

Operating Unwanted Medication Collections - A Legal & Safe Approach



With Funding from the U.S. Environmental Protection Agency



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This document addresses unwanted medications collected from individuals. These include over-the-counter, prescription, and veterinary medications. This document does *not* address issues associated with unwanted medications from doctor's offices, facilities, hospitals, nursing homes, hospice, or other organized medical delivery programs and services.

I Introduction

The Northeast Recycling Council, Inc. (NERC), a non-profit organization that focuses on issues related to solid waste, recycling, and the decreased toxicity of the solid waste stream, was awarded a grant by the U.S. Environmental Protection Agency (USEPA) to develop environmentally sound and legal strategies for collecting and destroying unwanted medications from consumers.

The need for such a project arose from the growing scientific evidence that over-the-counter and prescription medications are finding their way into water supplies. While excretion of medication and its metabolites is certainly the primary source of this contamination, disposing of unwanted medications down the drain, down the toilet, or in the trash has added to this problem.

This project sought to develop and test strategies to ensure that unwanted medications are collected and destroyed in an environmental sound and legal manner, and prevented from being stolen or used by unauthorized persons – also known as “diversion.”

Throughout this document, we refer to the materials being collected as “medication.” The word “drug” is avoided. In addition, every effort has been made to make clear that the medications are “destroyed” and not “recycled.” During the course of this project it became apparent that a great deal of confusion and misapprehension quickly arose if the words “drug” or “recycling” entered into the discussion. Word choice in this new and evolving area is critical.

II Background

An increasing number of studies, including a national reconnaissance of streams conducted by the United States Geological Survey (USGS) during 1999 – 2000, which looked for pharmaceuticals, hormones, and other organic wastewater contaminants, have detected medications in water supplies. The USGS study found medications in 80 percent of the streams they sampled.¹ A recent study by the Canadian National Water Research Institute for Health and Environment identified nine different medications from water samples taken near 20 drinking water treatment plants.² There are also studies

¹ <http://pubs.acs.org/cgi-bin/jtextd?esthag/36/6/html/es011055j.html>

Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance

² “Prozac and painkillers found in tap water”, Vancouver Sun, November 14, 2004.

that indicate a potential correlation between human medication and the phenomenon of male fish producing eggs.

“Our impression is that they are males that are being feminized [because] of the nature of the chemicals that are in the water, and most of them are estrogenic [meaning they stimulate development of female sex characteristics],” [David O. Norris, a professor in the University of Colorado's Department of Integrative Physiology] said. “Some of [the estrogenic chemicals] are natural urinary estrogenic products from humans, and some of them are pharmaceuticals—birth control pills.”³

The Solid Waste Solution

So, what can the solid waste community do? Unfortunately, the norm has been to recommend that unwanted medicines be flushed. Clearly, this is no longer a sound recommendation. Well-publicized best management practice recommendations and opportunities for collecting unwanted medications for safe disposal are needed.

NERC spent two years, with the assistance of an Advisory Committee, researching the legal considerations associated with the collection and disposal of unwanted medications and developed a strategy that is both effective and legal. As a result, it developed best management recommendations and held eight unwanted medication pilot collections.

This guidance document reflects the experience gained through the implementation of those pilot collections. The model outlined in this document satisfies all federal legal requirements, but individual state requirements must be addressed before holding a collection. If yours will be the first collection in the state, you are likely to have to be the one to confront and resolve these concerns. This document outlines the state-specific issues that are likely to arise and offers suggestions about how to address them.

Federal agencies that regulate the handling and disposal of prescription medications include the United States Drug Enforcement Administration (USDEA), USEPA, and the United States Department of Health & Human Services (USDHHS). In addition, state laws regulate prescription medications, and solid and hazardous waste. Because the management of unwanted medications is a new issue and one that has yet to fully evolve, the federal laws are not always compatible with each other, and state laws introduce additional complexities.

³ “Male Fish Producing Eggs in Potomac River”, *National Geographic News*, November 3, 2004
http://news.nationalgeographic.com/news/2004/11/1103_041103_potomac_fish.html#main

The guidance in this document is organized as follows:

- What to expect at a collection
- The law
 - Federal
 - State
- Legal strategy for collecting unwanted medications
- Holding a collection
- Case studies

III What to Expect at a Collection

NERC conducted eight unwanted medication pilot collection events in advance of developing this guidance. Each of the pilots accepted prescription, over-the-counter, and veterinary medications. Among the prescription medications were controlled and non-controlled substances.

Under federal law, the USDEA determines what is a controlled substance. These medications are listed in Title 21 of the U.S. Federal Register as a narcotic or non-narcotic drug. Examples of well-known controlled substances include Valium®, Oxycontin®, Percocet®, and codeine. Non-controlled medications are any prescription medication *not* listed in Title 21 of the Federal Register.

It is the management of controlled substances that introduces the legal complexities into collecting unwanted medications. Yet, it is neither practical nor advisable to tell the public “do not bring controlled substances.” Even with this hypothetical stricture, controlled substances will arrive and, thus, the collection must be prepared to handle this material.

Pilot Location	Number of Participants	Average Volume (Gallons) per Participant Non-Controlled Substance	Average Cost per Gallon Destruction of Non-Controlled Substance	Hazardous Waste Transportation Fee
Montague, MA*	6	0.8	\$30	\$350
S. Portland, ME*	51	0.7	\$24	\$250
Northampton, MA*	14	0.4	\$20	\$350
South Hadley, MA**	22	1.4	\$13	\$0
Wilbraham, MA**	18	1.4	\$12	\$0
Buckland, MA**	6	1.3	\$14	\$350
Rutland, VT*	28	1.1	\$17	\$225
Wolfeboro, NH**	27	0.7	\$7	\$0
AVERAGE	21.5	0.97	\$17	\$191

Stand-alone collection* With HHW event**

Figure 1: Overview of pilot collections

Amount collected: While several different types of collections were tested, the amount of materials collected at each event was surprisingly consistent. On average:

- Each person brought in approximately one gallon of non-controlled substances (in the original containers).
- Each person brought in one container of controlled substances.
- Approximately 4 percent of what was received was controlled substances. This figure ranged from a low of less than 1 percent to a high of 17 percent.

However, when the collections that were held in conjunction with HHW events were analyzed separately, the average amount of material brought in by each person was significantly higher: almost 1.25 gallons per person of non-controlled substances, as compared to 0.70 gallons per person from the events that were not associated with HHW collections. And, approximately 22 percent of the number of HHW collection event participants brought unwanted medications.

Participation: Turnout was relatively low for all events, with less than one percent of the population base participating despite heavy advertising in half of the programs.

Why? The theory is the unfamiliarity with the topic. As with the early days of household hazardous waste (HHW) programs, the public needs to be educated to save its medications and there needs to be programs to accept them. The common practice in the medical and health communities of advising consumers to put medications down the drain may contribute to the lack of public awareness. As this topic becomes more mainstream, and more collection events are available, it is reasonable to expect that volumes and participation will increase dramatically.

IV The Law

Federal Law

At the heart of legally managing and collecting unwanted medications is the necessity to comply with the USDEA laws and regulations. These specifically target controlled substances; e.g., Valium®, Oxycontin®, Percocet®, codeine. **The USDEA prohibits the transfer of dispensed controlled substances from an individual to a doctor, pharmacist, reverse distributor,⁴ or any other entity registered with the USDEA to handle or manage controlled substances.** The only exception is in the case of a recall or a dispensing error. Translated, this means that once a prescription has been filled, only the person to whom it was prescribed may legally be in possession of it. **Handing it back to a pharmacist or the doctor is illegal because federal law prohibits their having possession. The sole exception is that controlled substances may pass into the control and custody of law enforcement officials** because they are specifically authorized by USDEA laws and regulations to receive and possess controlled substances.

At this time, the USDEA has made it clear that reverse distributors may not accept dispensed controlled substances as part of the waste stream. There appears to be no federal constraint on reverse distributors accepting non-controlled substances, but state law may impose such limitations.

Thus, in order to legally collect unwanted controlled substances it is *an absolute necessity* that law enforcement officials be on-site, participate in the collection, take physical control and custody of all controlled substances, and be responsible for their destruction as required by state and federal law.

We recommend that during the planning stages for a collection event, that you contact the local or regional USDEA agent-in-charge and inform them in detail about the planned collection and the safeguards that will be taken to ensure that there will be compliance with federal controlled substance laws.

The reality is that it is a practical impossibility to prevent controlled substances from coming into a collection. The program *must* be designed and prepared to legally and safely handle these medications, and to destroy them.

⁴ A reverse distributor is a business that is authorized by the USDEA to collect medicines from pharmacies and other entities registered with the USDEA to be in possession of controlled substances. The medicines are then either destroyed or returned to the manufacturer for credit.

Federal Hazardous Waste Law

The U.S. Resource Conservation and Recovery Act regulates the transportation, treatment, and disposal of hazardous waste, but exempts waste generated by consumers (household waste) from regulation. Some prescribed and over-the-counter medications are known to require management as a hazardous waste when they come from an entity other than an individual. For example, nitroglycerin, NicoDerm® patches, epinephrine, Coumadin®, Leukeran®, lindane, and Alkeran® are listed hazardous wastes. And, many medications are hazardous waste due to their characteristics: ignitable due to the alcohol content – including rubbing alcohol, or toxic due to heavy metals such as mercury.

The U.S. Department of Transportation (USDOT) also regulates the transport of hazardous waste.

If you have a HHW program because you are concerned about hazardous waste entering the solid waste stream, then preventing medications from entering the solid waste stream makes sense for the same reasons.

As part of the NERC project, a list of the medications collected was examined by PharmEcology Associates, LLC to determine which materials collected should be considered a hazardous waste. This study estimated that approximately 10 percent of the over-the-counter and prescription medications that were collected, by type not by volume, should be considered hazardous waste.

State Hazardous Waste Law

Like federal law, most state hazardous waste laws do not regulate individuals. Thus, materials that have hazardous waste characteristics may, by law, be disposed of in the trash. However, some states do regulate household waste if it is consolidated in a central location, as would be the case in a collection event, and this must be taken into consideration if it is the case in your state. In addition, some states require that a permit or notification be in place for a collection event. Be sure to confer with the state environmental agency about requirements for holding an event that will include the participation of a hazardous waste hauler.

Other State Legal Requirements

A myriad of state laws and regulations have the potential to affect whether and how to hold unwanted medication collections. In addition to hazardous waste laws, state specific requirements may include:

- Board of Pharmacy regulations and laws
- Controlled substance laws and agencies
- Public safety laws about law enforcement being in possession of non-criminal evidence
- Privacy laws

It is essential that these be addressed in advance of holding a collection.

Board of Pharmacy

Each state Board of Pharmacy regulates the licensing of pharmacists, and the handling and dispensing of prescription medications. Because it is extremely important that a pharmacist participate in the collection, as will be explained in detail below, the Board of Pharmacy must have approved the activity. This approval, once obtained, should apply to all subsequent events, but this will require that a responsible party has interacted with the Board of Pharmacy, explained the program, and secured its express permission for the way in which the collection(s) will take place. We know from experience that the protocol for holding a collection described in this guidance document is acceptable to the Boards of Pharmacy with whom we have interacted.

Of primary concern to Boards of Pharmacy is the handling and disposal of controlled substances. As stated above, federal law (and all state laws echo this) prohibits dispensed controlled substances from being in the possession of anyone other than the person to whom they were dispensed. The sole exception to this is law enforcement. This means that a pharmacist *may never* be in physical possession of a controlled substance that has been dispensed, with the two limited exceptions described above that are irrelevant to these circumstances. The question becomes, *is the pharmacist's involvement in the collection event "possession?"*

As explained below, the primary role of the pharmacist in a collection is to determine whether a medication is a controlled substance. If identified as a controlled substance, the pharmacist conducts a physical inventory of the contents, replaces the materials into the original container, and hands it over to law enforcement. Some states may construe this as possession. To authorize such an activity, it will be necessary to persuade the Board of Pharmacy that adequate precautions will be in place to prevent diversion. Without this authorization, participating pharmacists are at risk of losing their licenses.

In order to secure this authorization, during the NERC project we developed an information packet for Boards of Pharmacy that describes how an unwanted medication collection event would be held in their state, including the safeguards against diversion. The Boards of Pharmacy were contacted individually, the information provided in advance, time on the Board's agenda secured, and a presentation made to the Board of Pharmacy with the request that it vote to authorize the holding of such events as described in the documentation provided. A sample of the information provided to a Board of Pharmacy is attached in Appendix 4.

In 2006, the National Association of Boards of Pharmacy (NABP) adopted a resolution that states

Whereas, patients often need guidance on the proper disposal of unwanted, unused, or expired medication; and

Whereas, the inappropriate disposal of unused or expired medication may pose a significant risk to the public and the environment; and

Whereas, there is an increased incidence of theft of prescription medications from homes and residential trash, resulting in the diversion and abuse of such medications; and

Whereas, patients with excess or unused medication often share their medication with other individuals in the absence of any pharmacist or medical supervision;

Therefore Be It Resolved that NABP and the boards of pharmacy work with the pharmacy community, environmental community, and regulatory agencies to develop programs whereby patients can safely and properly dispose of unwanted, unused, or expired medications; and

Therefore Be It Further Resolved that NABP develop guidance for the boards of pharmacy and the pharmacy community addressing the environmentally safe and legal collection and destruction of unwanted, unused, or expired medications from patients.⁵

As a result, we can be hopeful that Boards of Pharmacy will become allies in the effort to collect unwanted medications. That has been the experience during the NERC project.

Controlled substance laws and agencies

Many states have agencies specifically charged with the oversight of the movement and handling of controlled substances.⁶ Like the Board of Pharmacy, their primary concern will be the risk of diversion by the on-site pharmacist, other collection staff, or the general public. Designing a collection program that has safeguards built in specifically to prevent this will be essential in securing their permission. Advance permission from such agencies must be secured. Providing information such as is provided to the Board of Pharmacy and having individual conversations with these agencies to ensure that the collection program design satisfies the state requirements is essential.

In addition, a few states have a more extensive list of what constitutes a controlled substance than does the USDEA. Handling of state-specific controlled substance designations must be included in the program planning and implementation.

Public safety laws

Some states have laws that prohibit law enforcement from being in possession of non-criminal evidence. As is explained in detail below, at the very heart of ensuring that controlled substances will not be diverted is the physical and active involvement of law enforcement. Law enforcement takes possession of the controlled substances and is responsible for their destruction per USDEA and state requirements. This means, being in possession of non-criminal evidence.

⁵Resolution No. 102-2-06, Title: Safe and Environmentally Friendly Medication Destruction Programs, <http://www.nabp.net/ftpfiles/AM/102ndProceedings.pdf>

⁶ The National Association of State Controlled Substances Authorities (NASCSA) maintains a list of these agencies on its website. <http://www.nascsa.org/Folder5/memstates.htm>

The reality is that law enforcement agencies do, from time to time, come into possession of non-criminal evidence, such as narcotics found at the scene of a suicide or simply "found." Thus, it will be at the discretion of law enforcement whether to participate in the event and whether to take physical, permanent responsibility for the controlled substances. Although no state requires law enforcement to take non-criminal controlled substances into their possession, their doing so is a pre-requisite to a legal and safe collection program. Therefore it is imperative to secure their voluntary participation.

Privacy laws

While the federal privacy law, the USDHHS Health Insurance Portability and Accountability Act of 1996 (HIPAA), generally does not apply in the case of unwanted medication collections, state laws may be more stringent. If this is the case, ensure that all personal information is marked off of prescription containers before being handed to either the pharmacist or law enforcement official, while being sure that the medication information remains legible.

This raises the issue whether to remove the medications from their labeled containers. The medications should ALWAYS remain in their containers so that the identity of the medication can be established at all phases of the process. In the case of diversion or accidental poisoning, it is essential to know what medication was involved. Proper labeling is also essential to determine if the item is a controlled substance.

V A Legal Strategy for Collecting Unwanted Medications

While there are many steps for holding a successful legal and safe collection event, essential to the program are:

- Law enforcement participation, including taking possession of controlled substances, and assuming responsibility for their destruction.
- Segregation of controlled substances from non-controlled substances.
- Appropriate destruction of all medications.

Controlled substances are segregated from non-controlled substances

In order to ensure that controlled substances are secure from the risk of diversion and are handled as required by USDEA and state law, all controlled substances pass from the consumer to the custody of law enforcement. The collection strategy presented in this guidance document relies upon the expertise of a pharmacist to determine which medications are regulated as controlled substances and to direct law enforcement to take custody of these materials. While it is illegal for pharmacists to take possession of dispensed medications, with the permission of the state Board of Pharmacy, they may provide advice about the character of the collected medications.

As mentioned above, the controlled substances are destroyed as required by the USDEA, through the programs and systems in place with the custodial law enforcement agency.

All non-controlled medications are destroyed as hazardous waste

Throughout the research, development, and implementation of the pilot collections, an Advisory Committee guided the process and decision-making. The Advisory Committee included representatives from around the country with a myriad of backgrounds and expertise. These included the USDEA, an experienced and licensed hazardous waste hauler, reverse distributors, state environmental agencies, local recycling and hazardous waste officials, pharmacy representatives, pharmacists, and expert consultants in medication management and disposal. This Committee thought very carefully about the issue of *how* best to dispose of unwanted medications. The conclusion was a carefully crafted recommendation for hazardous waste disposal as the mechanism of choice, with caveats for alternative disposal methodologies. The complete text of that best management practice recommendation is in Appendix 5.

When deciding how best to dispose of collected unwanted non-controlled medications, several factors should influence the decision making process. Naturally, cost will be one factor. But when making a decision about which strategy to use, be sure to evaluate whether hazardous waste destruction is truly too expensive given the extra security requirements that would be necessary to transport medications by common carrier or law enforcement to a solid waste disposal facility, such as an incinerator or landfill. Also be sure to determine that the solid waste facility is permitted to handle medications, and if so, under what conditions.

It is also important to be able to track the medications from the point of collection through disposal. Due to the increased value and attractiveness of diverting medications to other users and uses, there is a growing concern about theft. As a collected material, it may appear to be a particularly attractive waste to scavenge. Precautions should be taken. Under all circumstances, state and federal drug management and disposal regulations, as well as solid waste management and disposal laws and permits must be observed.

Among the reasons for the determination to destroy non-controlled substances as hazardous waste were:

1. Cradle to grave tracking of the movement and destruction of the medications.
2. Decreased access to medications, thus preventing diversion and inappropriate use of medications, as well as minimizing the risk of poisoning children and pets.
3. The presence of medications with hazardous waste characteristics in the waste mix and the practical impossibility of separating them out.
4. Physical destruction of the medications for the purpose of rendering them unrecoverable, as required by federal law, is considered to be essentially a practical impossibility, with the exception of incineration.⁷
5. Sending a message about the importance of safe end-of-life management of medications.
6. Avoiding water pollution from medications in landfills and the risk of diversion when tipped out at disposal facilities.

⁷ Conversation with Vicky Seeger, USDEA, October 2004

VI Holding a Collection Event

Brief Overview

What happens at a collection event?

1. Individuals come in with their medications – ideally in the original containers. Experience says that individuals bring in a lot of material. On average each person will bring in approximately one gallon of medications (in their original containers). They bring it in cardboard boxes and in plastic grocery bags.
2. They drop off their medications and leave. An individual's on-site time is very brief. You may have a few survey questions for them before they leave.
3. The pharmacist sorts and categorizes the medications as controlled and non-controlled items. The non-controlled medications are put in hazardous waste containers. The controlled substances are inventoried and given to law enforcement.
4. At the end of the event, the controlled substance inventory is printed out and signed by the law enforcement official as well as the pharmacist.
5. At the end of the event, the hazardous waste hauler removes all of the non-controlled substances, creates manifests to document the materials per USEPA and USDOT regulations, and transports it to a hazardous waste incinerator.
6. After the hazardous waste hauler has left, the law enforcement official takes the controlled substances to the station and puts them in the evidence storage locker, awaiting destruction.

A Collection Event in Detail

The overriding goals of any unwanted medication collection must be to:

1. Be in full compliance with federal and state laws.
2. Avoid illegal diversion of the medications.
3. Ensure the safe and environmentally sound disposal of the medications.

Each of the following, and more, will be detailed below, but here is a brief overview of what is required for a legal and safe collection event:

1. Law enforcement presence (in uniform, previously agreed to take physical possession of controlled substances, and be responsible for witnessed destruction).
2. Pharmacist to determine if the medications collected are controlled substances and to conduct an inventory.
3. Properly licensed hazardous waste hauler.
4. An indoor site with electricity.

Any unwanted medication collection will be limited to a few hours on a specific day. This is due to the requirement of the active involvement of law enforcement and the practical limitations that this imposes.

Staff

No matter the venue, there are certain staff requirements essential to the safe and legal conduct of an unwanted medication collection event.

1. Law enforcement (on- and off-site)
2. Pharmacist
3. Greeter
4. Data entry
5. Supervisor
6. Hazardous waste company

Depending on the anticipated size of the event, it may be necessary to have multiples of law enforcement, pharmacists, greeter, and data entry staffing. Following is a description of the staff-specific responsibilities.

Law Enforcement

Responsibilities:

1. The primary responsibilities of the law enforcement official are to:

- Provide security
- Take possession of the controlled substances
- Transport the controlled substances to the agency's evidence storage locker, and take whatever steps are necessary to store the medications in that locker.



- The law enforcement official must be in uniform.

2. During the collection:

- The pharmacist will determine if a medication is a controlled substance. If it is a controlled substance, the law enforcement official will be alerted. (S)he should watch the physical inventory that will be conducted by the pharmacist and the return of the medications to the original container.



- After the inventory is completed,

the controlled substance will be handed to the law enforcement official. A container for collecting the controlled substances will be provided, for example a five-gallon pail.

- Once the inventory is completed, the controlled substances must stay in the sole physical possession of law enforcement throughout the collection and until placed in the evidence storage locker or taken for destruction. At no time may the container of medications leave the physical possession of law enforcement.

- At the end of the event, an inventory of controlled substances will be printed out. The pharmacist will sign as a witness that the inventory accurately represents what went into the custody of law enforcement. The law enforcement official will sign as well, verifying that (s)he received these materials. An original of the signed and witnessed inventory will be provided to accompany the controlled substances back to the evidence storage locker. Depending on the preference of the law enforcement agency, the inventory may be physically attached to the container of controlled substances, placed inside it, or carried separately.
- Depending on the type of container, the law enforcement agency chooses for transporting to and storing the controlled substances in the evidence storage locker, the law enforcement official may also be required to initial over a seal securing the container of medications.
- For security sake, law enforcement should stay on site until the container(s) of non-controlled substances are closed, labeled, and placed in the hazardous waste hauler's truck; effectively removing them from the site and public access.

It is essential that the law enforcement official be in a position to have visual contact with the individuals dropping off the medications and the point of drop-off. For example, if the collection is in conjunction with a HHW day and medications are being taken from people's cars and walked to the indoor site where the sorting and data collection is taking place, it will be necessary to have law enforcement shadowing or watching this activity and movement in order to ensure that no diversion takes place.

3. Off-site, after the collection:

- Maintain secured locked possession of controlled substances along with USDEA required inventory.
- Arrange for and ensure USDEA authorized witnessed destruction of controlled substances.

Timing: Law enforcement should be on-site at least one-half hour before the event begins and should remain on-site until the hazardous waste hauler has completed all of its paperwork, closed the containers, and put the containers on the hazardous waste truck. At that time, the law enforcement official should return to their office, complete whatever paperwork is necessary, and secure the controlled substances in the evidence storage locker or take it directly for witnessed destruction.

Pharmacist

Responsibilities:

The pharmacist must be licensed and in good standing in the state.



1. The pharmacist's primary responsibilities during the collection are to:

- Determine if a medication is a controlled substance.
- Make every reasonable effort to identify unknown or non-labeled medications. This will include using reference materials and may include calling poison control or other reference sources.

If it is not possible to identify the medication, the USDEA has indicated that it should be handled as a controlled substance.

- If it is a controlled substance, alert the law enforcement official as well as the person entering the inventory into the computer.
- Conduct a physical inventory of the controlled substance. Provide the medication name, dosage, and amount of material to the data entry person.

The information will be entered into the computer by the data entry person.

- Put medications back in the original container and hand the controlled substances to the law enforcement official.

- Put non-controlled substances in the hazardous waste container.

2. At the end of the event, an inventory of controlled substances will be printed out in triplicate. The pharmacist will sign as a witness that the inventory accurately represents what went into the custody of law enforcement. The law enforcement official will sign as well, verifying that (s)he received these materials. An original of the signed and witnessed inventory will be provided to the pharmacist for his/her records, and one copy should stay with the event organizer.

3. It is recommended that (s)he should wear a pharmacist jacket in order to make it visually obvious that it is a pharmacist.

4. Gloves must be worn at all times when handling/counting medications.

5. The pharmacist should provide tools for counting medications.

6. The pharmacist should provide reference materials for identifying unknown/non-labeled tablets.

7. Answer questions from the public.

8. Optional: Physically inventory all medications brought into the event, such as is done for the controlled substances.

Timing: The pharmacist should be on-site at least one-half hour before the event. The pharmacist should assume that (s)he will have to be on-site for at least one hour after

the event closes. There may be remaining inventory work to be done, the controlled substance inventory must be completed and signed, and supplies packed.

Greeter



Responsibilities:

1. Direct people to the collection and answer questions.
2. Ask if bringing any needles. If say yes, explain that the only needles that can be accepted are EpiPens. Other needles need to be removed.
3. Provide pens for obscuring personal information, as desired.
4. Optional: Conduct survey.
5. Optional: Distribute informational materials.
6. Optional: Take the medications from cars and transport them to the sorting table, if the police permit such a practice.
7. Optional: Help remove cardboard packaging for recycling.

Timing: Greeters should be on-site at least one-half hour before the event begins. The greeter is likely to be able to leave very shortly after the scheduled end of the event.

Data Entry

Responsibilities:

1. Enter inventory of medications into computer.
 - Should back-up data entry every few minutes on memory stick or other external memory device.
 - Print out inventory of controlled substances for witnessing.
2. Optional: Help remove cardboard packaging for recycling.
3. Optional: Put non-controlled substances in hazardous waste container.



Timing: The data entry person should arrive at least one hour before the event starts in order to set up the laptop and ensure that the printer is operational. This person will have to remain on-site until all of the medications have been segregated into controlled and non-controlled and the controlled medications inventory has been complete. Depending on the size of the event and whether non-controlled substances are being inventoried, this may take at least one hour beyond the time the event closes to the public.

Site Supervisor



Responsibilities:

On-site:

1. Provide all supplies and equipment.
2. Set up site.
3. Instruct each staff person about responsibilities and procedures.
4. Ensure that all operations are running smoothly and that personal protective equipment is being used.
5. Ensure that law enforcement does not leave site until all non-controlled medications have been

packed and placed on the hazardous waste truck.

6. Maintain records, including copy of witnessed controlled substance inventory.
7. Answer operational questions as they arise.

Off-site:

1. Recycling and trash.
2. Data analysis and reporting.
3. Paying invoices.
4. Thank you notes.
5. Follow-up with hazardous waste company to ensure destruction.

Timing: The site supervisor should arrive at least one hour before the start of the event. The site supervisor will have to remain on-site until all of the medications have been segregated into controlled and non-controlled, the controlled medications inventory completed and signed, the controlled substances packaged for transportation by law enforcement, the hazardous waste company has come and gone, and the site is entirely cleaned-up and put back together. Depending on the size of the event, this will take approximately two hours after the event closes.

Hazardous Waste Company

Responsibilities:

1. Provide drums/containers for collection of non-controlled substances.
2. Seal containers, prepare paperwork, and transport non-controlled substances for hazardous waste destruction.
3. Remove medications *on the same day as the event*.
4. Provide tracking paperwork from point of collection through destruction.
5. Incinerate non-controlled substances in licensed hazardous waste incinerator.
6. Provide certificate of destruction.
7. Optional: Provide weight of materials collected.

Timing: The hazardous waste company needs to drop-off containers at least one day before the event. The hazardous waste company should be scheduled to return for pick-up of the non-controlled medications and unused containers one hour after the

scheduled close of the event. Generally, it will take one-half hour to complete all of the necessary paperwork, to close the containers, and place them on the truck.

Medications should never be stored on-site after the event. It creates too great of a risk of theft.

If the event is held in conjunction with a HHW event, containers for the unwanted medication collection will be dropped off along with the drums for the HHW. As soon as all of the non-controlled medications are in the hazardous waste containers, they must be closed, labeled, and put on the hazardous waste truck, even if the rest of the HHW collection event is not over. The hazardous waste company needs to be alerted to this requirement in advance of the collection. This is essential to prevent diversion of the medications, and to limit the amount of time that law enforcement must be present for the medication collection; allowing them to return more promptly to the station to properly store the controlled substances.

Site Safety

A great deal of time and effort goes into determining the best on-site staffing, traffic flow, security, and equipment. The goals are public safety, ensuring that medications are not diverted, and that safe and legal disposal occurs. The presence of law enforcement, the hazardous waste company, and configuring the site to minimize the risk of diversion are essential to achieve these goals.

Simple safety precautions include a site set-up that positions law enforcement in such a way that no one can surprise them from behind. And, never store collected medications at a HHW facility or any other setting, other than in the custody of law enforcement. The risk of theft or accident is too great, and the dangers of such a result far outweigh any inconvenience or expense of ensuring that all medications are removed from the site on the day of the collection.

Personal Protective Equipment and Practices

It is very important that everyone working at the event (law enforcement, pharmacist, greeter, site supervisor, and anyone accepting medications from individuals) who may contact the containers of medications wear gloves (latex or non-latex) at all times when handling this material. The containers are powdery, sticky, and dirty. It is important to remember that these are medicines. Accidental ingestion (even through skin or breathing) should be avoided. Wearing facemasks should be considered, especially for the pharmacist who is doing the physical inventory of the medications.

Drinking or eating directly in the area that the medications are being collected and handled should be avoided – and be sure to take off the gloves before handling any food or beverages. Used gloves should be discarded in the hazardous waste container and replaced with new gloves after any breaks.

Greeters, or anyone, who is working with vehicles or lines of traffic must wear safety vests.

Packing Medications for Disposal

As has been discussed, controlled and non-controlled medications are packed separately. In both instances the medications are packed in their original containers. As discussed above, we strongly urge that the disposal mechanism be hazardous waste incineration for all non-controlled substances.

The project Advisory Committee carefully considered the question whether unwanted medications needed to be shipped in their original containers for disposal. Clearly, this adds to the cost since most disposal pricing is based on volume or weight. Especially in instances where pricing is based on volume, shipping medications in their original containers results in a great deal of “air” being paid for because few of the medications fill the original containers; in some instances only a few pills will remain. The *Committee came to the clear conclusion that it was important for the medications to be shipped in their original containers.* The complete recommendation is in Appendix 6.

Packing of non-controlled substances

There should be no loose pills in the hazardous waste container. Non-controlled substances, in their original containers, are placed in a hazardous waste drum or container for destruction. Sometimes pills will be brought in outside of the original container, for example a mix of pills in a plastic bag or several types of pills in one container. It is important that the pharmacist make a best faith effort to identify the medication. This will include using reference materials. Once identified, put the medication in a Ziploc® bag and mark the bag with an indelible marker indicating the type of medication and dosage. If the tablets remain unidentifiable, mark the bag “unknown.”

It is possible to save space by removing unnecessary packaging, specifically pressboard outer-packaging. This is commonly found around blister packaging and around unopened bottles of over-the-counter medications. Because blister packaging keeps the pills separated, it is considered original packaging.



Figure 2: Outer-packaging removed for recycling, right.

Figure 3: Blister packaging, right.

Shipping the medications in the smallest hazardous waste container that is available will help control costs.





While the majority of non-controlled substances will go in one container, two types must be separated: items under pressure and certain mercury-containing medications.

Figure 4: Hazardous waste container with medications, left.

Items under pressure: Items under pressure are, most typically, inhalers. Use a five-gallon pail because it is very unlikely that you will receive more than this and smaller containers are generally not available. Remove the plastic housing from the inhalers in order to ship less material to the hazardous waste company. If pricing is by weight or volume this can help control costs.



Figure 5: Items under pressure, right



Mercury-containing medications: Mercury-based antiseptics, such as Mercurochrome, need to be packed separately. Mercury-containing preservatives, a more common manifestation of mercury in medications, such as Thimerosal, do not require separate handling and can be packed with the rest of the non-controlled substances.

During the pilot collections people often brought medicines that were decades old. So, mercury-based medicines may be brought to your collection.

Figure 6: Elemental mercury, left.

Although advertising for programs should specifically state not to bring thermometers, one or two will probably come in. They can be shipped with the mercury-containing medications, but preferably, the thermometers will be diverted to a mercury-recycling program. Consider offering a digital thermometer exchange. In which case, having containers for recycling of mercury thermometers must be on hand and arrangements made for the recycling. It may be that a company other than the hazardous waste hauler will provide this service. Like sharps, many companies provide mercury recycling services via mail or other common carrier service.



Sharps: While sharps should be expressly excluded from the collection, inevitably they come in. Be prepared by having sharps containers that can be mailed back to a sharps management company after the event. There is one exception to this: EpiPens. While there is a sharp within the EpiPen, it is entirely sealed in a rigid plastic container and can be placed intact into the hazardous waste drum.

Figure 7: EpiPens for hazardous waste disposal.

Have the greeters ask people if they have brought needles, before accepting their medications. This is simple strategy to prevent the sharps from coming into the collection.

Items for the trash or recycling: Inevitably, someone will bring materials that you might decide to put in the trash. For example, sun block, lipstick, deodorant, or skin cream, frequently arrive in mixed bags or boxes of materials cleaned out of a bathroom cabinet. You will also throw out the rigid plastic housing from around inhalers.

Possible recyclables that will be generated include the cardboard over-packing mentioned above, plastic grocery bags, and cardboard boxes. Otherwise, this will be part of the solid waste stream. Experience indicates that these combined materials generate approximately five gallons for every 30 participants.



Packing of Controlled Substances

The controlled substances remain in their original containers. Indirectly, federal law requires this because of inventory control at the point of destruction. Depending on the volume of material received and the preferences of the law enforcement agency taking possession, the packing of the medications may vary. In several of the pilot events, the preference was for Ziploc® bags.

Figure 8: Packed controlled substances.

There are no set rules for how the controlled substances should be packed or transported to the evidence storage locker. This is at the discretion of the law enforcement agency. What is mandatory is that the signed inventory accompanies the medications and that it stays with them in the evidence storage locker and through the point of destruction. When the medications are destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is USDEA law.

If the Ziploc® bag approach is chosen, the medications are put inside a transparent one-gallon Ziploc® bag, the kind with the external slider. Depending on the preference

of the agency, the signed and witnessed inventory may be placed inside the bag, visible to the outside. The bag is closed and then packing tape is used to seal over the closure. The law enforcement official then uses an indelible pen to sign and date over the seal.

In other instances the use of a closed five-gallon pail was preferred, and in one case, a paper bag.

Pre-Event

The event organizer has a number of responsibilities in advance of the collection.

1. Ensure that all relevant state agencies have agreed to the procedures to be used
2. Budget
3. Site selection
4. Agreement of law enforcement to participate
5. Arrange for pharmacist
6. Hazardous waste hauler/disposal arrangements
7. Determine traffic flow and site set-up
8. Determine what will be collected
9. Arrangements for handling sharps
10. Arrangements for handling thermometers
11. Arrange on-site staff/volunteers
12. Secure equipment and supplies
13. Advertise/press release

State Agency Authorization

As discussed above, it is essential to ensure that all relevant state agencies and programs have authorized the collection and its procedures. It is possible that only the first collection event in the state will have to go through these steps. Be sure before proceeding that this has happened.

We also recommend that you contact the local or regional USDEA agent-in-charge and inform them in detail about the planned collection and the safeguards that will be taken to ensure that there will be compliance with federal controlled substance laws

Budget

While the final cost of this new program is hard to predict, examples can be found in the Case Studies, section VIII below, and in the discussion of Costs on page 31. We strongly recommend that this service be provided at no cost to the public. Particularly with the high cost of purchasing medications, being charged a disposal fee is likely to be an overwhelming disincentive.

Site Selection

Where the collection is held has only one pre-requisite: indoor with electricity. Other concerns will be local in nature - what type of event or entity to partner with, if any, traffic concerns, etc. If the collection will take place in a pharmacy, ensure that the

state drug control agency has approved the site configuration. There may be state laws that prohibit certain activities within or near where prescriptions are filled and dispensed.

Indoors is essential because of the nature of the material being collected, because of the use of a laptop and printer, and because an inventory needs to be done of at least some of the medications. If conducting the event at a public works garage or similar location, the inside of a garage bay will be adequate, as long as tables are provided and electricity is available.

Agreement of Law Enforcement

An absolute pre-requisite to holding a collection is the agreement of law enforcement to participate and provide all of the essential services, including taking physical possession of the controlled substances and being responsible for its destruction. Without this, the collection cannot take place.

The request for assistance should be in writing, and there should also be a follow-up memo sent to confirm the collection specifics and duties of the officer. See Appendices 7 and 8.

Arrange for Pharmacist

Arranging for the services of one or more pharmacists (depending on the anticipated size of the event and amount of data collection to be conducted) is a pre-requisite to the collection. Potential sources of pharmacists are:

- Retail pharmacies.
- Boards of Pharmacy.
- Colleges of Pharmacy.
- Hospitals.

Be sure that the pharmacist(s) are licensed and in good standing with the state Board of Pharmacy. If students from a College of Pharmacy will participate, ensure that a licensed pharmacist in good standing will be on site and will act as the pharmacist supervisor. Clarify payment arrangements at the beginning of the discussion. For many of the pilot collections, the services of the pharmacist were donated but employers paid the pharmacists. For example, regional hospitals provided the services of the pharmacists as a community service.

Hazardous Waste Hauler/Disposal Arrangements

Advance arrangements with the hazardous waste hauler include:

1. Agreement on fee schedule.
2. Agreement that all materials will be sent for hazardous waste incineration.
3. Guidance on packing of materials (e.g., can mercury-containing medications go into the same container as the other medications?)
4. Decision whether to ship under hazardous waste manifest.
5. Proof of insurance.
6. Size and number of containers to be provided.
7. When and where to deliver the containers.

8. Who will pay for their services.
9. Sign a contract.
10. Determine if an EPA ID number is required, and if yes, who will obtain it.
11. Schedule pick-up for no later than one hour after the close of the event, or if the medication collection is part of a HHW event that will finish after the unwanted medication collection, be sure that the hauler understands that it will need to close, label, and store the medication containers before the end of the rest of the event.

Medications should *never* be stored on site, or even off-site. This presents an extremely unsafe situation with a grave potential for diversion. If the collection is held in conjunction with a HHW event, then the medications will be transported for destruction along with the materials from the HHW event.

12. Arrange for certificate(s) of destruction.
13. Arrange for weights of containers to be provided, if desired.
14. Contact phone numbers for day of event.
15. Provide directions to container drop-off and collection site(s).

It is the responsibility of the event organizer to make these arrangements and ensure that all terms are satisfactorily fulfilled.

Determine Traffic Flow and Site Set-Up

Traffic flow and site set-up refers to vehicular as well as pedestrian traffic, and the configuration of essential staffing and equipment.

Vehicular: If the event is held in conjunction with a HHW event, this will be particularly important. Traffic flow has several requirements:

- Safety.
- Does not impede or interfere with HHW event.
- Law enforcement can see the transfer of medications from vehicles to greeter.

In a situation where the collection is not being held in conjunction with a HHW event, traffic flow issues are primarily those related to parking.

In pilot collections held in conjunction with HHW events, three traffic flow configurations were tested. In order to determine the best traffic flow, a site visit was held in advance of the event with the event organizer, site supervisor, and law enforcement. If appropriate, consider having the hazardous waste hauler participate in the site visit.

Whatever the traffic flow decision, it is important to have the medications removed *before* the car gets to the hazardous waste hauler. Because of the federal (and state) laws that prohibit controlled substances from being in the possession of anyone other than the person to whom they were dispensed or law enforcement, it is essential that there is no chance that the medications could be given to the hazardous waste hauler before controlled substances are segregated.

Traffic configurations tested:

1. Stay in line. In this example, the unwanted medication collection participants entered the same line as the HHW participants. The greeter went to each car and asked if they had unwanted medications. If yes, then the medications were handed to the greeter for transport to the sorting table. The greeter also asked a few survey questions. If the person had no materials for the HHW event, the site layout enabled them to pull out of the line and exit. This may not always be possible, requiring that the vehicle work its way through the HHW line.



In one instance, instead of the greeter removing the medications from the vehicle, the police officer did. He then handed the medications to the pharmacist.

2. Split lines at entrance to site. At another location, drivers were asked when they entered the site if they had unwanted medications. If the answer was yes, they were diverted to the unwanted medication collection table. The greeter removed the medications from the vehicle, and asked the survey questions. If there was also hazardous waste, the driver could enter the HHW line before exiting the site.

3. Dedicated collection site apart from HHW site. One HHW collection program took advantage of the requirement to pre-register and asked registrants if they would be bringing medications. If yes, they were

directed to one site for the unwanted medication drop-off and another for the hazardous waste drop-off. Postcards and email were used to confirm HHW registration and to provide directions for sites and procedures.

Pedestrian: In circumstances where individuals will transport the medications from their vehicles to the drop-off table, ensure that they are not crossing lines of traffic.



Site configuration of staff & equipment:

Placement of the workstation, law enforcement, and supplies is an important component of the program design. Key considerations include:

- Law enforcement is positioned so that no one can sneak up behind them.
- Law enforcement can see the collection and movement of the medications from the public to the

workstation (this may require more than one law enforcement official).

- Indoors.

- Electricity.
- Room for the hazardous waste containers (in use and awaiting use).
- Room for workstations. Each pharmacist, data entry person, and law enforcement official will need a chair. The pharmacist will require a six-foot table. Depending on the size of the event, the data entry person may be able to share that table or may require an additional four-foot table. There should be extra chairs for greeters. In addition, there needs to be room for a hazardous waste drum next to each pharmacist or data entry person, and recycling/trash.

Determine What Will Be Collected

At a minimum, all prescription medications should be accepted. This includes veterinary. It is recommended to accept over-the-counter medications. There is no environmental distinction between prescription and non-prescription medications; both are being detected in water supplies and many over-the-counter medications were at one time prescription, or are lower dosage versions of prescription medications.

If the program is fully equipped for sharps and thermometers, these can be included in the collection event. If the unwanted medication collection event is being held in conjunction with a HHW event, the range of materials accepted can be much broader.

Arrangements for Handling Sharps

Whether sharps are invited into the collection or not you must be equipped to handle them. Many companies offer mail-back service for sharps. Be sure to have the collection containers on site.

Figure 9: Small sharps container, right.



Arrangements for Handling Thermometers

Even if the advertising says “do not bring thermometers,” one or two are very likely to be received. Be prepared for this by having a container dedicated to collecting these materials – a five-gallon pail with some kitty litter in the bottom is ideal – and knowing *how* you’ll have them recycled. There are mercury-recycling companies that accept devices by mail or other common carrier service, or there may be a mercury-recycling program already in place in the community that will accept them.

Arrange for Staff/Volunteers

The required staffing is described below. The number of individuals required in each role will be a function of the potential size of the event. A minimum of two individuals as greeters is suggested. More than one pharmacist may be necessary, and more than one law enforcement official may also be necessary. For each pharmacist that is inventorying medications, a dedicated data entry person is required, along with a laptop.

Among the factors that will affect how many pharmacists will be required are:

- Population being served.
- How much advertising was done and how effective you think it was (phone calls received, for example).

- Data collection. If the only data being collected is for controlled substances, there will be less demand on the pharmacist(s) at the collection. So, *not* inventorying every item that comes in streamlines the process and requires less effort and potentially staffing.

Requiring pre-registration for the unwanted medication collection is an excellent way to predict the approximate size of the event.

Among the factors affecting how many law enforcement officials will be required are:

- Population being served.
- Site configuration.
- Traffic flow.
- Discretion of law enforcement agency.

It may take several weeks to arrange for law enforcement and pharmacists. Do not advertise a program until arrangements for these essential participants have been finalized.

Equipment and Supplies



Essential on-site equipment and supplies are:

- Tools for counting medications. The pharmacist should provide this.

Figure 10: Counting tray, left.

- Reference documents for researching unknown tablets⁸ (book or CD format). Ask the pharmacist to provide this.
- Tables.

- Chairs.
- Hazardous waste containers. These need to be on-site the day before the collection. Have 5-gallon, 16-gallon, 30-gallon, and 55-gallon containers dropped off. The unused containers will be taken back by the hazardous waste company when it picks up the medications. If the collection is being held in conjunction with a HHW event, the containers may be brought to the site on the day of the event.
- Containers for trash, recycling containers for cardboard, paperboard, plastic bags. Arrangements need to be made for trash



⁸ There are several resources available, but perhaps the most comprehensive is "Ident-a-Drug Reference," written by Jeff M. Jellin, PharmD, published by the Therapeutic Research Center. It is available in paperback, CD, PDA, and online. By using the codes written on pills in combination with their shape and color it is possible to identify most, if not all, tablets and capsules prescribed in the U.S. www.therapeuticresearch.com

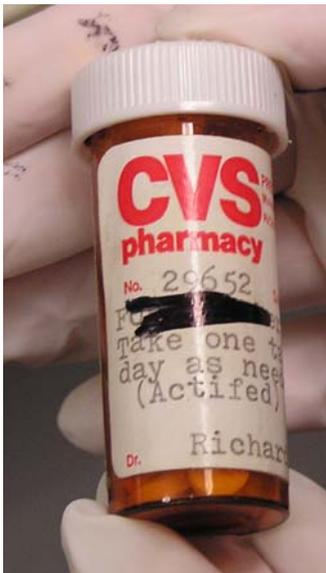
disposal and recycling. This may mean that “someone” will have to remove the materials from the collection site and take them to the disposal/recycling site.

- Gloves (Disposable non-latex preferably. Have at least two sizes (small and large)).
- Ziploc® bags (One-gallon and snack size, with external slide mechanism).
- Laptop(s) (With spreadsheet software and compatible with printer).
- Back-up memory (e.g. memory stick, CD).
- Printer (Compatible with laptop. Be sure there is enough ink and paper).
- Extension cords, grounded.
- Pens.
- Paper.
- Survey forms.
- Clipboard(s).
- Indelible markers (such as SHARPIE®).
- Packing tape.
- Drinking water.
- Toilet and sink.
- Instant hand cleaner/sanitizer.
- Phone.
- Sharps kits.
- Safety vests.

Advertising

In addition to promoting the collection event, advertising serves the purpose of educating the public about the need to properly manage and dispose of unwanted medications. As a new topic, most people have never thought about this and probably have not been saving medications in anticipation of an unwanted medication event. It is important to provide information about the specific collection opportunity, as well as to provide basic education to avoid improper disposal.

Advertising may include newspaper ads, fliers (posted at transfer stations, municipal buildings, and pharmacies), press releases, and community cable announcements. One way to encourage participation is to work in conjunction with a pharmacy.



Critical Information for the Event

- Medications stay in their original containers.
- Personal information can be crossed out, but keep information about medication legible.
- Do not remove labels.
- No sharps.
- No thermometers.
- No medical waste.
- Medications will be destroyed.
- If in a retail setting, no refunds and medications will not be resold or used.

- And, of course, where, when, hours of operation, and who to contact for more information.
- No cost to participate.

General Education

- NEVER flush unwanted or leftover medications down the drain. This can lead to water contamination and is affecting fish, frogs, and drinking water supplies.
- NEVER put the unwanted medicine in the trash. It could be stolen and used, or ingested by animals, potentially resulting in death or illness.
- NEVER give your unwanted medicine to someone else to use – it could kill them.
- NEVER take a prescription that was prescribed for someone else. It could kill *you*.
- Having unwanted medications around the home presents a danger to children, guests, and pets that could accidentally ingest them.

If medication is not used up, please remember *NOT* to put it down the drain or in the trash. If you flush it down the drain, it can cause environmental harm, and in the trash, there is the risk of people stealing the medications.

Proper disposal of outdated, unwanted medications is the right thing to do! Help protect your health, your family, your community, and the environment by disposing of unwanted medications safely.



Figure 11: Sample educational script language

A sample press release and two fliers are in Appendices 2 and 3.

Data Collection

To an extent, the amount and type of data collected will be a function of how you intend to use the data. An inventory of the controlled substances received is required. Federal law dictates that an inventory of the type, dosage, and amount of controlled substances accompany it through final destruction. The point of collection is the moment at which that data should be recorded. Below, figure 12, is a sample controlled substance inventory. Medications come in a number of forms, including tablets, liquid, ointment, inhalers, powders, and patches. The vast majority will be in the form of tablets, but when accounting for the amount of material, be sure to indicate if it is in a form other than a tablet, and what that form is.

Federally Controlled Substances Received		
Date ---		
Received by: Name & signature of law enforcement		
Witnessed by: Name & signature of pharmacist		
DRUG	DOSAGE	AMOUNT
Acetaminophen/codeine	#3	62 tablets
Alprazolam	0.25 mg	30 tablets
Ambien	10 mg	198 tablets
Clonazepam	.5 mg	177 tablets
Codeine sulphate	30 mg	49 tablets
Concerta	27 mg	27 tablets
Darvocet	100 mg	6 tablets
Diazepam	5 mg	2 tablets
Duragesic	75 mcg	1 tablets
Endodan	4.88/325	42 tablets
Hydrocodone-acetaminophen	650 mg	13 tablets
Hydrocodone/apap	5/500	120 tablets
Robitussin with codeine liquid		230 ml

Figure 12: Example of controlled substance inventory

In addition to an inventory of controlled substances, you may elect to do a complete inventory of all medications received. A sample of this type of inventory is below, figure 13. While this adds to on-site staff time and may require an additional pharmacist, there are several reasons for collecting this data.

1. A complete listing of what is shipped in the hazardous waste containers is available to the hazardous waste company. This can be valuable should there ever be a question of what was shipped and to verify that no controlled substances were in the container.
2. Learn how much material is brought in, on average, by each individual in your service area. This can be useful for planning future events and budgets.
3. Learn how much is able to be packed in what size containers, and if multiple events are held, how packing efficiencies improve and why.
4. National research is being conducted to determine waste in the pharmaceutical industry. You can provide your data to the Community Medical Foundation for Patient Safety national registry of unused and expired medicine <http://www.communityofcompetence.com/registries.htm>. One caveat about providing data to the registry is that it has data forms that it requests be used in order to provide the necessary information.

Non-controlled Medications Received		
Drug	Dosage	Amount
Aceon	4 mg	84 tablets
Acepromazine	5 mg	6 tablets
Acetaminophen	325 mg	3 tablets
Acetaminophen	160 mg	96 tablets
Acetaminophen	80 mg	120 tablets
Acetaminophen	500 mg	2 tablets
Acetaminophen, aspirin, caffeine	(headache)	200 tablets
Aciphex	20 mg	9 tablets
Actifed		36 tablets
Advil	200 mg	39 tablets
Advil children's liquid	1 oz	0.5 fluid
Afrin spray		5 ml
Aldactone	100 mg	88 tablets
Aleve	220 mg	66 tablets
Alka-Seltzer	325/1700/1000	14 tablets
Alka-Seltzer morning	500/65	144 tablets
Antibiotic ointment		½ ounce
Clobetasol	.05%	30 g
Erythromycin eye ointment		1.5 g
Fleet enema		1.5 fl oz
Flonase	50 mcg	9 g
Imodium ad	2 mg	21
Imodium ad liquid		1/2 oz
Oxytrol	3.9 mg	6 patches
Tiotropium Bromide Inhalation Powder		2 blisters

Figure 13: Example of non-controlled medication inventory

During the pilots, all of the collections conducted a short survey of participants. A sample is in Appendix 1. At a minimum, we suggest asking where people live, keeping track of the number of people that bring in medication, and learning what advertising strategies worked.

We also suggest that you keep track of:

- The volume of material shipped as hazardous waste.
- The volume of controlled substances.
- The weight of material shipped by the hazardous waste hauler.

This data will help you assess the amount of material brought in by individuals and to strategize about cost saving for future events. For example, might it have been less expensive to pay the hazardous waste hauler by weight rather than by volume?

Costs

How much an unwanted medication collection will cost is, of course, one of the most pressing questions. We cannot provide a definitive answer, but information from the eight pilot collections provides a starting point.

1. **Hazardous waste disposal.** All of the pilot collection events took place in New England and all of the events used Clean Harbors Environmental Services (Clean Harbors) as the hazardous waste hauler. The average person brought in approximately one gallon of material. The per gallon fee to Clean Harbors varied significantly for the events that were held in conjunction with HHW collections as compared to those that were stand-alone.

Type of Collection	Average Per Gallon for Disposal	Transportation Fee
With HHW	\$12	None ⁹
Stand-alone	\$23	\$294

Figure 14: Hazardous waste disposal costs

In addition, if the collection was *not* in conjunction with a HHW event, there was a transportation/pick-up fee. As a result, programs that were held in conjunction with HHW programs were much less expensive than stand-alone events. And, the one pilot collection that was held at a permanent HHW collection facility was even less expensive: \$7/gallon for disposal and no transportation fee.

We considered pricing by weight instead of by volume, but the cost advantage would not be realized until 55-gallons or more was collected.

2. **Law enforcement.** In all but one instance, overtime was paid for law enforcement participation. The hourly rate varied by jurisdiction, but on average was \$45/hour. This ranged from a low of \$25/hour to a high of \$64.59/hour.

In addition to time on-site, the hours charged are likely to include time getting to the event, going back to the office, and storing the medications in the evidence storage locker. Together, this may add at least one hour to the time charged. In addition, there may be a minimum number of hours that must be covered, and in one instance overtime could only be charged in four-hour blocks, even though the amount of time involved was under eight hours.

3. **Pharmacist.** During the pilots, we were frequently successful in having the services of the pharmacist donated by a sponsoring entity, or by the pharmacist himself. Nationally, the average salary for pharmacists is approximately \$50/hour.

⁹ One combination HHW/unwanted medication collection was charged a transportation fee because a separate collection site, on the same day as the main collection, was used for the unwanted medication.

4. **Controlled substance destruction.** In no instance did the law enforcement agency charge for the cost of destroying the controlled substances. The volumes were relatively low (ranging from ½ to 2.5 gallons) and in many cases another agency was responsible for the actual destruction of controlled substances.

Although there was no charge to the collections for the controlled substance destruction, the burden that this places upon law enforcement must be acknowledged. This includes using space in evidence storage lockers, which is generally quite limited under the best of circumstances, administrative and reporting obligations, and ensuring that there is witnessed destruction of the medications.

5. **Advertising.** How much advertising is done, and what form it takes, is an event specific activity.

6. **Staff time.** Planning for and implementing an unwanted medication collection is time-consuming. The key factors are securing law enforcement and a pharmacist. Once this is accomplished, the rest of the event is easy to plan, organize, and implement. Examples of time requirements are found in the case studies, Section VIII , below.

7. **Supplies.** Assuming that the majority of supplies are materials that are already on hand or can be readily borrowed, such as tables, chairs, a laptop and printer, the cost of supplies should be quite nominal. Providing water and disposable gloves will likely be the major costs.

Developing partnerships with pharmacies, police departments, hospitals, and other agencies may help to defray some of the costs. We found that police departments are in favor of these collections because it gets controlled substances out of homes and away from potential misuse on the streets. Working with TRIAD and other senior organizations can also be an effective way to collaborate and get the word out about the collections.

VII Conclusion

There is growing interest in and demand for environmentally responsible and legal ways to dispose of unwanted medications. Holding an unwanted medication collection requires careful compliance with state and federal legal requirements, and this can be daunting. This guidance document provides a roadmap for conducting such an event. We can hope that in time, federal and state laws may be modified to make the collection of unwanted medications less complex. This will lead to more collections and greater awareness of the need for safe disposal options.

VIII Case Studies

Case Study #1: Senior Center Montague, Massachusetts December 2004

Organizer: Franklin County Solid Waste Management District
info@franklincountywastedistrict.org

Collection Site: Montague Senior Center, Massachusetts. Held in conjunction with regular social hour.

Hours: Wednesday, 9 – noon.

Staff Hours¹⁰

Planning: 11 hours

- Gathering information on senior citizen centers, logistics, police, publications, etc.
- Plan logistics with senior center, hazardous waste hauler, local hospital, police.
- Finalizing arrangements with pharmacist, police.
- Site visit

Outreach: 17 hours

- Calls to senior centers
- Develop flier and press release. Distribute.
- Follow-up phone calls

On-site: 4 hours per person

Staffing

- Pharmacist
- Data entry
- Greeter
- Policeman

Follow-up: 5 hours

- Review, report, pay bills

¹⁰ This was the first collection event held and so the number of hours for planning and outreach were high.

Costs

- Staff
 - Data entry – 4 hours @ \$30/hour = \$120
 - Pharmacist: - services donated
 - Police: 4 hours @ \$37.50/hour = \$150
 - Organizer -
 - Primary staff = 36 hours, \$1,260
 - Assistant staff = 10 hours, \$350
- Hazardous waste disposal: \$450 (\$150 disposal, transportation \$300)
- Outreach:
 - 500 fliers & fact sheets - \$100
 - 30 mailings of fliers - \$12
- Supplies:
 - Poster board & stakes for on-site signage - \$5

Participation

- Open to 25 towns.
- Average population: 2,167.
- Furthest distance traveled: 17 miles.
- 4 towns represented.
- 6 participants (two of whom brought in one medication each).
- Received: 140 items¹¹ (25 controlled (18%)).
- Volume: 5 gallons non-controlled, 1 gallon controlled.

Lessons Learned

- Because several seniors forgot about the event, in the future purchased radio ads for the day of the event would be helpful to remind people about the event.
- Seniors do not like to travel (or are unable to travel) long distances. Holding events in each town/community will most likely prove to be most successful.
- Each participant tends to bring in multiple types of drugs. So, while participation at the pilot was low, the volume collected for a pilot was significant. This gives some indication that if a larger event is held, whether targeted toward the general public or again with seniors, volumes could be quite substantial.
- It is clear that a great deal of education is needed to inform the general public, as well as wastewater treatment officials, boards of health, and regulators to get the word out about the contamination problems posed by the disposal of drugs down the drain and in the garbage.
- There are better mechanisms available for outreach than we used, including the TRIAD program officers.

¹¹ An "item" is a container of medications. So, 140 containers of medications were received.

**Case Study #2: With Regional Household Hazardous Waste Event
Wilbraham, Massachusetts
September 2005**

Organizers: Wilbraham and East Longmeadow (Massachusetts) town recycling representatives

Collection Site: Minnechaug Regional High School, Wilbraham, Massachusetts. Four-town event.

Hours: Saturday, 9 – 1.

Staff Hours

Planning: 25 hours

- Arranging financial contribution by regional hospital
- Site visit
- Site logistics
- Arranging for volunteers to assist (2)
- Arranging for pharmacist
- Arranging for tent, use of printer in building, access to electricity

Outreach: 8 hours

- Press release
- Fliers
- Display advertising (modified display ad for household hazardous waste event)

On-site:

Staffing

- Pharmacist – 6 hours
- Pharmacist assistant – 6 hours
- Data entry/supervisor – 7 hours
- Greeters (2) – 4 hours each
- Policeman – 5 hours

Follow-up: 4 hours

- Data analysis, reports to each town, thank you to hospital, pharmacist, volunteers

Costs

- Staff
 - Data entry/supervisor – 7 hours @ \$30/hour = \$210
 - Pharmacist: Services donated by regional hospital
 - Police: 5 hours @ \$39/hour = \$195
 - Greeters – volunteers
 - Pharmacy assistant – volunteer
 - Organizing
 - Primary staff = 33 hours = \$1,000
 - Assistant staff = 15 hours = \$200
- Hazardous waste disposal: \$375. Paid for with donation from regional hospital.
- Tent rental: \$300. Paid for with donation from regional hospital.
- Sharps disposal - \$100 (unplanned cost)
- Outreach – costs included in hazardous waste collection.

Participation

- Collection open to 4 towns.
- Average population: 12,094.
- Participants from all towns. Furthest distance traveled 11 miles.
- 18 participants.
- 11% of number HHW collection participants brought medications.
- Received: 537 items (13 controlled (2%)).
- Volume: 31 gallons non-controlled, 1 gallon controlled.

Lessons Learned

- It takes many people working together and working hard. Even though there were only 18 participants, it required intensive and continuous work on the part of five people. And this work lasted longer than the scheduled collection hours.
- Access to electricity is an absolute requirement, as is shelter.
- There is a lot of paper recycling potential. It is primarily paperboard. It comes from removing the outer packing from medications. Approximately 15 gallons of paper were recycled and several cardboard boxes.
- There were two gallons of trash and six gallons of sharps. Sharps were *not* accepted at the events, but someone dropped off several boxes of unused hypodermics from a diabetic who had died. And, someone else dropped off a one-gallon sealed red sharps container. Because these materials were buried deep in boxes of lots of medications, we do not know this happened until the people had left.
- A significant number of medication samples came in.

**Case Study #3: With Permanent Household Hazardous Waste Collection
Wolfeboro, New Hampshire
August 2006**

Organizer: Lakes Regional Household Hazardous Product Facility, and the towns of Wolfeboro and Alton

Collection Site: Lakes Regional Household Hazardous Product Facility.

Hours: Saturday, 9 – noon.

Staff Hours

Planning: 10.5 hours

- Meetings with Board
- Site visit
- Securing pharmacist
- Arrangements with police
- Arrangements with hazardous waste hauler

Outreach: 17.5 hours

- Develop flier, press releases, distribution, radio interview
- Follow-up phone calls

On-site:

Staffing

- Pharmacist - 3.5 hours
- Pharmacist assistant – 3.5 hours
- Data entry– 4 hours
- Greeter– 3 hours
- Policeman– 4 hours

Follow-up: 2.5 hours

- Review, report, bill paying

Costs

- Staff
 - Greeter – volunteer
 - Data entry/site supervisor – 4 hours @ \$30/hour = \$120
 - Pharmacy assistant = 3.5 hours @ \$50/hour = \$175
 - Pharmacist: 3.5 hours @ \$50/hour = \$175.
 - Police: 5.5 hrs @ \$38 = \$209.00
 - Organizer – volunteer
 - Organizing
 - Primary staff = 25.5 hours @ \$25/hour = \$625
 - Assistant staff = 5 hours @ \$14.75 = \$73.75
- Hazardous waste disposal: \$138
- Copying: 10 reams of paper = \$25
- Supplies: Gloves, markers, water = \$35

Participation

- Collection was open to 27 towns.
- Average population: 1,242.
- 10 towns represented.
- Furthest distance was 32 miles.
- 27 participants.
- 40% of number household hazardous waste collection participants brought medications.
- Received: 392 items (16 controlled (4%)).
- Volume: 21 gallons non-controlled, 1 gallon controlled.

Lessons Learned

- We asked each person *before* we took their medications if they had any needles of any type. If they said yes, we explained that they needed to take them home with them. This worked out well and we diverted several people from leaving sharps with us.
- There is a real desire for these collections. Everyone was asked if they would like to have another opportunity for unwanted medication disposals and only one person said no.
- We thought at first that holding it as part of the monthly household hazardous waste event was going to be difficult and disruptive, but it worked very smoothly having it integrated into the regular activities.
- The police were thrilled with the one-gallon of controlled medications we “took off the street.” They commented that it was better than several pounds of marijuana in terms of crime and hoped that many more such events would take place.
- It is hard to get the word out and to get people to participate in a rural setting. The travel distances are significant.

**Case Study #4: In-pharmacy
South Portland, Maine
February 2005**

Organizer: Northeast Recycling Council, Inc. in cooperation with the CVS/Pharmacy Corporation.

Collection Site: CVS Mill Creek, South Portland, Maine

Hours: Saturday, 9 – 5.

Staff Hours

Planning¹²: 80 hours

1. CVS Pharmacy Supervisor – 40 hours, including headquarters discussions
2. Northeast Recycling Council, Inc. – 40 hours
 - Conference calls between CVS legal counsel, government relations staff, Maine DEP hazardous waste staff, Clean Harbors (hazardous waste professionals), PharmEcology Associates, LLC, and the USDEA.
 - Site and staffing logistics.
 - Regulatory compliance.
 - Arranging for police.

Outreach: 8 hours

- Designing and obtaining signage.
- Posting signage in store.
- Preparing and distributing press release and fliers. CVS attached fliers about the collection to every purchase made in a CVS in all CVS stores in southern Maine for two weeks preceding the collection.
- Follow-up conversations.

On-site:

Staffing

- Pharmacist – 11 hours
- Pharmacist assistant – 8 hours
- Data entry/site supervisor – 11 hours
- Greeter– 8 hours
- Policeman– 9 hours

Follow-up: 4 hours

- Review, report, pay bills

¹² This was the first in-pharmacy collection and the first collection open to the public, so the number of planning hours was unusually high.

Costs

- *Staff*

On-site

- CVS Pharmacist, 11 hours & CVS Pharmacy Technician, 8 hours: \$600
- Greeter, 8 hours @ \$25/hour = \$200
- Police, 9 hours @ \$35/hour = \$315
- Data entry/site supervisor, 11 hours @ \$30/hour = \$330

Planning

- CVS, 40 hours = ~ \$400
- NERC, 40 hours @ \$30/hour = \$120
- Hazardous waste disposal: \$1,150 (\$900 disposal, \$250 transportation)
- Advertising:
 - Display ads (3 in Portland Herald): \$1,000
 - Printing/copying for in-store fliers: \$75

Participation

- Open to whole region.
- Furthest distance traveled: 60 miles.
- People came from 14 towns.
- 51 participants.
- Received: 412 items (37 controlled (9%)).
- Volume: 38 gallons non-controlled, 1.5 gallons controlled.

Lessons Learned

- While we are very grateful to the South Portland Police Department for taking custody of and responsibility for the destruction of the controlled substances, some Advisory Committee members caution that relying on public sector financial support and goodwill should not be considered a sustainable model for the destruction of controlled substances.
- The in-store promotion (including in surrounding area CVS's) was very successful.
- 25% of the participants were *not* regular CVS customers.
- Space behind the counter was very limited. Having another person and container behind the counter would have been difficult without directly interfering with the flow of regular pharmacy business.
- CVS had a separate container available for confidential information destruction, so we were able to take off cardboard packaging with patient information and put it in there. We generated approximately 15- gallons of this material.
- While there were no HIPPA requirements that personal information be destroyed, CVS insisted that all such information be crossed out before being shown to the pharmacist. This required extra volunteer assistance.

**Case Study #5: With a Blood Drive
Rutland, Vermont
May 2006**

Organizer: Rutland County Solid Waste District rswd@rcswd.com

Collection Site: Diamond Run Mall, Rutland, Vermont

Hours: Saturday, 11 - 4

Staff Hours

Planning: 35 hours

- Arrangements with American Red Cross, Diamond Run Mall
- Securing pharmacist
- Coordinating with Sheriff's Department
- Site visit

Outreach: 10 hours

- Developing, copying, distributing press releases and fliers
- Follow-up phone calls

On-site:

- Site Supervisor – 7 hours
- Solid Waste Advisory Committee staff – 5 hours
- Greeters – 4 hours each
- Sheriff – 7 hours
- Pharmacist – 5.5 hours
- Pharmacist assistant – 5 hours
- Data entry – 7 hours

Follow-up: 4 hours

- Reports, data analysis

Costs

- Staff
 - Site supervisor – 7 hours @ \$25/hour = \$175
 - Greeters – 2 volunteers
 - Data entry – 7 hours @ \$30/hour = \$210
 - Pharmacy assistant - volunteer
 - Pharmacist: 7 hours - donated
 - Sheriff: 6.5 hours @ \$25/hour = \$162.50
 - Organizer -
 - Primary staff = 59 hours, \$1,515
 - Assistant staff = 4 hours, \$88
 - Solid Waste Advisory Committee staff = 10 hours, \$300

Hazardous waste disposal: \$742 (\$225 transportation, \$517 disposal)

Outreach:

- 2,000 fliers copied - \$45
 - Fliers mailed to 23 town clerks - \$20
 - Banners/Posters - \$190
 - Rutland Herald display ads (2) - \$455
 - Rutland Business Journal display ad (1) - \$265
- Total: \$975

Supplies:

Lunch & drinks for staff: \$35

Participation

- Open to the whole County.
- Participants from 10 towns.
- Furthest distance traveled: 18 miles.
- Average town size among towns represented: 1,375.
- 28 participants.
- Received: 632 items (44 controlled (7%)).
- Volume: 30.5 gallons non-controlled, 2.5 gallons controlled.

Lessons Learned

There was a great deal of outreach and we were disappointed by the number of participants. Flyers were distributed through the Meals on Wheels program (500 copies), a notice was put on the public access channel, articles, and notices were placed in the Rutland Business Journal, Sam's Good News, the Mountain Times, and the Rutland Herald. Flyers were distributed to all the Town Clerk's offices, several libraries and to several nursing homes in the area. Notices were also placed at various locations at the Mall.

- Collaborating with the Mall and with the American Red Cross Blood Drive was a good strategy and one we would repeat.

IX APPENDICES

1. Sample survey
2. Sample press release
3. Sample fliers (2)
4. Collection Overview for State Agency Consideration
5. Best Management Practice Recommendations for the Disposal of Unwanted Medications Not Controlled by the USDEA Generated at Consumer Collection Programs
6. Medications Should Stay in their Original Containers for Disposal
7. Sample Letter to Police Requesting Participation
8. Follow-up Memo to Police Confirming Collection Details
9. References

APPENDIX 1: Sample Survey

Unwanted Medications Collection DATE

Town you live in: _____

Why is the medicine being disposed of?

- Didn't like the medicine (made me ill, etc.)
- Expired/out-of-date medicine
- Taken off medicine/no longer needed
- Death (family member/friend)
- Cleaning house
- Never used the prescription
- Drug was pulled off the market
- Other _____

Whose medication was it?

- Mine
- Family or household member
- Friend
- Pet

How did you find out about this event?

Comments/Recommendations:

APPENDIX 2: Sample Press Release
LETTERHEAD
TIME SENSITIVE PRESS RELEASE - FOR IMMEDIATE USE

Date

For more information, contact:

Free Collection & Disposal of Unwanted Medication



Do you have unwanted medicine in your home? Help protect your family, community and the environment by properly disposing of them.

On DATE, TIME [Host] is offering a free medicine disposal opportunity. The collection will take place at LOCATION. This is a free event for environmentally safe disposal. **NO REFUNDS OR EXCHANGES WILL BE PERMITTED.**

WHAT TO BRING TO THE COLLECTION SITE:

- Expired or unwanted prescriptions and medicine,
- Vitamins,
- Veterinary medications, and
- Over the counter medicines.

Do NOT bring thermometers, needles, or medical waste of any type.

WHAT TO DO: This is an opportunity to clean out your medicine cabinets and bring all unwanted medications, including pet medications, to the event for proper disposal.

WHAT WILL HAPPEN: There will be a police officer present to supervise the collection. All medicine will be sent to a hazardous waste facility for secure incineration. ***NO MEDICINE WILL BE RE-USED OR RE-SOLD.***

WHAT ABOUT PERSONAL INFORMATION ON BOTTLE LABELS? Please use a marker to cross off your name. Be sure to leave the name of the medication visible.

WHAT INFORMATION WILL BE ASKED OF YOU? You will be asked a few general questions, such as town of residence, why the medicine is no longer wanted and how long they've been kept, and how you heard about this event. *No personal information will be requested.*

You have the opportunity to safely dispose of your unwanted prescription medications at no cost. Spread the word to your friends and family. This is an important new program that will help to protect your health, your children's and grandchildren's health, our community and the environment.

For more information, call _____

APPENDIX 3: Sample Fliers

HAZARDOUS WASTE & MEDICATION COLLECTION

Saturday, September 9th
Montague Highway Garage
Rt. 2 Park & Ride, Charlemont
Orange Transfer Station

It's Free!



Pre-Registration Required by September 1st
Register online at the xxx website: www.xxx
or fill out the form on the back of this sheet.

For residents of the following towns: xxxxxxxx



WHAT TO BRING

Any substance labeled
**CAUSTIC, TOXIC, CORROSIVE,
 POISON, FLAMMABLE, WARNING, DANGER, CAUTION**

From the yard

Pesticides
 Insect sprays
 Fungicides
 Flea powder
 Herbicides
 Root killers
 Rodent killers
 Muriatic acid
 No-Pest strips
 Pool chemicals
 Lighter fluid

From the Garage

Used motor oil
 Engine degreaser
 Gas treatments
 Gasoline
 Kerosene
 Solvents
 Automobile batteries
 Brake fluid
 Carburetor cleaner
 Creosote sealer
 Asphalt sealer
 Refrigerants
 Antifreeze
 Transmission fluid

From the Workshop

Roofing tar
 Solvents
 Varnish
 Sealants
 Wood strippers
 Rust inhibitors
 Paint thinners
 Degreasers
 Wood preservatives
 Wood strippers
 Stains
 Lead & oil-based paints
 (No latex paint)
 Photo chemicals

From the Home

Oven cleaners
 Furniture polish
 Upholstery cleaner
 Metal polish
 Mothballs
 Spot remover
 Drain cleaners
 Toilet cleaners
 Fluorescent light bulbs
 Mercury thermometers
 Mercury thermostats
 Chemistry kits
 Arts & crafts supplies
 NiCad & button batteries



What Not To Bring

Latex paint, empty containers from hazardous products, asbestos, gas cylinders, radioactive material, explosives (including ammunition & fireworks)



Special Unwanted Medications Collection

To be held in conjunction with the Household Hazardous Waste Collection on September 9th, at the Montague Highway Garage. This is an opportunity for you to clean out your medicine cabinets, drawers, & cupboards & bring all expired & unwanted medications (prescription & over-the-counter) for proper disposal. Pre-registration required. For more information contact the Solid Waste District at xxx or visit:

www.xxx

Do you have unwanted medications around your home? Help protect your family, community, and the environment by properly disposing of them.

FREE UNWANTED/EXPIRED MEDICATIONS COLLECTION

SATURDAY, SEPTEMBER 9TH
MONTAGUE HIGHWAY GARAGE

**By Appointment Only.
You Must Pre-Register to Participate.**

It's easy to participate, it's FREE, and you can enter to win a \$25 gift certificate from Brooks Pharmacy!

WHAT TO BRING TO THE COLLECTION

- ◆ Expired or unwanted prescriptions or over-the-counter medicines
- ◆ Drugs that didn't work for you, a family member, or pet
- ◆ Drugs that are no longer used
- ◆ Medicine from deceased family members
- ◆ Unknown tablets and capsules

Register on-line at:
www.franklincountywastedistrict.org
or call 772-2438.

APPENDIX 4: Collection Overview for State Agency Consideration

NERC

Northeast Recycling Council, Inc.

139 Main Street, Suite 401 • Brattleboro, Vermont 05301-2800
802.254.3636 • 802.254.5870 fax • www.nerc.org • info@nerc.org

How an Unwanted Medication Collection & Destruction Project Would Operate in New Hampshire

BACKGROUND

The Northeast Recycling Council, Inc. (NERC), a non-profit organization that works on issues related to solid waste, recycling, and decreased toxicity of the solid waste stream, has been awarded grants by the U.S. Environmental Protection Agency and Department of Agriculture to develop environmentally sound and legal strategies for collecting and destroying unwanted medications from consumers.

The need for such a project arose from the growing scientific evidence that over-the-counter and prescription medications are finding their way into water supplies. While non-metabolized medication is certainly the primary source of this contamination, disposing of unwanted medications down the drain or in the trash has added to this problem. This project has sought to develop and test strategies for preventing unwanted medications from environmentally unsound disposal, while ensuring that they are destroyed and protected from diversion.

A component of the grants is to develop and test collection strategies throughout the multi-state region. All collections are supervised by law enforcement and all collected medications are destroyed. In 2005, collections were held in Maine and Massachusetts, with the hope of holding events in Connecticut, New Hampshire, New Jersey, and Vermont in 2006.

Any collection event held in New Hampshire will fully implement all best management practices and legal requirements that have been identified and developed through these grants. The development of collection strategies has been the result of the collaborative efforts of many individuals and organizations, including:

- Rutland County (VT) Solid Waste Management District
- Rutland County (VT) Sheriff's Department
- CVS headquarters legal and government relations offices
- Franklin County (MA) Solid Waste Management District
- Maine Department of Environmental Protection
- Massachusetts Department of Public Health
- Massachusetts Board of Pharmacy
- Massachusetts Department of Environmental Protection

- Vermont Agency of Natural Resources
- Clean Harbors Environmental Services
- PharmEcology Associates, LLC
- Pharmacy Supervisor for CVS Mill Creek, South Portland, Maine
- Bayer Pharmaceutical

In addition, guidance was provided by the U.S. Drug Enforcement Agency (DEA).

The Law

Federal Drug Law

The U.S. DEA prohibits the transfer of dispensed controlled substances from an individual to a pharmacist, reverse distributor, or any other entity registered with the U.S. DEA to handle or manage controlled substances. The only exception is in the case of a drug recall or a dispensing error. However, controlled substances may pass into the control and custody of law enforcement officials because they fall outside of the registrant system.

Thus, in order to legally collect unwanted controlled substances it is *an absolute necessity* that law enforcement officials be on-site, participate in the collection, and take physical control and custody of all controlled substances.

Federal Hazardous Waste Law

The U.S. EPA Resource Conservation and Recovery Act regulates the transportation, treatment, and disposal of hazardous waste, but exempts waste generated by consumers (household waste) from regulation. Some prescribed and over-the-counter medications are known to require management as a hazardous waste when they come from an entity other than an individual.

In addition, the U.S. Environmental Protection Agency has made clear that reverse distributors may not accept dispensed medications as part of the waste stream. It would be a violation of federal hazardous waste laws.

State Hazardous Waste Law

Like federal law, New Hampshire state hazardous waste laws do not regulate individuals. Thus, materials that have hazardous waste characteristics may, by law, be disposed of in the trash. PharmEcology Associates, LLC has estimated that up to 25% of over-the-counter and prescription medications, by type not by volume, would be considered a hazardous waste if generated by a business.

Collection Logistics

The EPA and USDA grants to NERC include several tasks prerequisite to conducting an unwanted medication collection:

- Identify strategies for the collection and end-of-life management of unwanted medications that comply with state and federal solid waste, hazardous waste, and drug laws.

- Determine and implement best management practices for disposal of unwanted medications.
- Test various collection strategies.

Each of these requirements have been carefully researched and implemented for the pilots held to date. Of particular significance is that all medications collected are destroyed, and that controlled and non-controlled substances are segregated from each other with controlled substances passing directly into the custody of law enforcement.

All medications are destroyed

A multi-stakeholder Advisory Committee that includes individuals with extensive experience in the management and disposal of medications, as well as pharmacists, solid waste and environmental professionals has provided essential guidance and direction for this project. An underlying premise has been that all collected medications, whether controlled or not, will be destroyed per U.S. DEA destruction criteria for controlled substances. In addition, controlled medications are subject to witnessed destruction. The Committee has determined that non-controlled medications should be managed and incinerated as hazardous waste.

Among the reasons for the determination to destroy non-controlled substances as hazardous waste were:

1. Decreased access to medications, thus preventing diversion and inappropriate use of medications, as well as minimizing the risk of poisoning children and pets.
2. The presence of medications with hazardous waste characteristics in the waste mix.
3. Physical destruction of the medications for the purpose of rendering them unrecoverable, as required by federal drug law, is considered to be essentially a practical impossibility in most settings, with the exception of hazardous waste incineration.¹³
4. Sending a message about the importance of safe end-of-life management of medications.
5. Avoiding water pollution from medications in landfills.

Controlled substances are segregated from non-controlled substances

In order to ensure that controlled substances are secure from the risk of diversion, all controlled substances pass from the consumer to the custody of law enforcement. The collection strategy **relies upon the expertise of a pharmacist** to determine which medications are regulated as controlled substances and to direct law enforcement to take custody of these materials. While it is illegal for pharmacists to take possession of dispensed medications, they may provide advice about their character.

Testing of Collection Strategies

The overriding goals that have guided the development of the collection strategy have been to:

¹³ Conversation with Vicky Seeger, U.S. DEA, October 2004

- 1) Be in full compliance with federal and state laws;
- 2) Maximize site safety; and
- 3) Ensure the safe disposal of the medications.

NERC has already participated in the successful implementation of pilots in a Senior Center, a pharmacy, as part of a conference session, and as part of Household Hazardous Waste Collections.

Collection Details

Any unwanted medication collection held in New Hampshire will, of necessity, be limited to a few hours on a specific day. This is due to the requirement of the active involvement of law enforcement and the practical limitations that this imposes. In addition, any event will be held in partnership with a New Hampshire organization or subdivision of the State. NERC will *not* be the host or lead organization. Nor will it be providing financial support. NERC's role is limited to technical assistance, guidance, data collection, and facilitation.

STAFF

No matter the venue, there is certain staff essential to the safe and legal conduct of an unwanted medication collection event.

- a. Law enforcement – on- and off-site
- b. Pharmacist
- c. Greeter
- d. Data entry
- e. Supervisor
- f. Hazardous waste company

Following are staff-specific roles and responsibilities.

LAW ENFORCEMENT

On-site:

- Safety (prevent diversion)
- Take custody of controlled substances
- Sign and date inventory of controlled substances as witness that materials received
- Initial sealed container of controlled substances being taken off-site
- Transport controlled substances to secure evidence storage locker
- If pharmacist does not conduct inventory, law enforcement official conducts physical inventory
- Stay on-site until all medications have been packed, sealed, and placed onto hazardous waste company truck.

Off-site:

- a) Maintain secured locked possession of controlled substances along with U.S. DEA required inventory
- b) Arrange for and ensure U.S. DEA authorized destruction of controlled substances

Pharmacist

- 1) Determine if a medication is a controlled substance
- 2) Inventory controlled substances. The U.S. DEA required inventory is the name of the medication, dosage, and amount. For example:

Federally Controlled Substances		
DRUG	DOSAGE	AMOUNT
acetaminophen with codeine	#3	62
Alprazolam	0.25 mg	30
Ambien	10 mg	198
Clonazepam	0.5 mg	177
codeine sulphate	30 mg	49
Concerta	27 mg	27

- Put medications back in original container and hand to law enforcement official
- Sign and date the printed inventory as a witness that accurately lists what went into custody of law enforcement
- Answer questions from the public and discuss why the medication may be "unwanted" by the patient to determine if there is any underlying issue that may require follow up medical attention.
- Optional role: conduct inventory for all medications brought to event

Greeter

- Direct people to collection
- Provide pens for obscuring personal information, as desired
- Optional: Conduct survey

Data Entry

- Enter inventory of medications
- Print out inventory for witnessing
- Maintain copy of witnessed inventory

Site Supervisor

- Ensure that all operations are running smoothly
- Ensure that law enforcement does not leave site until all medications have been removed by hazardous waste company
- Maintain records
- Answer operational questions as they arise

Hazardous Waste Company

- Provide drums/containers for collection of non-controlled substances
- Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction
- Takes place on same day, at close of event
- Provides tracking paperwork from point of collection through destruction
- Incinerates non-controlled substances in licensed hazardous waste incinerator

SITE SAFETY

A great deal of time and effort goes into determining the best on-site staffing, traffic flow, security, and equipment. The primary considerations are public safety, ensuring that medications are not diverted, and that safe and legal disposal occurs. The presence of law enforcement, the hazardous waste company, and ensuring that the site is configured to minimize the risk of diversion is essential.

DESTRUCTION OF MEDICATIONS

All non-regulated medications will be packed and disposed of as hazardous waste through a licensed hazardous waste hauler. In the instance of New Hampshire, because the potential pilot location has not been identified, we do not yet know who the hazardous waste hauler may be. To date, Clean Harbors has been the company used for all events. With any hazardous waste hauler that is used, the medications will be packed in containers that meet federal Department of Transportation requirements for the shipment of hazardous waste. The materials will then be sent to a hazardous waste incineration facility that is authorized to dispose of medications.

As mentioned above, the controlled substances are destroyed as required by the U.S. DEA, through the programs and systems in place with the custodial law enforcement agency.

Conclusion

Every effort has been made to design a safe and secure protocol for the collection and destruction of unwanted medications from the public. The advice and guidance of the New Hampshire Board of Pharmacy and other agencies is encouraged and welcomed to help ensure that any collection event held in the state meets all required procedures, operates safely, and effectively.

For more information, please contact:

Lynn Rubinstein, Executive Director, Northeast Recycling Council

lynn@nerc.org

802-254-3636

APPENDIX 5: Best Management Practice Recommendations for the Disposal of Unwanted Medications Not Controlled by the USDEA, Generated at Consumer Collection Programs

Introduction

When deciding how best to dispose of collected unwanted medications, several factors should influence the decision making process. Naturally, cost will be one factor. But when making a decision about which strategy to use in your community, be sure to evaluate whether an incinerator or landfill is permitted to handle medications; and if so, under what conditions.

It is also important to be able to track the unwanted medications from the point of collection through disposal. Due to the increased value and attractiveness of diverting medications to other users and uses, there is a growing concern about theft. As a collected material, it may appear to be a particularly “attractive” waste to scavenge. Precautions should be taken.

The disposal hierarchy that follows is based on the following essential criteria:

1. Controlled substances are separated from the medications before being shipped for disposal, and there are no controlled substances knowingly included.

A USDEA controlled substance is a medication that because of its abuse potential is regulated by the federal Drug Enforcement Administration. Because of this, controlled substances cannot be accepted by anyone other than a law enforcement official at a collection site, and are subject to specific federal disposal regulations; including witnessed destruction.

2. Under all circumstances, state and federal drug management and disposal regulations as well as solid waste management and disposal laws and permits must be observed.

Recommended Best Management Practices for the Disposal of Non-Controlled Substances

BEST: Hazardous waste incineration

SECOND BEST: Municipal solid waste incineration facility, as long as the facility has an operating permit that permits the incineration of waste pharmaceuticals. This option is based on the assumption that the State in which the medication was collected and will be disposed regards household generated hazardous waste as excluded from RCRA and state hazardous waste regulations, even if consolidated at a collection event.

NOT A BEST MANAGEMENT PRACTICE, but if no other available option

Solid Waste Landfill as long as the facility’s operating permit allows for the disposal of pharmaceuticals. In order to prevent diversion or theft, the containers should be immediately made non-recoverable, such as buried upon receipt, or a like-procedure appropriate to the specific facility. Again, the assumption is made that the states of origin and disposal regard household generated hazardous waste as excluded from RCRA regulations, including Land Disposal Restriction Forms, when accumulated at a central collection facility.

NEVER! Flush it down the drain or toilet.

ⁱ These recommendations are *not* those of these Agencies.

ⁱⁱ Other destruction options may be available, but due diligence would be required to assess the level of destruction and compliance with federal and state regulations.

APPENDIX 6: Medications Should Stay in their Original Containers for Disposal

Primarily due to the wasted space that medication containers take-up in disposal drums, the question has arisen “why not dump the medications out and dispose of the containers separately?” The Advisory Committee for this project has concluded that the medications should stay in their original containers for disposal. There are many reasons for this decision, but they include:

1. Loose, unlabeled medications pose a health hazard if diverted and ingested. The practice of some people to sell and/or consume unlabeled drugs as “trail mix” can lead to serious overdoses and death. It is not good medication management policy under any circumstances.
2. Encouraging consumers to combine them at home and then bring them in is even more fraught with risk. You only need one case of accidental poisoning to give the program a black eye.
3. Some states, like Maine, regulate household generated waste as hazardous (if it meets RCRA criteria) if returned to a facility. The drum would need to be manifested with waste codes, such as P, U, and D. If the medications were co-mingled it would be very hard to verify the contents if the barrel is inspected at the incinerator which could cause the load to be rejected.
4. Some medications are hazardous waste and even those that aren't can have hazardous properties. Handling of loose pills, especially broken pills, present a risk to individuals handling them. In addition, the dust and fumes that can be released through the “dropping” of loose pills into a container may present additional worker exposure concerns.
5. Anytime you remove medications from the identifying labels there are worker exposure and public safety risks.

APPENDIX 7: Sample Letter to Police Requesting Participation

NERC

Northeast Recycling Council, Inc.

139 Main Street, Suite 401 • Brattleboro, Vermont 05301-2800
802.254.3636 • 802.254.5870 fax • www.nerc.org • info@nerc.org

Date

Chief Ed Googins
South Portland Police Dept.
30 Anthoine St
South Portland, ME 04106

Dear Chief Googins,

As we discussed on the phone today, the Northeast Recycling Council, Inc. (NERC) hopes to hold an unwanted medication event in cooperation with CVS at its S. Portland store on Saturday, February 5, 2005, from 9 – 5.

We will be accepting both controlled and non-controlled medications for incineration. In order to comply with federal and state DEA requirements, a law enforcement official must be present and take physical possession of the controlled substances. We are asking for the services of a South Portland Law Enforcement Officer to assist us with the collection.

The overall flow of the event will be as follows:

- 1) CVS will be dedicating one of its “intake” windows to this event.
- 2) An individual will bring in unwanted medications and hand them to the CVS pharmacist.
- 3) The pharmacist will inventory the medications (type, dosage, and amount) and make a determination if it is a controlled substance.
- 4) If it is a controlled substance, it will be handed to the Law Enforcement Officer to be placed in a designated container (most likely a 5-gallon bucket with a locking lid).
- 5) At the end of the day, the Law Enforcement Officer will be presented with an inventory of the controlled substances and be asked to sign copies of the document certifying to having received the drugs. It will be witnessed by the CVS pharmacist.
- 6) Then the Law Enforcement Officer will take the controlled substances back to the police station and place them, along with the inventory, in a locked storage area. We anticipate that at the most this will involve 3 5-gallon pails.

Due to the nature of the event, and wanting to be sure that everything runs as smoothly as possible, we ask that the Law Enforcement Officer be on site at 8:30 a.m. We propose to compensate for the outside overtime from 8:30 – 5:30. If extra time is involved due to currently unforeseen circumstances, we will pay for that time as well. We understand that the hourly outside overtime rate is \$35.03/hour.

I look forward to hearing back from you on this matter. Naturally, if you have any questions, I will be happy to answer them. I look forward to working together on this exciting new project.

Sincerely,

A handwritten signature in cursive script that reads "Lynn Rubinstein".

Lynn Rubinstein
Executive Director

APPENDIX 8: Follow-up Memo to Police Confirming Collection Details

MEMO

Date: xxx
To: Raymond Zukowski, Montague Police Chief
From: Athena Lee Bradley, Program Director
RE: Collection of Unwanted/Expired Medication

This is to confirm the information that we discussed over the phone about the unwanted medications collection on Saturday, September 9th at the Montague Highway Garage.

The officer to staff the event should be onsite by 8:00 am. I am not sure yet what time we will be done, but definitely by late morning. I will be able to confirm the time better as we get closer to the date, since people have to preregister with us. The officer should be in full uniform. We will have a staff person and a registered pharmacist onsite, along with volunteers to help with traffic flow.

The pharmacist will do the sorting of the controlled from the non-controlled substances. He will do a count and a staff person will keep a record on a laptop; an inventory will be printed for your officer at the end of the collection. During the collection event the controlled substances are handed directly from the pharmacist to the police officer for placement in a 5-gallon pail. The pail is to remain with the officer at all times.

At the end of the collection we will put the collected controlled substances into an envelope, and secure it with duct tape. A copy of the inventory will be placed inside the envelope and another copy taped to the outside. A large label identifying the collected medications as "non-evidence and non-confiscated" will also be placed on the envelope.

This collection method meets the criteria for both the Drug Enforcement Agency (DEA) and the Massachusetts Department of Public Health (MA DPH). In past collections we have not had more than a half gallon's worth of controlled substances, which fit into a manila envelope.

Under the guidelines established by MA DPH, the collected controlled substances are to be stored "in a readily separable and distinguishable manner from the evidence/confiscated medications." They must be kept in identified separate containers and isolated in some manner from the evidence/confiscated medications. They can be kept in the storage locker, but law enforcement needs to have a non-criminal incident report associated with the collected medications. As per MA DPH requirements, we will arrange for destruction of the collected controlled substances at a DEA approved incinerator.

Our collection site has a covered area in case of rain. We will have coffee and other beverages. There is a restroom on site.

We will reimburse the department for the officer's time. Please call me at 772-2438 if you have any concerns or comments about the collection.

Thank you for your assistance.

APPENDIX 9: References

1. EPA website on Pharmaceuticals and Personal Care Products (PPCPs) as Environmental Pollutants
<http://www.epa.gov/nerlesd1/chemistry/pharma>
2. Brochure from Michigan on Pharmaceutical Disposal
<http://www.deq.state.mi.us/documents/deq-ess-tas-cau-RXbrochure.pdf>
3. California Integrated Waste Management Board - Guidance on Medical Waste at Home
<http://www.ciwmb.ca.gov/WPIE/HealthCare/PPCP.htm>
4. Managing Pharmaceutical Waste (Hazardous Waste and Toxics Reduction Program, Washington State, Department of Ecology)
<http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html>
5. Recycling and Disposal of Dispensed Drugs" (NAPRA, National Association of Pharmacy Regulatory Authorities - Canada)
<http://www.napra.org/docs/0/97/194/184.asp>
6. An Assessment of U.S. Pharmaceutical Donations: Players, Processes, and Products (Reich MR, ed., Harvard School of Public Health, 1999, Boston, MA)
<http://www.hsph.harvard.edu/faculty/reich/donations/>
7. Post-Consumer Residual Stewardship Program Regulation Medications 2001 Annual Report (Canada)
<http://wlapwww.gov.bc.ca/epd/epdpa/ips/meds/meds2001.html>
8. USAID Guidelines for Donating Pharmaceuticals and Medical Supplies
http://www.usaid.gov/hum_response/pvc/ofdadrug.doc