRA-hazardous or radioactive be incinerated. They may not be disposed of with ordinary trash or sewered.

4. Why is there currently no region-wide campaign educating residents to take back unused or expired medications to household hazardous waste events?

Household hazardous waste programs lack the funding to accept new waste streams; therefore, an analysis of funding needs is essential before an outreach campaign of this type is developed.

5. Do pharmacies take back expired medications?

Currently there is no consistent take-back policy. Pharmacists are not required to take back unused or expired medications. Contact your local pharmacist and ask if they take back and how they dispose of unused or expired medications. In the absence of regional or statewide practices it is still an ad hoc practice.

6. How do you handle the containers?

In order to comply with the privacy laws there are two options:

- Residents could be asked to remove their personal information from the container prior to disposal, or, alternatively,
- Residents could dump the waste into a secondary container and leave with their empty pill containers

6. Resources and Reference Materials

California Health and Safety Code: www.leginfo.ca.gov/calaw.html.
Code of Federal Regulations: http://www.gpoaccess.gov/cfr/index.html. (CFR), 40, Part 261. Guidance on classification of RCRA wastes can be found at http://www.epa.gov/epaoswer/general/orientat.

EPA National Exposure Research Laboratory website on Pharmaceuticals and Personal Care Products as Environmental Pollutants
http://www.epa.gov/nerlesd1/chemistry/pharma/faq.htm#Whatdoes
{the home page is: http://epa.gov/nerlesd1/chemistry/pharma/}
http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf}

Hospitals for a Health Environmental (H2E) is a joint project of the American Hospital Association, the Environmental Protection Agency, Health Care Without Harm, and the American Nurses Association. The primary goal of the H2E effort is to educate health care professionals about pollution prevention opportunities in hospitals and health care systems. General information about pollution prevention for hospitals can be found on the H2E web site at http://www.h2e-online.org/.

"Managing Pharmaceutical Waste: What Pharmacists Should Know," Charlotte Smith, Journal of the Pharmacy Society of Wisconsin, Nov/Dec 2002. A copy may be found on-line at http://www.pharmecology.com/pedd/pdf/Managing%20Pharmaceutical%20Waste.pdf.

Appendix A – Medical Waste Regulation Summary1

Department of Health Services (DHS) regulates the disposal of medical waste in California according to the Medical Waste Management Act (MWMA), codified in the Health and Safety Code (HSC), Sections 117600 to 118360.

Under the MWMA, there are three types of waste pharmaceuticals:

1. **RCRA-hazardous waste pharmaceuticals.** If a waste pharmaceutical is a RCRA-hazardous waste, it must be managed as a hazardous waste. To determine if a waste pharmaceutical is a RCRA-hazardous waste, follow the usual procedures to determine if a waste is a RCRA-hazardous waste (i.e., determining if it is a listed waste or has the characteristics of a hazardous waste). The full regulations governing RCRA-hazardous waste characterization can be found in 40 Code of Federal Regulations (CFR) Part 261. Guidance on classification of RCRA wastes can be found at www.epa.gov/epaoswer/general/orientat. A good article on RCRA regulations as they apply to pharmaceuticals is "Managing Pharmaceutical Waste: What Pharmacists Should Know," Charlotte Smith, Journal of the Pharmacy Society of Wisconsin, Nov/Dec 2002. A copy may be found on-line at http://www.pharmecology.com/pedd/pdf/Managing%20Pharmaceutical%20Waste.pdf.

2. **Radioactive wastes.** These are regulated under the Radiation Control Law. See the HSC starting with Section 114960.

3. **Medical wastes.** HSC Section 117635(g) defines all pharmaceutical wastes that are not RCRA or radioactive wastes to be biohazardous wastes. Biohazardous wastes are a subset of medical wastes and must be disposed of in accordance with medical waste regulations. Per HSC Section 118222, biohazardous wastes that are pharmaceuticals must be incinerated, steam sterilized, or disposed of by another method approved by DHS. DHS has not yet approved of any alternative disposal methods. Therefore, California law requires that all waste pharmaceuticals that are not RCRA-hazardous or radioactive be incinerated. They may not be disposed of with ordinary trash or sewered.

   DHS has chosen to interpret this law differently. DHS maintains that only pharmaceutical wastes that would meet the characteristics of a California-hazardous waste are regulated as medical wastes. DHS believes that waste pharmaceuticals that are not RCRA-hazardous wastes, California-hazardous wastes, or radioactive materials may be put in ordinary trash or sewered, with POTW authorization.

If you have questions about medical waste management, contact the DHS Medical Waste Management Program at 906/327-6904 or MedWasteInfo@dhs.ca.gov

[19] Modified from Tri-TAC Memo to POTW Pretreatment Coordinators and Managers, September 23, 2003, A copy may be found on-line at http://www.ciwmb.ca.gov/WPIE/HealthCare/TriTACMemAtt.pdf

Table A-1: Some RCRA-listed chemicals that have major medicinal therapeutic uses[20].

P list	U list
Epinephrine (adrenaline) PO42	Chlorambucil (Leukeran) U035
Nicotine P075	Cyclophosphamide (Cytoxan, Neosar, Procytox) U058
Nitroglycerine P081	Daunomycin (Dauorubicin, Cerubidine) U059
Physostigmine P204	Diethylstilbestrol U089
Physostigmine salicylate P188	Melphalan (Akeran) U150
Warfarin >0.3% P001	Mitomycin C (Mutamycin) U010
	Paraldehyde U182
	Phenacetin U187
	Reserpine U200
	Saccharin U202
	Selenium sulfide U205 (e.g. dandruff shampoos)
	Streptozotocin (Zanosar) U206
	Uracil mustard U237
	Warafin (Coumadin) <0.3% U248

Note: P-listed includes 239 chemical substances, which have been identified as acutely hazardous, although they also may be reactive or exhibit other characteristics. U-listed chemicals includes 521 substances identified as toxic wastes. They may have additional hazardous properties such as being ignitable, reactive, or corrosive.

[20] Daughton, Christian G. Cradle to Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health. II. Drug Disposal, Waste Reduction, and Future Directions, Environmental Health Perspectives, Volume 111, number 5: 111:775-785 [available: http://www.epa.gov/nerlesd1/chemistry/ppcp/images/green2.pdf]

Appendix B – Related laws

Household Pharmaceutical Waste

State law exempts medical and biohazardous waste generated by households from regulation under medical waste laws, per HSC Section 117670. This includes pharmaceutical waste. Subsequently, most waste pharmaceuticals generated by households are not classified as medical wastes and may be handled by household hazardous waste collection programs.

Clean Water Act Authorities

Section 307 of the Federal Water Pollution Control Act (more commonly referred to as the Clean Water Act) called for the Environmental Protection Agency to develop national pretreatment standards to control industrial discharges into sewerage systems. Included in this program are "Prohibited Discharge Standards," which are uniform national requirements that restrict the level of pollutants that may be discharged by non-domestic sources to sanitary sewer systems. All POTWs that are required to implement a Pretreatment Program must enforce the federal standards. Prohibited Discharge Standards specifically prohibit the discharge of pollutants that cause pass through or interfere with a POTW's operations. A pass through is a discharge that, alone or in conjunction with discharges from other sources, is a cause of a violation of any requirement of a POTW's discharge permit, per 40 Code of Federal Regulations, Part 403.5(a)(1). Wastewater discharge permits issued by the California Regional Water Quality Control Board for POTWs pursuant to the Clean Water Act generally contain a requirement that wastes discharged shall not contain any substances in concentrations toxic to human, animal, plant, or aquatic life. This means that no pharmaceutical wastes may be sewered that in and of themselves, or in conjunction with other wastes discharged by businesses or households, could create a concentration of the pharmaceutical in the treatment plant effluent that, when discharged to surface or groundwater, adversely impacts humans or aquatic life. Individual POTWs have the authority to determine what wastes may adversely impact their own wastewater treatment plant.

Hazardous Waste Regulations

The California Environmental Protection Agency's Department of Toxic Substances Control (DTSC) and various local agencies implement hazardous waste regulations in California. California does not allow hazardous wastes to be sewered (California Code of Regulations, Sections 66261.3 and 66261.4). Listed hazardous wastes include epinephrine, nitroglycerin, and many chemotherapy agents. Characteristics that make a waste a hazardous waste include ignitability (including formulations with more than 24% alcohol, collodion, and oxidizers such as potassium permanganate and silver nitrate), corrosivity (having a pH less than 2 or greater than 12.5), reactivity (including nitroglycerin, which is generally exempt from federal hazardous waste regulations but not California hazardous waste regulations), and toxicity.

There are a number of considerations to determine if a waste exhibits the characteristic of toxicity under California standards. The material must not contain concentrations of certain chemicals above certain concentrations, as defined in the California Code of Regulations Sections 66261.24(a)(1) and 66261.24(a)(2). The material must also not have an acute oral LD_{50}

less than 2,500 mg/kg, an acute dermal LD_{50} less than 4,300 mg/kg, an acute inhalation LC_{50} less than 10,000 parts per million as a gas or vapor, or an acute aquatic 96-hour LC_{50} less than 500 mg/L when measured in soft water using fathead minnows, rainbow trout, or golden shiners. Additionally, a waste is hazardous waste if "it has been shown through experience or testing to pose a hazard to human health or environment because of its carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative properties or persistence in the environment." Violation of any of these criteria makes the waste a hazardous waste.

The generator of a waste has the responsibility to determine whether a waste is hazardous or not. For pharmaceutical wastes, all criteria that may reasonably be expected to make a waste a hazardous waste need to explored before a waste can be disposed of as non-hazardous. Improper determination of whether a waste is hazardous does not shield the generator from felony criminal liability for illegal hazardous waste disposal. For more information on hazardous waste regulations and disposal, please contact DTSC or your local hazardous waste agency.