

Best Management Practices for Holding Unwanted Medication Collections A Legal & Safe Approach for Community Pharmacies

Written by Lynn Rubinstein Supported with a grant from the Community Pharmacy Foundation © November 2008

NERC | Northeast Recycling Council, Inc.

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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.

CONTENTS

	nowledgements tents	ii, iii
I	Introduction	1
II	Background The Solid Waste Solution	1
Ш	What to Expect at a Collection	2
IV	The Law	3
	Federal Law	3
	Federal Hazardous Waste Law	3
	State Hazardous Waste Law	3
	Other State Legal Requirements	3
	Board of Pharmacy Controlled substance laws and agencies	5
	Public safety laws	5
	Privacy laws	5
٧	A Legal Strategy for Collecting Unwanted Medications	6
	Controlled substances are segregated from non-controlled substances All non-controlled medications are destroyed as hazardous waste	6 6
VI	Holding a Collection Event	7
	Overview	7
	Your Collection Event, A Detailed Guide	8
	Staff	8
	Law Enforcement	g
	Pharmacist	10
	Pharmacy Students and Pharmacy Technicians	11
	Greeter	11
	Data Entry Event Organizer/Supervisor	11 12
	Hazardous Waste Company	13
	Signage	14
	Site Safety	14
	Personal Protective Equipment and Practices	14
	Packing Medications for Disposal	14
	Packing of Non-controlled Substances	15
	Packing of Controlled Substances	16
	Items for Trash or Recycling	16
	Number and Size of Containers	16
	Before Your Event, A Guide for the Event Organizer	17
	Pre-Event	17
	State Agency Authorization	17
	Budget Site Selection	17
	Agreement of Law Enforcement	17 18
	Arrange for Staffing	18

CONTENTS continued

	Hazardous Waste Hauler/Disposal Arrangements	19
	Determine Site Set-Up	19
	Determine What Will Be Collected	19
	Arrangements for Handling Sharps	20
	Arrangements for Handling Thermometers	20
	Equipment and Supplies	20
	Advertising	21
	Data Collection	22, 23
	Costs	24, 25
VII	Conclusion	26
VIII	Case Studies	27
	Case Study – Ukrop's Super Markets	27
	Case Study – CVS/Caremark, Windsor, Connecticut	34
	Case Study – Eaton Apothecary, Wellesley, Massachusetts	44
IX	APPENDICES	57
	APPENDIX 1: Sample Survey	58
	APPENDIX 2: Collection Overview for State Agency Consideration APPENDIX 3: Best Management Practice Recommendations for the Disposal of Unwanted Medications Not Controlled by the USDEA Generated at	59-63
	Consumer Collection Programs	64
	APPENDIX 4: Medications Should Stay in their Original Containers for Disposal	65
	APPENDIX 5: Sample Letter to Police Requesting Participation	66
	APPENDIX 6: Follow-up Memo to Police Confirming Collection Details	67
	APPENDIX 7: APhA Guidance on Disposal	68
	APPENDIX 8: White House Guidance on Disposal	69
TAB		_
	Table 1: Overview of pilot collections	2
	Table 2: Number of containers to be delivered	16
	Table 3: Example of controlled substance inventory	22
	Table 4: Example of non-controlled medication inventory	23
	Table 5: Hazardous waste disposal costs	24
FIGU	JRES	
	Figure 1: Outer-packaging removed for recycling	15
	Figure 2: Blister packaging	15
	Figure 3: Hazardous waste container with medications	15
	Figure 4: Items under pressure	15
	Figure 5: EpiPen™ for hazardous waste disposal	15
	Figure 6: Packed controlled substances	16
	Figure 7: Small sharps container	20
	Figure 8: Counting tray	20
	Figure 9: Sample educational script	21 38
	LIQUIE IV. DOU SUIICI SOIIDIE	.00

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 Community Pharmacy Foundation to work with community pharmacies to hold pilot unwanted medication collections, and then to develop best management practices and guidance for how to safely and legally hold such events.

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."

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 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 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 community pharmacy 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. The White House Office of National Drug Control Policy and the American Pharmacists Association (APhA) have both published guidance on the proper disposal of unwanted medications, and both encourage accessing community take-back events.

Prior to the Community Pharmacy Foundation grant, 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 part of that previous effort, it developed best management recommendations and held seven unwanted medication pilot collections, including two in community pharmacies. Through the Community Pharmacy Foundation grant, NERC helped to organize five additional community pharmacy-based collections. This guidance document reflects the experience gained through the implementation of those pilots.

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), United States Environmental Protection Agency (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.

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

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.

^{3 &}quot;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

III What to Expect at a Collection

NERC conducted seven unwanted medication pilot collection events in community pharmacies 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.

Table 1: Overview of pilot collections

Pilot Location	Number of Participants	Average Volume in Gallons per Participant	Average Cost per Gallon Destruction of Non-Controlled Substance	Hazardous Waste Transportation Fee
CVS Pharmacy – Portland, ME (February 2005)	51	0.77	\$24	\$250
CVS Pharmacy – Simsbury, CT (September 2006)	49	1.20	\$11	\$100
Big Y Pharmacy – Tolland, CT (September 2007)	15	1.67	\$19	\$200
Ukrop's Pharmacy – Richmond, VA (September 2007)	17	0.97	\$41	\$220
CVS Pharmacy – Windsor, CT (April 2008)	122	1.48	\$14	\$210
Eaton Apothecary – Wellesley, MA (June 2008)	41	0.84	\$16	\$250
Eaton Apothecary – Wellesley, MA (October 2008)	80	0.90	\$12	\$250
AVERAGE	54	1.1	\$20	\$211

Amount collected: While the collections had varying degrees of participation, the amount of material collected from each participant was high. On average:

- Each person brought in approximately 1.1 gallons of non-controlled substances (in the original containers).
- Each person brought in 2 containers of controlled substances.
- Approximately 15 percent of what was received was controlled substances. This figure ranged from a low of 9 percent to a high of 36 percent.



Participation: Turnout was relatively low for most events, with less than one percent of the population base participating despite heavy advertising in most of the programs. Why? The theory is unfamiliarity with the topic, but this is changing. For example, Eaton Apothecary held two collections at the same store - the first in June 2008 and the second in October 2008. The advertising strategy was similar, but the response was quite different; twice as many people at the second event. There is increasing national and state media attention on the issue and more customers are looking for environmentally sound disposal options. The historic 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 the topic becomes more mainstream, and more collection events are available, it is reasonable to expect that volumes and participation will increase dramatically.

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 distributor4, 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 allowed 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. Several reverse distributors have requested waivers from the USDEA to be allowed to conduct or participate in these events. At the time of this writing, those waivers have not been granted. Should circumstances change, the reverse distribution industry can be expected to be a source of information and support for these events.

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.

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, 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.

As part of a previous 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-thecounter 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.

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.

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 2.

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;
- 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 be 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.

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
- 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

As referenced above, efforts that preceded the Community Pharmacy Foundation grant included the assistance of an Advisory Committee. The Advisory Committee included representatives from around the country with a myriad of backgrounds and expertise. These included the USDEA, a 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 3.

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 noncontrolled substances as hazardous waste were:

- 1. Cradle to grave tracking of the movement and destruction of the medications.
- Decreased access to medications, thus preventing diversion and inappropriate use of medications, as well as minimizing the risk of poisoning children and pets.
- The presence of medications with hazardous waste characteristics in the waste mix and the practical impossibility of separating them out.
- 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
- Sending a message about the importance of safe end-of-life management of medications.
- Avoiding water pollution from medications in landfills and the risk of diversion when tipped out at disposal facilities.

VI Holding a Collection Event

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 1.1 gallons 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. Any medications not in the original containers are identified using Ident-a-Drug or similar reference materials. Any unknowns are managed as a controlled substance.
- 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.
- 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.

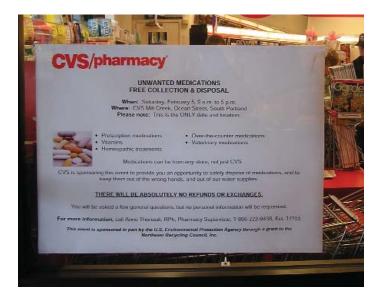


Your Collection Event

A Detailed Guide

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

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





Each of the following, and more, will be detailed on the pages that follow, but here are the key elements 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.
- Properly licensed hazardous waste hauler.
- An indoor site with electricity.
- Signage directing people to the event.

Any unwanted medication collection in a community pharmacy is likely to 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. Many community pharmacies have expressed interest in ongoing collection programs. To accomplish this, and be in full compliance with federal and state laws, it is mandatory that controlled substances never be accepted by the pharmacy. On a practical level, this will require that each container of medication brought in for disposal is reviewed in the presence of that individual. This will include:

- Opening the container to be sure what the label says it contains, it
- Identifying any unknown items and returning those that remain unidentified to the individual.

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 and assistants
- 3. Greeter
- 4. Data entry
- 5. Event organizer/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.

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.
- Ensure the witnessed destruction of the controlled substances.

The law enforcement official must be in uniform.

During the collection



- The pharmacist will determine if a medication is a controlled substance. If it is a controlled substance (or an 'unknown'), 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 covered 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. It is suggested that the inventory be printed and signed in duplicate, and that the community pharmacy retain a copy for its records.
- 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 example if a Ziploc® bag is used.
- 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. It is also important the law enforcement official be positioned in such a way as to prevent an unanticipated confrontation.

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.

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

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.

Frequently, pharmacy students or pharmacy technicians participate in the events and assist in identifying unknowns. This can be a time intensive effort and their focused attention to this is of great assistance. If they determine that something is a controlled substance, it is essential that the pharmacist be alerted and that the pharmacist be the person to conduct the actual inventory.

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. If it the medication remains 'unknown,' that should be listed in the inventory as well and a separate bag or other container created that is so labeled. For example, a Ziploc® bag that has 'unknown' written on it and the number of tablets.
- Put medications back in the original container and hand the controlled substances to the law enforcement official.
- Put non-controlled substances in their original containers in the hazardous waste container.

During the collection

Medication	Dosage
Ibuprofen	200 mg
Penicillin	500 mg
Ibuprofen	800 mg
Absorbine Jr™	
Acetaminophen	325 mg
Airborne™	
Aldara [™] cream	0.25g
Benadryl™	2%

- It is recommended that the pharmacist wear a 'pharmacist jacket' in order to make it visually obvious that it is a pharmacist.
- Gloves must be worn at all times when handling/counting medications.
- The pharmacist should provide tools for counting medications.
- The pharmacist should provide reference materials for identifying unknown/non-labeled tablets.
- Answer questions from the public.
- Optional: Physically inventory all medications brought into the event, such as is done for the controlled substances. In several cases, the hazardous waste hauler requires an inventory of the non-controlled substances. Be sure to understand these requirements in advance of the event. For example, it may be required to develop an inventory of all containers of medications, but not their content. See example (left).

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 the pharmacist for his/her records. It is suggested that one copy should stay with the event organizer.
- The hazardous waste hauler removes all non-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, the hazardous waste company paperwork is completed, and supplies packed.

Pharmacy Students and Pharmacy Technicians

Staffing suggestion



As mentioned on page 10, the participation of students and pharmacy technicians is of great value in a collection. They can help with the inventory of non-controlled substances, with identifying unknowns, and in providing other support.

The question is frequently asked, how many? Based on the pilot experiences, we recommend the following staffing levels:

- Pharmacist(s) 2
- Pharmacy students 3
- Pharmacy Technicians 2.

For large urban areas, it would be worthwhile considering a higher level of staffing.

Greeter

Responsibilities

- Direct people to the collection and answer questions.
- If the collection is not accepting sharps, ask participants if they are bringing any needles or sharps. If they say yes, explain that the only needles that can be accepted are ones that are part of a drug delivery system; for example EpiPens™ and Lovenox™. Other needles need to be taken back with the customer. Being prepared to provide quidance about how to properly dispose of sharps is encouraged.
- Provide pens for obscuring personal information, as desired.
- Optional: Conduct survey.
- Optional: Distribute informational materials.
- Optional: Help remove cardboard packaging for recycling.

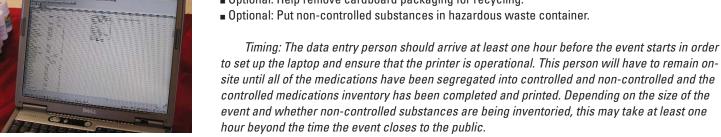
Timing: Greeters should be on-site at least one-half hour before the event begins. The greeter is likely to be able to leave very shortly after the scheduled end of the event.

Data Entry

Responsibilities



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





Responsibilities

- Arrange for the hazardous waste company (including securing a contract, pricing agreement, arranging for containers to be delivered in advance of event, etc.)
- Arrange for staffing.
- Provide all supplies and equipment.
- Set up site.
- Instruct each staff person about responsibilities and procedures.
- Ensure that all operations are running smoothly and that personal protective equipment is being used.
- Ensure that law enforcement does not leave site until all non-controlled medications have been packed and placed on the hazardous waste truck.
- Maintain records, including copy of witnessed controlled substance inventory.
- Answer operational questions as they arise.
- Ensure that recycling and trash are taken care of.
- Data analysis and reporting.
- Paying invoices.
- Follow-up with hazardous waste company and law enforcement agency 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.



Responsibilities



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

Timing: The hazardous waste company needs to drop-off containers at least one day before the event. The site supervisor should instruct the hazardous waste company, at least one week in advance, of the number and size of containers to be delivered. This is discussed in more detail below, under packing of materials.

The hazardous waste company should be scheduled to return for pick-up of the noncontrolled 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 and could create additional legal and reporting requirements.

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.

Entering into a contract with a hazardous waste hauler is essential

Before entering into a contract with a hazardous waste hauler be sure of the following:

- Licensed to collect and transport hazardous waste in the state in which the collection will take place.
- That the company is in good standing with the state environmental and transportation agencies.
- That it is able (and willing) to accept pharmaceuticals making clear that no controlled substances will be shipped with them.
- If possible, secure recommendations from another community pharmacy, or a community household hazardous waste event, about their experiences with the company.

In negotiating the terms of the contract, you should anticipate paying for the following:

- Disposal by size of container
- Transportation/pick-up fee
- Fuel surcharge

You should not have to pay for empty containers, the delivery of the containers to the pharmacy the day before the event, or being listed as an additionally insured.

Important



Having signage on the day of the event that clearly identifies that a collection is taking place and where to go is important. Elderly participants, in particular, have expressed confusion about where to go and what to do unless there is simple and visible direction.

Site Safety

Take necessary precautions

Focused time and effort should go 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 in any 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

Things to do

It is very important that everyone working at the event (law enforcement, pharmacist, students, pharmacy technicians, 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.

Packing Medications for Disposal

Original containers

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 4.

Recommendations

Figure 1: Outer-packaging removed for recycling



Figure 2: Blister packaging



Figure 3: Hazardous waste container with medications



Figure 4: Items under pressure



Figure 5: EpiPen™ for hazardous waste disposal



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 (or other staff) 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" and manage it as a controlled substance.

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.

Another useful strategy to contain costs and ship as few containers for hazardous waste destruction as possible is to shake the container from time to time; or even bang it up and down. This helps to settle the voids and ensure that the containers are packed as densely as possible.

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, several types must be separated. Be sure to clarify in advance with the hazardous waste hauler what their packing requirements are as they relate to how the materials must be segregated. The following categories of medications are likely to require separate packing (in 5-gallon pails):

- Items under pressure,
- Needle delivery medications.
- Certain mercury-containing medications, and
- Nitro-based medications.

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.

Needle delivery medications: Medications such as EpiPen™ and Lovenox™ can usually be accepted by the hazardous waste hauler, but arrangements need to be made in advance.

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.

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.

Mercury-containing medications: Mercury-based antiseptics, such as Mercurochrome, may need to be packed separately. Mercury-containing preservatives, a more common form 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.

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 if they are packed separately, 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.

Nitro-based medications: Some hazardous waste companies may require that nitro-based medications be packed separately. This is because they contain reactive ingredients.

Figure 6: Packed 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.

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.

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.

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.

Number and Size of Containers

Too many rather than too few should be the approach to how many containers to have delivered by the hazardous waste hauler in advance of the event. And, be sure that in the contract with the hauler that there is no cost for empty containers. They will remove the unused ones along with the full ones at the end of the event. While it is impossible to predict exactly how much material will be received, we recommend the following formula for number and size of containers to have delivered:

Table 2: Number of containers to be delivered

Population of Service Area	55 gallon	30 gallon	16 gallon	5 gallon
< 100,000	6	5	3	8
< 500,000	10	5	5	10
> 500,000	15	10	8	15

Before Your Event

Guide for the Event Organizer



Pre-Event

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

- Ensure that all relevant state agencies have agreed to the procedures to be used
- 2. Budget
- 3. Site selection
- Agreement of law enforcement to participate
- Arrange for staffing
- Hazardous waste hauler/disposal arrangements
- 7. Determine site set-up
- Determine what will be collected
- Arrangements for handling sharps
- 10. Arrangements for handling thermometers
- Secure equipment and supplies
- 12. Advertise/press release
- 13. Arrange for adequate signage

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. And, letting the Board of Pharmacy know, in advance, of each planned collection is an important courtesy and precaution.

Budget

While the final cost of this new program is hard to predict, examples can be found in the Case Studies, Section VIII, and in the discussion of Costs on page 24. 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 a disincentive to participation.

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 community pharmacy, ensure that the state Board of Pharmacy has approved the site configuration. There may be state laws that prohibit certain activities within or near where prescriptions are filled and dispensed. Ensuring that there is adequate physical separation from the collection event and the business of pharmacy are essential.

Examples of collection sites tested during the pilot included:

- Adjacent to the pharmacy inside a grocery store (Ukrop's Case Study)
- In the Fire Department community room, hosted by the community pharmacy in association with an environmental group (CVS Windsor Case Study)
- In the storage room adjacent to the pharmacy
- In retail space on the floor below the pharmacy (Eaton Apothecary Case Study).

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.

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 5 and 6.

Arrange for Staffing

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.

Based on the pilot experiences, we recommend the following staffing levels:

- Pharmacist(s) 2
- Pharmacy students 3
- Pharmacy Technicians 2

For large urban areas, it would be worthwhile considering a higher level of staffing.

Be sure that the pharmacist(s) are licensed and in good standing with the state Board of Pharmacy. If pharmacy students will participate, ensure that a licensed pharmacist in good standing will be on site and will act as the pharmacist supervisor.

- Greeters 2
- Law Enforcement 1
- Data entry same as number of pharmacists

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
- 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. Remember, the requirements for developing an inventory of the non-controlled substances will likely be up to the hazardous waste hauler.

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.

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. Requirements relative to inventorying of medications.
- 8. When and where to deliver the containers.
- 9. Who will pay for their services.
- 10. Sign a contract.
- 11. Determine if an EPA ID number is required, and if yes, who will obtain it.
- 12. Schedule pick-up for no later than one hour after the close 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.
- 13. Arrange for certificate(s) of destruction.
- 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 Site Set-Up

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.
- Not behind the pharmacy counter.

Each pharmacist, student, technician, data entry person, and law enforcement official will need a chair. The pharmacist, students, and technicians will require a six-foot table for every two people. 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, as well as recycling and trash containers.

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.

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.

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 glass jar with a tight fitting lid or 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.

Equipment and Supplies

Essential equipment and supplies are:

- Tools for counting medications. Electronic counting devices are preferred (one for each pharmacist).
- Reference documents for researching unknown tablets® (e.g., book, CD format, online access).
- 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.
- Containers for trash, recycling containers for cardboard, paperboard, plastic bags. Arrangements need to be made for trash 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 with external slide mechanism and lunch bag size).
- Laptop(s) (With spreadsheet software and compatible with printer one for each pharmacist).
- 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.





Figure 8: Counting tray



⁸There 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.

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 municipal buildings and pharmacies), press releases, and community cable announcements. Samples are in the Case Studies.

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.
- No refunds and medications will not be resold or used.
- 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 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.

A sample press release and fliers can be found in the Case Studies, Section VIII.

Figure 9: Sample educational script

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.

Protect your health, your family, your community, and the environment by disposing of unwanted medications safely.

Proper disposal of outdated, unwanted medications is the right thing to do!

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, Table 3, is a sample controlled substance inventory. 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. Unknowns should include a brief description of the item.

Table 3: Example of controlled substance inventory

Federally Controlled Substances Received	ed	
Date:		
Received by: Name & signature of law	enforcement	
Witnessed by: Name & signature of phase	rmacist	
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 patch
Endodan™	4.88/325	42 tablets
Hydrocodone-acetaminophen	650 mg	13 tablets
Hydrocodone/apap	5/500	120 tablets
Robitussin™ with codeine liquid		230 ml
Unknown		4 white oval tablets

In addition to an inventory of controlled substances, you may elect to do a complete inventory of all medications received - or the hazardous waste hauler may require it. A sample of this type of inventory is below, Table 4. While this adds to on-site staff time and may require an additional pharmacist, there are several reasons for collecting this data:

- 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.
- 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.
- Learn how much is able to be packed in what size containers, and if multiple events are held, how packing efficiencies improve and why.
- 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.

Table 4: Example of non-controlled medication inventory

Non-controlled Medications Received		
DRUG	DOSAGE	AMOUNT
Aceon™	4 mg	84 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
lmodium™ ad	2 mg	21
lmodium™ ad liquid		1/2 oz
Oxytrol™	3.9 mg	6 patches
Tiotropium Bromide Inhalation Powder		2 blisters

- During the pilots, all of the collections conducted a short survey of participants. Samples can be found in the Case Studies, Section VIII. At a minimum, we suggest asking where people live, keeping track of the number of people that bring in medication, finding out if they are regular customers of your community pharmacy, 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.

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?

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 pilot collections provides a starting point.

Hazardous waste disposal. All of the events, with the exception of the Ukrop's collection, used Clean Harbors Environmental Services (Clean Harbors) as the hazardous waste hauler. The Ukrop's collection used Veolia Environmental. The average person brought in approximately 1.1 gallons of material.

Table 5: Hazardous waste disposal costs

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

Pilot Location	Average Cost per Gallon Destruction of Non-Controlled Substance	Hazardous Waste Transportation Fee
CVS Pharmacy – Portland, ME (Feb. 2005)	\$24	\$250
CVS Pharmacy – Simsbury, CT (Sept. 2006)	\$11	\$100
Big Y Pharmacy – Tolland, CT (Sept. 2007)	\$19	\$200
Ukrop's Pharmacy – Richmond, VA (Sept. 200	7) \$41	\$220
CVS Pharmacy – Windsor, CT (April 2008)	\$14	\$210
Eaton Apothecary – Wellesley, MA (June 200	8) \$16	\$250
Eaton Apothecary – Wellesley, MA (Oct. 2008	3) \$12	\$250
AVERAGE	\$20	\$211



Law enforcement. In order to have law enforcement staffing, overtime is paid to the law enforcement agency. The hourly rate varied by jurisdiction, but on average was \$46/hour. This ranged from a low of \$30/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 (4 hour blocks was the norm).

There may also be costs associated with the destruction of the controlled substances. For example, in Massachusetts, an additional eight hours for two police officers (16 additional hours) was necessary for transporting the controlled substances for destruction. The Board of Pharmacy required that two officers perform this task.

- **Staffing.** In some cases, staff has volunteered their time in order to participate in the events, but this should not be expected of staff.
- Controlled substance destruction. In most cases, the law enforcement agency did not charge for the cost of destroying the controlled substances. The volumes were relatively low (ranging from 1.5 to 10 gallons) and in many cases another agency was responsible for the actual destruction of controlled substances. In Massachusetts, however, due to state requirements, there was a cost incurred (in addition to the law enforcement) for the destruction. It was \$500 for up to one ton of material paid to the incinerator.

Even when there was no charge to the community pharmacy 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. See the Case Studies, Section VIII for examples and descriptions.
- Staff time. Planning for and implementing an unwanted medication collection is timeconsuming. The key factors are securing law enforcement, ensuring that arrangements are in place for the destruction of the controlled substances, and ensuring compliance with all state laws and requirements. Once this is accomplished, the rest of the event is easy to plan, organize, and implement.
- 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, Ziploc® bags, and disposable gloves will likely be the major costs.

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.

Ukrop's Super Markets Richmond, Virginia Tuesday, September 25, 2007

Case Study

Host: Ukrop's Super Markets. Ukrop's is a family owned grocery store chain with 30 stores in central Virginia. Twenty-three (23) of the stores have pharmacies.

Management Contact: Director of Pharmacy and Health Services

Collection Site: Richmond, Virginia – in front of Wellness Center adjacent to pharmacy

Collection Hours: 10 – 2

Participation

- 17 participants
- Volume: 14.5 gallons non-controlled, 2 gallons controlled
- Average of 0.94 gallons per participant
- 13% of items received were controlled

Most people arrived between 11 and 12.

One person had dropped off a bag of medications the previous week at a different store. The pharmacist brought the materials over for processing.

Background:

The Northeast Recycling Council, Inc. (NERC), through a Community Pharmacy Foundation grant, worked closely with the Ukrop's Director of Pharmacy (John Beckner) to develop and implement a one-day unwanted medication collection.

Discussions about the possibility of holding an unwanted medication collection first began with Ukrop's in March 2007, after a presentation at the Virginia Board of Pharmacy, at which Mr. Beckner expressed interest in such an event.

Mr. Beckner accepted NERC's offer to take the lead in organizing the event, including identifying a hazardous waste hauler and being the site supervisor/coordinator during the collection.

The Brook Run Richmond store was selected because it was centrally located, had an elderly demographic, good store traffic, and a store layout that was conducive to holding such an event. A Tuesday was selected because of the desire to target the senior population and is one of the busier days of the week. It was determined to hold the collection in September because of the desire to avoid the flu clinic season, which begins in October.

NERC's sole role was to provide organizational and administrative support. This assistance was provided through a Community Pharmacy Foundation grant. No direct financial support for the collection was provided. Thus, all expenses were the responsibility of Ukrop's.

VIII Case Study 1: Ukrop's

Planning

TIMELINE	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
Decision/commitment to hold collection	V	V	~				
Site and date selection			~	V	~		
Site visit with pharmacist and store manager to determine equipment, supply, storage, signage						~	
Secure agreement of law enforcement to participate						~	
Identify hazardous waste hauler, negotiate terms, sign contract				✓	~	✓	
Develop marketing plan						✓	
Implement marketing plan							✓
Collection event		·					V

Site Visit



NERC staff visited the store in the company of the Pharmacy Director and the Manager of Loss Prevention. The grocery store manager was not available, but was assured that he was supportive of the event and would provide the staffing and equipment needed. The site prevented a challenge since there was no "back" to the area being proposed – to the right of the pharmacy counter, adjacent to the Wellness Center, and abutting the bakery.

Previous conversations with the store manager had suggested the construction of a barrier perpendicular to the Wellness Center, thereby creating a space for the collection to take place. A scheme was then developed about how the collection site could be configured, based on the construction of this barrier. Part of the plan included having the Wellness Center door open. In this way more floor space would become available while providing access to electricity, access to the internet for research of unknown tablets, and space for container storage.

During the visit, we also reviewed the supplies and equipment that would be needed – from tables and chairs to signs and plastic bags - that would be provided by the store manager on the day of the event. It was also agreed that grocery store staff would be available to help set up and take down the collection site, as well as to move containers during the event should that be necessary. In addition, an assessment was made about where in the storeroom the empty hazardous waste drums would be stored prior to the event.

A second site visit took place the day before the collection at which time the store manager met with the NERC representative and the Pharmacy Director. Detailed discussions about the barrier requirements, as well as the equipment that would be needed, were held. It was important that the barrier be solid and tall enough that someone could not reach over it. We also needed to be careful about not going too far into the general store traffic flow - the collection was being located in front of the bakery. It was determined that an "L" configuration of the tables would best suit this need. The barrier was to be erected overnight.

The containers that had been delivered by the hazardous waste company were also examined. It was discovered that far fewer then had been ordered were delivered and that they were of a type (metal) that would require tools to open. This too had been addressed in advance with the hazardous waste hauler. A call to the hauler quickly resulted in containers being brought over.

Law Enforcement

The Ukrop's Manager of Loss Prevention arranged with the Henrico County Police to provide staffing at the collection and to take custody of the controlled substances. The overtime charge for the County Police was \$30/hour.

Hazardous Waste Hauler

The pricing agreement was as follows:

General Medications

55 gallon	\$330
30 gallon	\$265
16 gallon	\$185
5 gallon	\$165
Under pressure 5 gallon	\$115
Mercury based 5 gallon	\$265
Nitro compounds 5 gallon	\$165
EpiPen™s 5 gallon	\$165
Pick-up/Transportation	\$220

Sample of container inventory follows:

Drug	Container Volume
Magnesium	40_
Ibuprofen	60
chlo-amine	4 tabs
prevacid™	30
altace™	40
warfarin sodium	16
warfarin	40
avapro™	30
altace™	40
toprol xl™	40
stool softener	29
warfarin sodium	16
protonix™	20
atropine	15 ml
atropine	15 ml
prevacid™	5 tabs
caltrate plus™	39 tabs
Prilosec™	39 tabs
Aspirin	30
Ibuprofen	13
tussin cf	4 fl oz
nexium™	45 tabs

Ukrop's did not have an ongoing relationship with a hazardous waste hauler. As a result, NERC was asked to identify a hazardous waste hauler to provide the necessary services. Three companies were contacted and asked to provide quotes. NERC negotiated with the two companies over their pricing and the terms of services. A comparison of the pricing structures was provided to Ukrop's along with a recommendation that Veolia Environmental Services be selected. Ukrop's accepted this recommendation and signed a contract with Veolia.

Ultimately, a low turnout resulted in 14.5 gallons of material being shipped for hazardous waste destruction. The cost for the hazardous waste hauler was \$850. This averages as approximately \$59 per gallon and \$50 per participant.

Veolia required that a detailed inventory (printed) be provided for each container shipped so that it could ensure the hazardous waste profile of each. The inventory needed to provide the name of the medication and the container volume. Since most tablet containers do not indicate size, the pharmacist assigned drams to the containers when necessary.

In addition, Veolia required that the following materials be packed separately:

- Under pressure (such as inhalers)
- Mercury based (such as mercuraform)
- Nitro compounds (such as nitroglycerin)
- EpiPen™s
- Other sharps containing medications

By pre-arrangement, containers were delivered the day before the collection and stored in the grocery storeroom. The following containers were delivered:

- 5 55 gallon (fiberboard)
- 5 30 gallon (fiberboard)
- 5 20 gallon (fiberboard)
- $\blacksquare 5 5$ gallon (plastic)

On the morning of the event, grocery store staff brought most of the containers to the pharmacy area for use during the collection. Should more containers have been needed, grocery staff would have been asked to bring the additional containers from the storage area.

The hazardous waste hauler was scheduled to pick-up the medications at 2:30. They arrived on time, but it took almost two hours for the paperwork to be completed for four containers. The driver reviewed the inventories for each of the containers and determined that segregating one of the medications into a separate container would be necessary due to its chemical characteristics and because it was in a sharp. The sharps required paperwork in addition to that for "simple" hazardous waste.

The store manager signed the manifests and other documents as the representative of Ukrop's. The driver was not able to take all of the empty containers with him because he had a small truck and arranged to return before the weekend to pick them up. The store manager agreed to this.

Marketing



A meeting was held with a member of the Ukrop's public relations team to develop a marketing strategy for the collection. In support of this effort, NERC prepared several draft marketing pieces for Ukrop's, but most were not used. The marketing pieces that were prepared in draft were:

- Press release
- Display advertisement (paid newspaper advertisement)
- Sign for store
- Counter-top sign
- Flier/bag stuffer

NERC, based on previous experience, had proposed the following marketing strategy:

- A press release is distributed to media outlets at least two weeks before the event.
- A newspaper advertisement be placed local papers, at least three times in the week preceding the event (Sunday, Wednesday and Saturday – the day of the event)
- Post a large color sign made at the entrance to the store.
- Distribute bag stuffers for all purchases in the Brook Run store, as well as stores in the area, for at least one week before the event.
- Post an 8.5 x 11 black and white desktop sign at the pharmacy counter publicizing the event.

The Ukrop's public relations representative suggested that Ukrop's post an announcement on their website, use their email "blast" system, their store circular, and pursue radio and television promotion.

Ukrop's:

- Posted color signs at the entrance to several stores in the area one week before the event,
- Posted a color counter-top sign at the pharmacy in all Richmond area stores one week before the event.
- Prepared and distributed ¼ page bag stuffer that was put in pharmacy purchases for the two weeks prior to the event in all Richmond area pharmacies.
- Put an announcement in the store circular the week before.
- Distributed a media alert about a week ahead of the collection. 5.

There were no contacts from the press in advance of the event. However, on the morning of the collection a television crew arrived and did a short spot on the noon news, which resulted in a few individuals bringing medications to the collection. In addition, another local television station came over, did a much more in-depth interview, and ran a piece about the collection on the evening news that night.

During the collection, an in-store announcement was made several times over the public address system. The intention was to make customers aware of the event and to encourage them to return to the store with unwanted medications.

Ukrop's in-store announcement

"Today, from 10 – 2, Ukrop's is hosting a free collection for unwanted medications. Stop by the pharmacy with medications you no longer need or want and they will be safely destroyed."

Site Set-up





NERC staff arrived at the store at 7:30 a.m. to set-up the collection site. As promised, a barrier had been constructed overnight, and tables and chairs were in place. Grocery store staff brought the hazardous waste containers out and provided containers and boxes for recycling, trash, and controlled substance collection, as well as the other miscellaneous supplies necessary for the collection. NERC staff set up the site alone. It took about 45 minutes.

An unanticipated problem arose, which was the inability to open the Wellness Center Door. Only the pharmacy department staff had a key and they did not arrive until 9. At which time it was discovered that the door literally would not stay open and so lost access to that room. In addition, an electrical cord could not be run under the door. A long extension cord had to be run from behind the pharmacy counter, across its top, and then down across the floor.

At 9:30 an Ukrop's IT person arrived with a printer and cables to be connected to the laptop provided by NERC. At that time, it was also learned that the computer in the Wellness Center, which



had been intended to be used to research unknown medications via the internet, was not operating. The IT person went to Ukrop's corporate offices, came back with a laptop with in-store wireless capability, and set it up as well.

When the pharmacist arrived, she brought with her an electric pill counter, which was a valuable addition to the collection. However, there were now more electrical devices than outlets on the extension cord and the IT person had to find an adaptor (two laptops, printer, and electric pill counter).

A poster was moved from the front door of the store to an easel near the collection area to help orient people to the activity.

Collection Staffing

In addition, grocery store management and personnel assisted with setting up and taking apart the collection site.

There were two primary staffing components: NERC staff time in organizing and holding the event, and Ukrop's staff in supporting the project development and participating in the event. In addition, there was staff from the Henrico County Police, and pharmacy students from the University of Virginia School of Pharmacy. Mr. Beckner arranged for the student participation.

NERC staff time was covered by a grant from the Community Pharmacy Foundation. The only staffing that had an out-of-pocket expense was for the police.

Staff	Cost Paid By	Time On-Site
Pharmacist	Ukrop's	8:30-2:00
Policeman	Ukrop's	9:30 - 3:00
Pharmacy students (3)	Volunteers	9:30-2:00
Data entry/site supervisor	Community Pharmacy Foundation grant	7:30-4:30
Loss Prevention Specialist/ Greeter	Ukrop's	9:45-2:00
IT Specialist	Ukrop's	9:30 - 10:30

Personal Information/Prescription Labels

In planning for the event, Ukrop's determined that personal information on the unwanted medication containers would be crossed out by Ukrop's in two circumstances:

- If empty containers came in that were then to be put in the trash, and
- If cardboard that is removed from a medication has a prescription label on it.

Such cardboard would be shredded pre-disposal.

However, customers were provided indelible markers for use if they wanted to cross out their name on the prescription bottle prior to leaving it at the collection.

Sharps & Thermometers

Because of their flu clinics, Ukrop's has an ongoing sharps management program and therefore decided to accept sharps at the collection. A number of individuals brought only sharps and all mentioned how grateful they were for the opportunity. "You have no idea how hard it is to find a way to dispose of these in the Richmond area," was a common comment. More than five gallons of used sharps were received at the collection, as well as approximately 1.5 gallons of unused sharps.

Supplies Used

- Counting tools Electronic pill counter and two counting trays.
- Reference materials for researching unknown tablets on-line via a laptop.
- Tables 1 8' and 1 6' folding tables arranged in an "L."
- Chairs 6
- Hazardous waste containers –1 16-gallon fiberboard drum, 3 5-gallon plastic containers.
- Container for controlled substances cardboard box
- Containers for trash and recycling
 - 1 30-gallon pail with plastic liner for trash
 - 1 30-gallon pail with plastic liner for recycling cardboard and office paper (thin & corrugated)
 - 1 box for shredding of thin cardboard with prescription labels
 - 1 30-gallon pail with plastic liner for recycling plastic bags
- Gloves, non-latex disposable 2 boxes of 50 (medium and large)
- Ziploc® bags 25-lunch bag sized with external slides.
- Laptops 2 with power cords.
- Extension cord.
- Surge protector with extra outlets (two laptops, electric pill counter, and printer)
- Back-up memory Flash card.
- Printer and paper (20 pages).
- Pens 5.
- Indelible markers 3 SHARPIE®s.
- Surveys 100 brought to site, used 17.
- Clipboards for surveys 2.
- Drinking water 1 dozen bottles.
- Toilet and sink.
- Instant hand cleaner/sanitizer 1.
- Phone.
- Sharps container 8.2 quarts (for unused sharps).

Incentives

Ukrop's distributed coupons for \$5 off a new or transferred prescription. They will be able to track their usage due to a coupon code.

Lessons Learned

- Needed more promotion. Recommendations include:
 - Do press releases one at least two weeks in advance and another approximately five days before the event.
 - Paid advertising
 - Promote in store circular
 - Promote in store magazine
 - Website
 - Email blast announcements
- 2. Having pharmacy students assisting was a great addition. They helped to count noncontrolled medications and to identify unknown tablets.
- Fill small (16-gallon for example) hazardous waste containers and then transfer to larger hazardous waste containers, as necessary, for shipment.
- The timing of the collection conflicted with other media buy commitments. In this instance, the upcoming flu clinics used all of the pharmacy advertising budget.
- The collection would have been better timed for the middle of the month to take advantage of the in-store marketing opportunities. For example, the market magazine goes out the first of the month and an advertisement in there would be well-timed for a mid-month event.
- The day of the week and store location was not ideal for high participation rates. Tuesday is a slow day for them, with Mondays, Fridays, and Saturdays being the big shopping days. The pharmacy's busiest days are Monday and Friday. In addition, this was not one of the high volume stores.

Survey

A survey was developed for Ukrop's by NERC. The greeter asked each participant the following questions and completed the survey for them. The survey asked the following questions:

- Town you live in:
- Are you a regular Ukrop's Pharmacy customer? Yes _____ No ____ 2.
- Are you a regular Ukrop's Grocery customer? Yes ____ No ___ 3.
- How did you find out about this event?

Survey Results

Town	Distance (Miles) to Store	Percent of Participants
Henrico County	6	41%
Glen Allen	8	18%
Richmond	4	18%
Chesterfield	20	12%
Midlothian	16	6%
Hanover County	14	6%

How Heard	Percent
Flier	37%
Store sign	21%
TV	21%
Newspaper	16%
Other	5%

- Are you a regular Ukrop's Pharmacy customer? Yes 53% No 47%
- Are you a regular Ukrop's Grocery customer? Yes - 100%

CVS/Caremark Windsor, Connecticut Saturday, April 5, 2008

Case Study

Host: CVS/Caremark (CVS) collaborated with the Farmington River Watershed Association (FRWA) and the Windsor Fire Department.

Management Contact:

CVS/Caremark Manager, Quality Assurance & Patient Safety Farmington River Watershed Association, Water Quality & Projects Coordinator Windsor Fire Chief

Collection Site: Community room of the Windsor, CT Fire Department

Collection Hours: 10-2

Participation

Total participants: 122

- 25 communities represented
- 39% from Windsor, CT
- 27% from abutting towns
- Furthest distance traveled 28 miles
- 34% traveled more than 10 miles
- 6% traveled >20 miles

Total volume collected: 180 gallons

- Controlled substances: 10 gallons (6%)
- Non-controlled substances: 170 gallons (94%)

Average volume per participant: 1.5 gallons

- Average volume per participant controlled substances: 0.1 gallons
- Average volume per participant non-controlled substances: 1.4 gallons

Total number of items9 collected: 2.443

- Number of controlled items: 215
- Number of non-controlled items: 2,228

Average number of items per participant: 20

- Average number of controlled items per participant: 1.8
- Average number of non-controlled items per participant: 18.2

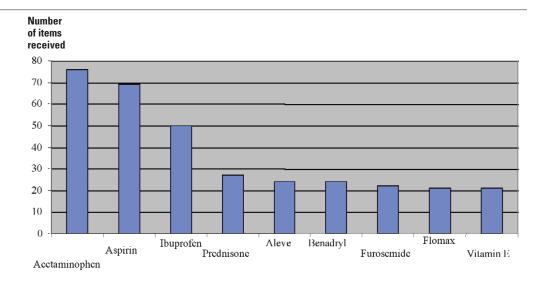
Background:

NERC, through a Community Pharmacy Foundation grant, worked closely with the CVS Manager, Quality Assurance and Patient Safety and the Farmington River Watershed Association, Water Quality and Projects Coordinator to develop and implement a one-day unwanted medication collection.

NERC's sole role was to provide organizational and administrative support. This assistance was provided through the Community Pharmacy Foundation grant. No direct financial support for the collection was provided. All expenses were the responsibility of CVS.

⁹ An item is one container of medication.

Most Received Medications



Overview

A unique approach to an unwanted medication collection yielded dramatic results in Windsor, Connecticut. CVS/Caremark (CVS) collaborated with the Farmington River Watershed Association (FRWA) to host a regional unwanted medication collection on April 5, 2008. The collection was held in the community room of the Windsor Fire Department, and benefited from the coordinated promotion of CVS, FRWA, as well as the Connecticut Departments of Environmental Protection and Drug Control. The Northeast Recycling Council, Inc. (NERC), through a grant from the Community Pharmacy Foundation, helped to organize the collection and participated in its implementation.

In addition to providing funding for the collection, CVS provided staffing on the day of the event. Two pharmacists, two six-year pharmacy interns, and five Pharmacy Technicians helped to sort, count, and identify the medications. A representative from the Connecticut Board of Pharmacy also helped to identify and count medications. The Farmington River Watershed Association had four volunteers present helping to welcome the public, conduct a simple survey, and answer questions. Other staffing included two volunteers: one student from the Plainfield High School Honor Society in Plainfield, Connecticut, and a Massachusetts town volunteer. In addition, assistance was provided by a representative of the Metropolitan District Commission, Hartford, Connecticut, and NERC staff provided oversight and data entry. The Connecticut Drug Control

Division provided a Field Agent who took responsibility and custody of the 10-gallons of controlled substances that were collected. One police officer was present for safety and protection. Clean Harbors Environmental took the non-controlled substances for secured hazardous waste incineration.

VIII Case Study 2: CVS

Planning

TIMELINE	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Decision/commitment to hold collection	V	~	~	~					
Site and date selection			~	~	~				
Secure agreement of law enforcement to participate					~				
Secure pricing from hazardous waste hauler, negotiate terms, sign contract					~	V	v		
Site visit at Fire Dept.								V	
Develop marketing plan								/	
Implement marketing plan		·							✓
Collection event									✓

Law Enforcement

Once a date was selected, NERC contacted the local police to determine if they would be willing and able to provide overtime police to provide security for the collection.¹⁰ A verbal agreement was followed by a letter agreement prepared by NERC. The letter was put on CVS/Caremark letterhead and signed by them. One week before the collection, NERC confirmed that a police officer would be on site.

In addition, due to Connecticut state law pertaining to controlled substances, it was necessary for the state Division of Drug Control to provide an agent to participate in the event. This person's role would be to take custody of the controlled substances and to ensure their safety and destruction according to USDEA requirements. NERC contacted the Division of Drug Control to see if the agency would be willing to commit the necessary staff resources and they quickly agreed to support such an event. There was no charge for this support.

¹⁰ The hourly rate was \$50, with billing in 4-hour blocks.

Hazardous Waste Hauler

Due to previous experience with using Clean Harbors Environmental as the hazardous waste hauler for unwanted medication collections, CVS determined to use their services at this event. On behalf of CVS, NERC requested pricing and facilitated the signing of a contract between CVS and the hauler.

The pricing agreement was as follows:



Clean Harbors Medicine Collection Quote MARCH 2008

2008 SERVICE AND TREATMENT COSTS:

Setup fees below include labor, travel time, drums, packaging material, labels, placards, paperwork, and safety and spill control equipment required to transport the material in accordance with Federal and State laws and regulations.

> SET-UP FEE: \$0.00 **CREW SIZE:** 1 DRIVER

COST PER DRUM

OF PRESCRIPTION MEDS: \$525.00/55DM

> \$393.00/30DM \$315.00/15DM \$157.00/05DM

NOTES: There will be a \$210 Transportation fee per pickup.

A variable energy and security fee currently at 11.5% will be applied to the total of the invoice.

CVS signed the contract with Clean Harbors with a price cap of \$3,000 unless authorization received to exceed that amount. It was agreed that should the public response to the collection warrant exceeding that limit that on the day of the event CVS would authorize such a cost overrun.

The turnout was outstanding, resulting in 170 gallons of material being shipped for hazardous waste destruction. Thus, the actual cost for the hazardous waste hauler was \$2,156. This averages to approximately \$17.70 per participant and \$12.60/gallon

By pre-arrangement, containers were delivered the day before to the nearby CVS store and then transported over by personal truck to the Fire Station. The following containers were delivered:

8 – 55 gallon (fiberboard) 5 - 16 gallon (fiberboard) 6 – 30 gallon (fiberboard) 5 – 5 gallon (plastic)

The hazardous waste company was scheduled to come to pick-up the medications at 3 p.m. (one hour after the close of the event). They were punctual. No paperwork needed to be signed or reviewed because under state law, and the terms of the contract, Clean Harbors Environmental was deemed the generator of the waste. Thus, once the hazardous waste hauler had removed the container with the unwanted medication and placed it in their truck (escorted by the police officer), there was no need for additional staff time or supervision. The hazardous waste hauler also removed the unused containers.

Site Visit

NERC staff met with the Fire Chief, a representatives of CVS and the FRWA to look at the site to determine the floor plan for the collection. The supplies and equipment that would be needed for the collection were reviewed and agreed upon.

Marketing

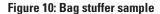
The marketing pieces were prepared by NERC and CVS pharmacy. These included the following:

- Display advertisement (paid newspaper advertisement)
- Sign for store
- Press release
- Counter-top sign
- Flier/bag stuffer
- Question and answers fact sheet

The question and answers fact sheet was used by pharmacy staff to see what towns participated in the event.

Based on previous experience, NERC had proposed the following marketing strategy:

- 1. A press release distributed to media outlets at least two weeks before the event. a. Press releases were distributed by CVS, FRWA, 11 and the CT Division of Drug Control
- Place a newspaper advertisement in local papers, at least three times in the week preceding the event (Sunday, Wednesday, and Saturday – the day of the event).
- Post a large color sign made at the entrance to the store for two weeks in advance of the collection (photo, top left).
 - a. Two types of signs were used in the local CVS and the other CVS's in the immediate area.
 - i. Small 8.5 x 11 inch sign for the front door
 - ii. Large 36 x 24 inch sign hung in the back of the pharmacy department in the waiting area
 - b. The Connecticut Department of Environmental Protection posted the poster on its website and forwarded information about the event to communities in the region.
- Pharmacy bag stuffers were used in the local CVS locations for all purchases (see text, below).
- Post an 8.5 x 11 black and white desktop sign at the pharmacy counter publicizing the event. a. This was done, along with large, colored wall posters in the pharmacies (photo, left)
- FRWA posted a flyer at libraries, senior centers, and community bulletin boards throughout the area. See Case Study 2, Appendix B.



Let CVS/Pharmacy Help You Spring Clean!!



Free Collection and Safe Disposal of Unwanted Medication

(All medications must be in original containers, with name crossed out)

- -Expired or unwanted prescription medication
- -Over-the-Counter medicines
- -Vitamins/Nutritional supplements
- -Veterinary Medications

Saturday, April 5, 10 am-2 pm

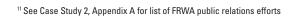
Wilson Fire Department

50 Pine Lane

Windsor, CT 06095

For more information, contact Erin Lewis at CVS/Pharmacy, Windsor, CT., (860) 947-5078

Sponsored by CVS/Pharmacy, Farmington River Watershed Association, Wilson Fire Dept., in conjunction with the Northeast Recycling Council and Community Pharmacy Foundation.

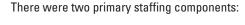


Site Set-up



CVS, FRWA, Windsor Fire, and Police Department staff arrived at the Fire Station by 8 a.m. to begin set-up for collection. Areas were set up for greeting the public, display tables for information about the FRWA, DEP, and CVS. Empty containers and other supplies had been delivered to the Fire Station by CVS staff the day before collection.

Staffing





- Organization NERC, CVS, and FRWA
- Implementation NERC, CVS, and FRWA.

The collection was also supported by the State Division of Drug Control, the local fire and police department, pharmacy students from the University of Connecticut School of Pharmacy, a High School Student from Plainfield High School, the Metropolitan District Commission, and a member of the state Board of Pharmacy.



Staff	On-site Responsibilities	Cost Paid By	Time On-Site
Pharmacists (2)	Identifying controlled substances, counting medications, site set-up	CVS	8:00 - 3:30
Connecticut Drug Control Division Field Agent	Witnessing controlled substance inventory, taking custody of controlled substances	Connecticut Drug Control Division	9:30 – 3:00
Windsor Police Officer	Security	CVS	8:00 - 3:00
Pharmacy students (2)	Identifying unknown medications, assisting with inventory of non-controlled substances	CVS	9:30 – 3:00
Pharmacy technicians (5)	Identifying unknown medications, assisting with inventory of non-controlled substances	Volunteers	9:30 – 3:00
Data entry/site supervisor	Ensure legal and safety protocols practiced, answered questions/problem-solving, entering medication inventory into spreadsheet	Community Pharmacy Foundation grant	8:00 – 3:00
Greeters/survey takers (5)	Welcome, answer questions, conduct survey, take medications and deliver to processing tables, site set-up	FRWA volunteers	8:00 – 3:00
Commissioner of Pharmacy	Identifying unknown medications, assisting with inventory of non-controlled substances	Volunteer	9:30 – 3:00
Metropolitan District Commission	General assistance & support, taking possession of sharps	Metropolitan District Commission	10:00 – 3:00
Fire Chief	Facility management, site set-up, removed garbage	Town of Windsor	8:00 - 3:30

Personal Information/Prescription Labels

In planning for the event, CVS determined that if any personal information were on the label they would either cross it out with black marker or put empty containers in a separate blue bag for secured destruction. Approximately 4 gallons of this material was collected.

Sharps & Thermometers



Sharps are always an issue at collection events. While certain medications brought for destruction will includes sharps - such as EpiPen™s - the majority of sharps the public wants to get rid of are used. CVS advertising stated that sharps and thermometers would not be accepted, yet preparations were necessary because there is always the chance that someone will bring in used syringes or thermometers.

The FRWA contacted the Metropolitan District Commission – who is the regional solid waste authority – and it volunteered to take responsibility for any sharps received at collection. It provided sharps containers and staffing at the event. Approximately 2.5 gallons of sharps were collected for disposal.

Supplies

- Counting tools Electronic counters (2) and manual counting trays (9)
- Reference materials for researching unknown tablets Loaded onto a laptop
- Tables 8 6' folding tables 1 table for every two staff, additional for displays and "in take"
- Chairs enough for each staff person, including greeters and law enforcement
- Hazardous waste containers
- Container for controlled substances 5-gallon pail provided by hazardous waste hauler
- Containers for trash and recycling:
 - 1 30-gallon pail with plastic liner for trash
 - Cardboard boxes for recycling thin cardboard (30 gallons recycled)
 - Cardboard box or bag for secure disposal of thin cardboard with prescription labels and empty prescription containers (4 gallons recycled)
 - Empty plastic bag stuffed with other plastic bags for recycling (3 stuffed grocery bags recycled)
- Gloves non-latex disposable (medium and large)
- Ziploc® bags lunch bag sized with external slides.
- Laptops (4) with power and extension cords
- Back-up memory flash card
- Printer (with paper and ink) used Fire Department's
- Pens (for surveys)
- Indelible markers (marking plastic bags of unknowns, available for crossing out personal information)
- Surveys
- Clipboards for surveys
- Drinking water
- Toilet and sink
- Instant hand cleaner/sanitizer
- Phone
- Sharps containers (small and large)

Survey

A survey was developed for CVS by NERC. The greeter asked each participant the following questions and completed the survey for them.

Unwanted Medications Collection Windsor, CT - CVS SURVEY April 5, 2008				
Town of Residence:	•			
What pharmacy do you normally use?	O CVS O Walgreen's			
	 Rite-Aid Arrow Other			
Why is the drug being disposed of?	 Didn't like the medication (made me ill, etc.) Expired/out-of date medicine Death (family member/friend) Cleaning house Never used prescription Drug was pulled off the marked Other 			
Whose medication was it?	MineFamily or household memberFriendPet			
How did you learn about the collection?	 Newspaper Newsletter Flier Cable TV CVS flier Website Other 			

Survey Results What pharmacy do you normally use? CVS 60% Walgreen's 7% Rite-Aid 4% Stop & Shop 8% Mail order 7% Other 14%

6%
54%
13%
7%
9%
1%
11%

Mine	29%
Family or household member	59%
Friend	2%
Pet	10%

How did you learn about the collection?				
Newspaper	60%			
Newsletter	6%			
Flier	8%			
Cable TV	3%			
CVS flier	10%			
Website	3%			
Other	11%			

Conclusion

This was a very successful collection event. It benefited by the coordinated and extensive promotion and outreach done by the FRWA and CVS. The majority of the participants learned of the event from outreach done by the FRWA, indicating that the extensive efforts they made were productive.

The event ran smoothly thanks to the high level of staffing. Everyone worked hard throughout the entire event, and it took a full hour after the event closed to complete processing and packing of the medications.

CASE STUDY 2, APPENDIX A Public Relations for 2008 Unwanted Medication Collection By Farmington River Watershed Association

Newspapers

- Reminder Community Newspapers:
- Windsor Reminder
- Windsor Locks Reminder
- Enfield Reminder
- Hartford Courant
- · Calendar, brief in regular news

Journal Inquirer (Manchester)

- CT Life Publications
- Imprint Newspapers
- Windsor Journal
- Windsor Locks Journal
- · Bloomfield Journal
- Hartford Advocate
- New York Times

Radio and Television

- WTIC News
- WWUH
- Fox 61 News
- NBC 30 News
- WFSB Channel 3 News
- WTNH Channel 8 News

Web Calendars

- Environmental Headlines & Calendar (Christopher Zurcher)
- Guidezilla, your guide to what's going on
- CT Green Scene
- REI Events Calendar

Other

- CT Department of Environmental Protection
- CT Department of Consumer Protection, Drug Control Division
- The Metropolitan District
- Local Resource Recovery Committees such as:
 - Bristol Resource Recovery Facility Operating Committee
 - Simsbury Recycling Committee
- Retirement Communities such as Duncaster; Seabury
- Towns such as: Windsor; South Windsor
- Corporate Environmental Teams such as Hamilton Sunstrand
- Garden Clubs such as Simsbury Garden Club

DON'T FLUSH THAT LEFTOVER MEDICINE!



Free Collection & Safe Disposal of Unwanted Medication

(All medications must be in original containers, with name crossed out)

- -Expired or unwanted prescription medication
- -Over-the-Counter medicines
- -Vitamins/Nutritional supplements
- -Veterinary Medications

Saturday, April 5, 10 am-2 pm

Wilson Fire Department 50 Pine Lane Windsor, CT 06095

For more information, contact Erin Lewis at CVS/Pharmacy, Windsor, CT., (860) 947-5078





Sponsored by the Farmington River Watershed Association, Windsor Fire Department, and CVS/pharmacy, in conjunction with the Northeast Recycling Council, with support from the Community Pharmacy Foundation

Eaton Apothecary Wellesley, Massachusetts Saturday, June 7, 2008

Case Study

Host: Eaton Apothecary

Management Contact: Director of Clinical Services

Collection Site: Eaton Apothecary, Wellesley, Massachusetts

Collection Hours: 10 – 2

Participation

Total participants: 41

Total volume collected: 31.5 gallons

- Volume of controlled substances: 3.5 gallons (10%)
- Volume of non-controlled substances: 31 gallons (90%)
- Mercury thermometers: 5

Average volume per participant: .84 gallons

- Average volume per participant controlled substances: 0.09 gallons
- Average volume per participant non-controlled substances: 0.76 gallons

Total number of items¹² collected: 685

- Number of controlled items: 102 (15%)
- Number of non-controlled items: 583 (85%)

Average number of items per participant: 17

- Average number of controlled items per participant: 2.5
- Average number of non-controlled items per participant: 14.2

Percent prescription: 72%

Percentage Eaton Pharmacy Customers: 51% Costs: \$2,565 (average per participant \$62.55)

- Hazardous waste disposal: \$909.65
- Controlled substance destruction (with police): \$1,270
- Police on-site: \$385

Background:

NERC, through a Community Pharmacy Foundation grant, worked closely with the Eaton Clinical Director and the head pharmacist from the Eaton Newton store to develop and implement a one-day unwanted medication collection. NERC's role was to provide organizational and administrative support. This assistance was provided through the Community Pharmacy Foundation grant. No direct financial support for the collection was provided. All expenses were the responsibility of Eaton.

For a general overview about how to set up and operate an unwanted medication collection, and for detail than is provided in this Case Study, see the guidance document Operating Unwanted Medication Collections - A Legal & Safe Approach.

¹² An item is one container of medication

Overview

This collection came about as a result of a two-year effort by Eaton Apothecary (Eaton) to find a way to hold an unwanted medication collection. After learning of a grant from the Community Pharmacy Foundation to the Northeast Recycling Council, Inc. (NERC) to work with pharmacies to organize such events, Eaton contacted NERC and requested its assistance.

Eaton Apothecary is a community pharmacy chain operating in Massachusetts. Currently, there are 20 stores in the greater Boston region.

Planning

TIMELINE	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Decision/commitment to hold collection	~	~	V	'					
Site and date selection			~			~			
Secure agreement of law enforcement to participate			~	✓	✓	~	~		
Secure pricing from hazardous waste hauler, negotiate terms, sign contract					~	~	~		
Arrangements for witnessed destruction of controlled substances					~	•	•	~	•
Permission from State DPH and Board of Pharmacy						~	~		
Develop marketing plan			✓						
Implement marketing plan								~	~
Collection event									~

Site Visits, Date Selection, & Agreement of Law Enforcement to Participate



Eaton had originally intended to hold the collection event in its Newton store. The head pharmacist from that store had been the catalyst for Eaton's interest in such an event, and she was very committed to the opportunity. A site visit was held at that store, which was attended by NERC, the Newton head pharmacist, and Eaton's Director of Clinical Services. A plan for how the collection would take place, including traffic flow and signage, was agreed to and tentative dates selected.

NERC then contacted the Newton Police Department (Department) to secure its willingness to participate in the event. A memo (Case Study 3, Appendix A) detailing what was being asked of them was written and emailed to them following the initial phone contact. In brief, the role of law enforcement is to provide security during the event, take possession and responsibility for controlled substances received, and ensure witnessed incineration of the controlled substances.

Although the Department expressed support for the event and a general willingness to participate, it ultimately was not able to provide the necessary support. Internal Department reporting requirements would have required that the controlled substance inventory be repeated in-house by police department staff, and then logged into its database. Due to budget and staffing constraints, the Department did not believe it had the capacity to provide this service.

Upon learning of the barrier to a collection in Newton, Eaton considered other store locations. It was determined that the Wellesley store was a suitable candidate. The Newton pharmacist conferred with Wellesley store staff and secured its agreement to host the event at that location. A site visit was held at that store with NERC staff and the Newton pharmacist. The suggestion was that the collections take place in the basement medical supplies section of the store. A back set of

Site Visits, Date Selection, & Agreement of Law Enforcement to Participate continued



stairs would provide access for the hazardous waste hauler to deliver and remove containers, while the public would enter and exit through the main stairs at the front of the store. It would be necessary to clear out the basement in order to have work areas and unencumbered access for the public and hazardous waste hauler. The manager of the medical supplies department was on-hand during the site visit and she expressed hesitation about the need to relocate product and the ability to have the materials available for sale during the event. It was also unknown at the time if the hazardous waste hauler would be willing to move containers up and down stairs. Ultimately, the medical supplies manager agreed to allow the collection to take place in that area of the store as long as everything was put back in its original location and sales could continue during the event. The hazardous waste hauler, after being emailed a photo of the stairs in question, also agreed to the downstairs location.

NERC then contacted the Wellesley Police Department and provided it with a document modeled on the one provided to the Newton police. After deliberation, the Wellesley Police Department agreed to participate in the event. Its primary concern was the several week period during which it would be responsible for the secure storage of the controlled substances while the waste-to-energy facility determined if the materials were acceptable. See discussion below about Witnessed Destruction. There was also concern that perhaps the incinerator would not approve all of the materials. NERC assured them that there would be no problem in this regard since none of the materials could be considered hazardous waste under Massachusetts law.

Eaton's responsibilities would include paying the Police Department for an officer to be on site during the collection, 13 as well as for the cost of destruction and the two police officers' time to transport and witness the destruction. A verbal agreement to this effect was negotiated by NERC with Eaton's approval.

One week before the collection, NERC confirmed with the Wellesley Police Department that a police officer would be on site. On the day of the event, the officer was not from the Wellesley Police Department but rather the Norfolk Sheriff's Department. At the last minute, Wellesley could not provide overtime staffing and arranged for the Norfolk Sheriff's Department to provide the staffing. The financial arrangements remained with the Wellesley Police Department. The Sheriff, at the end of the collection event, took the controlled substances to the Wellesley Police Department for storage pending the witnessed destruction.

Arrangements for Witnessed Destruction

In Massachusetts controlled substances that come into the custody of law enforcement due to criminal investigations are destroyed under the supervision (and budget) of the State Department of Public Health (DPH). The Board of Pharmacy is also within the DPH. Discussions several years ago with the DPH and Board of Pharmacy about how to hold unwanted medication collection events made explicit that controlled substances received must be kept separate from criminal evidence materials and destroyed outside the criminal evidence system. The practical result is that controlled substances received at an unwanted medication collection event would have to be destroyed through arrangements made specifically for this purpose; and not under the authority or budget of the DPH. Witnessed incineration by law enforcement is the method of required destruction.

Several waste-to-energy facilities (WTE) in Massachusetts are licensed to incinerate controlled substances. The nearest such facility to Wellesley is owned and operated by Covanta Energy in Haverhill, MA. Covanta was contacted to learn of the steps and costs involved in arranging for a witnessed incineration of controlled substances. A simplified overview of the steps is as follows:

- 1. Waste Disposal Agreement provided by Covanta submitted by Eaton in advance of the collection event.
- Credit application provided by Covanta submitted by Eaton at least two weeks in advance of the collection event.
- Material Characterization Form completed by NERC and submitted along with detailed inventory of controlled substances immediately following collection event to Covanta. This documentation is used by Covanta to determine if the materials are acceptable for destruction. This determination could take up to three weeks. During this time, the Wellesley Police Department is responsible for secured custody of the materials. Once the approval was received, scheduling of the witnessed incineration could take place within 24 hours. NERC would coordinate with the Wellesley Police Department to make these arrangements.

Eaton would be responsible for the cost of the witnessed destruction (minimum charge of \$500 for up to one ton of material), as well as the associated police time. Per Massachusetts requirements, two law enforcement officers must transport at and witness the destruction.

Permission for the Department of Public Health & Board of Pharmacy

In Massachusetts, obtaining the permission from the Department of Public Health (DPH) and Board of Pharmacy is essential in advance of holding a collection event. A written description of how the event will proceed is required and these entities may require modifications to that plan. Permission from both entities can be sought from the same individual as he serves as the key staff person to both relevant entities.

Case Study 3, Appendix C presents the written request made of the DPH. Permission to proceed was received via a phone conversation with NERC. In addition, the week before the event, the Eaton Director of Clinical Services emailed the director of the Board of Pharmacy to remind him of the upcoming event. She received an enthusiastic response to this contact.

ENVIRONMENTAL SERVICES. INC.

Hazardous Waste Hauler



Due to NERC's previous experience with Clean Harbors Environmental as the hazardous waste hauler providing services to unwanted medication collections in New England, Eaton determined to hire this company. NERC requested pricing on behalf of Eaton, negotiated the terms of the contract, and facilitated the signing of a contract between Eaton and Clean Harbors.

The pricing agreement was as follows:

Clean Harbors Medicine Collection Quote 5/31/08 - TES F

2008 SERVICE AND TREATMENT COSTS:

SFT-UP FFF: \$0.00 **CREW SIZE:** 1 DRIVER

COST PER DRUM

OF PRESCRIPTION MEDS (D92K): \$365.00/55DM

\$325.00/30DM \$225.00/15DM \$115.00/05DM

NOTES: There will be a \$250 Transportation fee per pickup.

A variable energy and security fee currently at 13.0% will be applied to the total of the invoice.

Per pound surcharge will apply to this waste Classification Codes as follows:

D92K - Base price up to 500 lbs., \$1.68/lb. thereafter

Eaton Apothecary signed the contract with Clean Harbors with a price cap of \$3,000 unless authorization received to exceed that amount. It was agreed that should the public response to the collection warrant exceeding that limit that on the day of the event Eaton would authorize such a cost overrun.

It was also agreed that Clean Harbors would deliver empty containers to the store the day before the event, and remove any unused containers after the event. No charges were incurred for the containers themselves. NERC contacted Clean Harbors approximately two weeks before the event to indicate how many containers, and of what size, should be delivered. They were:

8 – 55 gallon (fiberboard) 5 – 16 gallon (fiberboard) 6 – 30 gallon (fiberboard) 5 – 5 gallon (plastic)

The hazardous waste company was scheduled to come to pick-up the medications at 3 p.m. (one hour after the close of the event). Because of the size of the truck (an 18-wheeler), they were not able to use the back entrance as had been planned. Instead, they carried the containers, by hand, 14 up the front stairs and out to the truck waiting on the street. The Sheriff assisted with traffic control while the truck turned around on the relatively narrow street. Thus, once the hazardous waste hauler had removed the container with the unwanted medication and placed it in their truck (escorted by the police officer), there was no need for additional staff time or supervision.

The turnout for the event was slightly above the average for retail pharmacy collection events to date; 41 individuals. The total amount shipped as hazardous waste (non-controlled substances) was 31.5 gallons. Thus, the actual cost for the hazardous waste hauler was \$909.65. This averages to approximately \$62.55 per participant, which is much higher than the average; which are \$27 per participant. The above average costs can be attributed to a few factors:

- Fuel surcharge cost of 13%
- Receipt of medications in syringes (Lovenox™) requiring separate packing (\$115 additional cost)
- The cost of the 30-gallon container as full. The cost of a 55-gallon container is nominally more (\$40), and so the per gallon cost is higher for a 30-gallon container is \$5/gallon higher than for a 55-gallon container.

¹⁴ Clean Harbors estimated that the 30-gallon container weighed in excess of 100 pounds. It was very tightly packed and full.

Marketing

NERC prepared several marketing pieces for Eaton. The marketing pieces that were prepared by NERC in draft were:

- Press release
- Display advertisement (paid newspaper advertisement)
- Sign for store
- Counter-top sign
- Flier/bag stuffer
- Question and answers fact sheet

The question and answers fact sheet was for use by pharmacy staff in responding to questions about the upcoming event.

Based on previous experience, NERC proposed the following marketing strategy:

- 1. A press release distributed to media outlets at least two weeks before the event.
- Place a newspaper advertisement in local papers, at least three times in the week preceding the event (Sunday, Wednesday, and Saturday – the day of the event).
- Post a large color sign made at the entrance to the store for two weeks in advance of the collection.
- Distribute bag stuffers for all purchases, including the pharmacy, in the Wellesley store as well as other Eaton stores in the area, for at least one week before the event.
- Post an 8.5 x 11 black and white desktop sign at the pharmacy counter publicizing the event.

Eaton did a very thorough job of promoting the event. The implemented marketing plan follows.

Promotion of June 7, 2008 Medication Collection, Wellesley Signs:

- Preliminary signs and fliers at store by 5/5/08
- Preliminary signs and fliers at senior center by 5/5/08
- New, bigger signs and bag stuffers delivered to Wellesley, Newton, Weston, and Waltham locations 1 week prior to event
- Other locations include Whole Foods Newton, Trader Joes Newton & Needham, Wellesley Dump, & library 7-10 days prior to event
- All Eaton locations notified of event 5/8/08 and reminded on 6/6/08 in weekly newsletter/ updates

Press Release,15 dates of issue:

■ Wellesley Townsman: May 7 & May 22 (for June 5)

■ Newton Tab: May 28 ■ Weston Paper: May 28

■ Metrowest Daily News: May 28

Paid Ads:

■ Metrowest Daily News: June 6

On air promotion:

■ Wellesley Community Access Channel community newscast 6/5/08

Media Outreach: (to cover event)

- Channel 5 WCVB
- Channel 7 WHDH
- Boston Globe
- Wellesley Community Access Channel

¹⁵ A sample press release is in Case Study 3 Appendix C.

Marketing continued

Sample flier



Let us help you clean out your medicine cabinet the safe way! We are proud to be hosting a free unwanted medication collection allowing you to dispose expired, unwanted, or unneeded medications without harming the environment, pets, or people!

> When: Saturday June 7, 2008, 10AM - 2PM Where: Eaton Apothecary, 266 Washington Street, Wellesley Please note: This is the ONLY date and location What to bring:

- Prescription medications Over-the-counter medications
 - Vitamins Veterinary medications
- Mercury thermometers Sharps will not be collected Medications from any pharmacy will be accepted. Please bring the medications in their original containers with the name of the medicine

visible, and cross out any personal information.

THERE WILL BE ABSOLUTELY NO REFUNDS OR EXCHANGES

Medications will not be reused or resold.

Medications will be accepted only from the public – no businesses or doctor's offices please. For more information, please call 781-235-1464

Sample poster



Unwanted Medication Collection Saturday June 7, 2008 10AM-2PM 266 Washington St, Wellesley 781-235-1464

Let us help you clean out your medicine cabinet the safe way! We are proud to be hosting a free unwanted medication collection allowing you to dispose expired, unwanted, or unneeded medications without harming the environment, pets, or people!

Site Set-up



Eaton staff cleared out the basement space several days in advance of the event, including bringing in the folding tables and chairs that would be necessary for the event. On the day of the event, NERC staff arrived by 8:30 to set up tables and arrange equipment and supplies. The Eaton store manager assisted with ensuring that necessary equipment and supplies were in place in a timely fashion. At the end of the event, Eaton collection event staff ensured that the area was clean and back in order.

Staffing



There were two primary staffing components:

- NERC staff time in organizing and holding the event, and
- Eaton staff in organizing, implementing, and promoting the event.

Eaton staff included:

- Director of Clinical Services
- Newton Head Pharmacist
- Pharmacy Technicians (3)
- Pharmacist (served as Greeter, directing people downstairs to the collection, answering questions). In addition to providing its own staff on the day of the event, Eaton arranged for two pharmacy students to assist.

NERC staff provided site supervision and data collection on the day of the event, and also served as a greeter/survey taker.

Staff	Responsibilities T	ime On-Site
Pharmacists (2)	Identifying controlled substances, counting medications, site set-up	8:30 - 3:00
Sheriff	Took possession of controlled substance, security	9:30 - 3:30
Pharmacy students (2)	Identifying unknown medications, assisting with inventory of non-controlled substances	9:00-2:00
Pharmacy technicians (3)	Identifying unknown medications, assisting with inventory of non-controlled substances	9:00-2:00
Data entry/site supervisor	Ensure legal and safety protocols practiced, answered questions/problem-solving, entering medication inventory into spreadsheet	8:30 – 3:00
Greeters/survey takers (2)	Welcome, answer questions, conduct survey, take medications and deliver to processing tables, site set-up	8:30 - 3:00

Personal Information/Prescription Labels



Sharps & Thermometers

In planning for the event, Eaton determined that personal information on the unwanted medication containers would be crossed out. The pharmacist or student/tech processing the medication used an indelible marker to cross the information out. Any empty containers with prescription labels or cardboard that was removed from a medication that had a prescription label on it would be put in a separate container for secured destruction. Approximately 4 gallons of this material was collected.

Sharps are often an issue at collection events. While certain medications brought for destruction will includes sharps - such as EpiPens - the majority of sharps the public wants to get rid of are used. Eaton advertising stated that sharps would not be accepted, yet preparations were necessary because there is always the chance that some would "sneak in." Eaton was equipped with sharps collection containers but no sharps were received.

The public was invited to bring mercury thermometers to the event and non-mercury thermometers were being distributed. As a cost savings measure, arrangements were made with the Wellesley municipal recycling program for Eaton to bring thermometers to them for recycling. There would be a minimum charge of \$30. The hazardous waste hauler had originally quoted a minimum price of \$160. Five mercury thermometers were collected and taken to the municipal recycling center by Eaton staff on the Monday following the event.

Supplies

The following supplies were used during the event:

- Counting tools Electronic counters (2) and manual counting trays (5)
- Reference materials for researching unknown tablets.
- Tables 8 6' folding tables 1 table for every two staff, additional for displays and "in take"
- Chairs enough for each staff person, including greeters and law enforcement
- Hazardous waste containers
- Container for controlled substances 5- gallon pail provided by hazardous waste hauler
- Containers for trash and recycling
 - 1 30-gallon pail with plastic liner for trash
 - Cardboard boxes for recycling thin cardboard (30 gallons recycled)
 - Cardboard box or bag for secure disposal of thin cardboard with prescription labels and empty prescription containers (4 gallons recycled)
 - Empty plastic bag stuffed with other plastic bags for recycling (3 stuffed grocery bags recycled)
- Gloves non-latex disposable (medium and large)
- Ziploc® bags lunch bag sized with external slides.
- Laptops (2) with power and extension cords
- Back-up memory flash card
- Printer (with paper and ink)
- Pens (for surveys)
- Indelible markers (marking plastic bags of unknowns, available for crossing out personal information)
- Surveys
- Clipboards for surveys
- Drinking water
- Toilet and sink
- Instant hand cleaner/sanitizer
- Phone
- Sharps containers (small and large)

Suvey

A draft survey was developed for Eaton by NERC, and then finalized by Eaton to address its specific needs. A greeter asked each participant the following questions and completed the survey for them.

Unwanted Medications Collection – Wellesle June 7, 2008	y, MA
City or Town you live in:	
Have you been to an Eaton Apothecary before? Yes No	-
What pharmacy do you usually use to fill your prescriptions?	
How did you find out about this event? (Check all that apply)	
 Store signs: Which store? Advertisement: Which paper? Press release: Which paper? Friend Other (please specify) 	
Whose medication was this? Mine Household member Friend Pet	
Do you have any comments?	

Survey Results

City or Town you live in

Wellesley	70%
Weston	8%
Newton	8%
Natick	5%
Needham	3%
Dedham	3%

Have you been to an Eaton Apothecary before?

Yes	87%
No	13%

What pharmacy do you usually use to fill your prescriptions?		
Eaton	51%	
CVS	21%	
Professional pharmacy	8%	
Newton-Wellesley Hospital	8%	
Rite Aid	5%	
Harvard Pilgrim	3%	
Online	3%	
Variety	3%	

Thank You!

How did you find out about this event?		
Store signs	32%	
Advertisement	20%	
Stuffer	18%	
Press release	14%	
Other	11%	
Friend	5%	

whose medication was it?	
Household member	50%
Mine	37%
Friend	9%
Pet	4%

Conclusion

This was a very successful event. Eaton did an outstanding job of publicizing the event, and secured excellent media coverage as a result. This was the first unwanted medication collection held anywhere in the Boston metropolitan area, and as a "first" had the burden of both promoting the specific event and providing public awareness of the issue and the opportunity.

This event enjoyed the participation of a higher than average number of individuals, and also a higher than average percentage of controlled substances. In general, collections receive an average of 8% controlled substances. In this case, it was 15%; demonstrating the great public health and safety impact of this single event.

CASE STUDY 3, APPENDIX A

December 13, 2007

Captain Mintz Community Resources Unit Newton Police Department

RE: Request for participation of Newton Police Department in unwanted medication collection to take place at the Eaton Apothecary, April 12, 2008

Dear Captain Mintz,

Lieutenant Dangelo requested that I write to you and explain the request being made of the Newton Police Department relative to participating in an unwanted medication collection that Eaton Apothecary would like to hold on April 12, 2008.

First, some background: the Northeast Recycling Council, Inc. (NERC) has a grant from the Community Pharmacy Foundation to work with retail pharmacies to organize and hold unwanted medication collections. Such events are opportunities for the public (not businesses, doctors offices, or nursing homes, for example) to get rid of unwanted medications from their homes. All medications received are incinerated - the non-controlled as hazardous waste, the controlled substances per USDEA and Massachusetts Department of Public Health required witnessed burning.

Attached is an overview of the role of law enforcement at an unwanted medication collection event. NERC has organized and participated in eleven unwanted medication collection events, several of which have been in pharmacies. The collection event at Eaton Apothecary will last for four hours (10-2).

Eaton Apothecary will be responsible for compensating the Newton Police Department for duty time for its participation in the event, as well as for the cost of destroying all controlled substances.

So, what are we asking of the Department?

- A commitment that a Newton Police Officer will participate in the event; providing security and taking possession of controlled substances.
- That the Newton Police Department will take permanent physical possession and custody of any controlled substances.
- That the Newton Police Department will transport the controlled substances for witnessed incineration and provide documentation to Eaton Apothecary that such witnessed destruction took place. This must be apart from the evidence destruction system implemented by the Massachusetts Department of Health.

We will be happy to assist in making the arrangements for the witnessed destruction, including with scheduling.

Specific instructions from the Police Department about how it wants to manage the controlled substances. For example, the Police Officer will take the controlled substances back to the station on April 12 and then would like to have the witnessed destruction take place that week. Or, that arrangements must be made for the immediate transport of the medications to the witnessed destruction. I would be happy to discuss the particulars and your requirements in this regard.

If you have any questions, please do not hesitate to contact me. Thank you.

Case studies about two recent unwanted medication collections held in pharmacies are available on the NERC website at http://www.nerc.org/documents/case_study_big_y.pdf for a recent collection in Connecticut, and http://www.nerc.org/documents/case_study_ukrop.pdf for an event in Virginia.

Sincerely,

Lynn Rubinstein **Executive Director**

Cc: Sophie McIntyre, Director of Clinical Services, Eaton Apothecary Lieutenant Dangelo, Newton Police Department

Attachments

CASE STUDY 3, APPENDIX B

March 21, 2008

Grant M. Carrow, Ph.D., Deputy Director Bureau of Quality Assurance and Control Department of Public Health 99 Chauncy Street Boston, MA 02111

RE: Proposal by Eaton Apothecary to conduct an unwanted medication collection, June 7, 2008 - Wellesley

NERC currently has a grant from the Community Pharmacy Foundation to work with community pharmacies to set up and hold unwanted medication collections. Through that effort, I was approached by Eaton Apothecary and they have decided that they would like to hold an event at their store in Wellesley on June 7, 2008. The Wellesley Police Department has agreed to participate per the terms and conditions that you require. I am doing the organizing on their behalf and will be on-site supervising and coordinating activities.

I would like to outline for you the details of how the event will operate and to seek your express approval of the process (or to learn of desired changes). As you can imagine, Eaton Apothecary wants to be sure that they will be in full compliance with all Massachusetts legal and licensing requirements.

- It will take place inside the Eaton Apothecary retail establishment located at 266 Washington St., Wellesley, Massachusetts.
 - a. The event will take place in the basement retail space of the store. The pharmacy is located on the street level.
 - b. The event will be open to the public from 10 2.
- Materials will be accepted only from the public no businesses, nursing homes, or other institutions.
- The collection will be staffed by at least the following individuals:
 - a. Maria Cognilia, RPh, Eaton Apothecary Pharmacist
 - b. Sophie McIntyre, PharmD., Eaton Apothecary
 - c. Myself
 - d. Another member of the NERC staff who has participated in a number of collection events.
 - e. A Wellesley Police Officer, in uniform
 - f. A "greeter"

There is the intention of securing the assistance of two or more pharmacy students or interns to assist with identifying any unlabeled or unknown medications that come in.

- The Wellesley Police Department will take possession and custody of all federally controlled substances (Schedule 2 - 5) and any medications that are not identified. They will be provided with a printed and signed copy of the inventory of controlled substances. They have agreed to ensure witnessed destruction of the controlled substances and not to use the evidence destruction system for this. Two Wellesley officers will transport the controlled substances to a Waste-to-Energy facility that is permitted to destroy pharmaceuticals, and will watch the destruction. They will provide documentation to Eaton Apothecary of the witnessed destruction. Eaton Apothecary will be responsible for the associated costs.
- The non-federally controlled substances will be incinerated as hazardous waste. Clean Harbors Environmental will be the hazardous waste company. It will pick-up and remove these materials at the end of the event, so there will be no on-site storage of any medications collected.
- The pharmacy will not be the holder or generator of the inventory of medications. The Northeast Recycling Council, Inc. will assume this responsibility.
- The medications collected or received will in no way become part of the inventory of materials of the pharmacy for the purposes of accountability.

Sincerely, Lvnn Rubinstein **Executive Director**

CASE STUDY 3, APPENDIX C

Sample Press Release

PRESS RELEASE

For immediate release **CONTACT:** Sophie McIntyre Date: May 7, 2008 **Eaton Apothecary** (508) 429-8506 ext 13

DON'T FLUSH THAT LEFTOVER MEDICINE!

Eaton Apothecary to hold Free Collection and Safe Disposal of Unwanted Medication Saturday June 7, 10 a.m. to 2 p.m. **Eaton Apothecary 266 Washington Street** Wellesley, MA

BACKGROUND:

Everyday, unwanted, or expired medicine is disposed of via indoor drains—down the sink or in the toilet. Antibiotics, antidepressants, and hormone medications are now found in waterways nationwide because they slip through septic systems and sewage plants untreated. Trace amounts of pharmaceuticals have also been identified in some drinking water supplies. Although using the toilet or sink prevents someone from accidentally taking the medications, disposing of them in this way causes water pollution and has adverse effects on aquatic species, including fish. There may be human affects because the release of antibiotics in the environment fosters the spread of antibiotic resistance among microbes.

Eaton Apothecary has partnered with the Northeast Recycling Council to hold Massachusetts' first-ever unwanted medication collection in a pharmacy. Northeast Recycling Council has held similar events in neighboring states, collecting and safely incinerating hundreds of gallons of unwanted and expired medicine that may otherwise have ended up contaminating our waters.

COLLECTION:

The Unwanted Medication Collection will be held on Saturday, June 7, from 10 a.m. until 2 p.m. at Eaton Apothecary, 266 Washington Street, Wellesley MA. Items that will be collected are:

- Expired or unwanted prescription medicine
- Over the counter medicines
- Vitamins and nutritional supplements
- Veterinary Medications

Medications must be in their original containers. To prepare for the collection, participants should cross out the patient's name on prescription drug labels, but leave the name of the medication visible. This event is open to the public, regardless of where the medications were purchased. However, medications cannot be accepted from businesses such as nursing homes and doctor's offices. In addition, sharps will not be accepted. The Wellesley Police Department will supervise the collection. All medicine will be sent to a waste facility for secure incineration. No medicine will be re-sold or re-used.

Outdated and unused medications pose a danger in the home, and when improperly discarded, contaminate our environment with a dangerous blend of chemicals. This is an opportunity for Massachusetts residents to clean out their medicine cabinets and bring all unwanted medications to the collection for proper disposal, and in so doing safeguard the home, and preserve our environment for future generations.

Eaton Apothecary organizes this event in conjunction with the Northeast Recycling Council, with support from the Community Pharmacy Foundation, the Department of Public Health, and the Wellesley Police Department.

For more information please contact Eaton Apothecary at 266 Washington Street, Wellesley MA, (781) 235-1464.

APPENDICES ΙX

APPENDIX 1: Sample Survey

APPENDIX 2: Collection Overview for State Agency Consideration

APPENDIX 3: Best Management Practice Recommendations for the Disposal of Unwanted Medications Not Controlled by the USDEA Generated at Consumer Collection Programs

APPENDIX 4: Medications Should Stay in their Original Containers for Disposal

APPENDIX 5: Sample Letter to Police Requesting Participation

APPENDIX 6: Follow-up Memo to Police Confirming Collection Details

APPENDIX 7: APhA Guidance on Disposal

APPENDIX 8: White House Guidance on Disposal

APPENDIX 1: Sample Survey

Unwanted Medications Collection – Wellesley, MA June 7, 2008
City or Town you live in:
Have you been to an Eaton Apothecary before? Yes No
What pharmacy do you usually use to fill your prescriptions?
How did you find out about this event? (Check all that apply)
O Store signs: Which store?
Whose medication was this? Mine Household member Friend Pet
Do you have any comments?
Thank You!

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 multistate 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 (USDEA).

APPENDIX 2: Collection Overview for State Agency Consideration continued

The Law

Federal Drug Law

The USDEA prohibits the transfer of dispensed controlled substances from an individual to a pharmacist, reverse distributor, or any other entity registered with the USDEA 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.

APPENDIX 2: Collection Overview for State Agency Consideration continued

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 USDEA 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.
- The presence of medications with hazardous waste characteristics in the waste mix.
- 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.¹⁶
- Sending a message about the importance of safe end-of-life management of medications.
- 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:

- Be in full compliance with federal and state laws;
- Maximize site safety; and 2.
- 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.

APPENDIX 2: Collection Overview for State Agency Consideration continued

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.

Federally Controlled Substances

DOSAGE

0.25 mg

10 mg

0.5 mg

30 mg

27 mg

#3

AMOUNT

62

30

198

177

49 27

DRUG

acetaminophen

with codeine

Alprazolam

Clonazepam

codeine sulphate

Ambien

Concerta

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

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

Pharmacist

- 1. Determine if a medication is a controlled substance
- Inventory controlled substances. The USDEA required inventory is the name of the medication, dosage, and amount (see chart, left).
- 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

Graatar

- 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 USDEA, 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 3: 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.
- 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 Substances¹ **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.

¹ 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 4: 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 If 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.
- 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 eve.
- 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.
- 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
- Anytime you remove medications from the identifying labels there are worker exposure and public safety risks.

APPENDIX 5: Sample Letter to Police Requesting Participation

Date

Chief Terrence Cunningham Wellesley Police Department

RE: Request for participation of Wellesley Police Department in a community unwanted medication collection to take place at the Eaton Apothecary

Dear Chief Cunningham,

Eaton Apothecary would like to hold an unwanted medication collection in Wellesley. Such events are opportunities for the public (not businesses, doctors offices, or nursing homes, for example) to get rid of unwanted medications from their homes. All medications received are incinerated - the non-controlled as hazardous waste, the controlled substances per USDEA and Massachusetts Department of Public Health required witnessed burning.

Eaton Apothecary would like to host such an event at its Wellesley store sometime this spring or early summer and is requesting the participation of the Wellesley Police Department in the collection event. Without its participation, the event cannot and will not occur in your jurisdiction.

Following is an overview of the role of law enforcement at an unwanted medication collection event. The collection event at Eaton Apothecary will last for four hours (10-2), probably on a Saturday, on a date to be

Eaton Apothecary will be responsible for compensating the Wellesley Police Department for duty time for its participation in the event, as well as for the cost of destroying all controlled substances. Eaton Apothecary will also be responsible for all other costs associated with the collection, including the hazardous waste destruction of the non-controlled substances.

So, what are we asking of the Department?

- A commitment that a Wellesley Police Officer will participate in the event; providing security and taking possession of controlled substances.
- That the Wellesley Police Department will take permanent 2. physical possession and custody of any controlled substances.
- That the Wellesley Police Department will transport the controlled substances for witnessed incineration and provide documentation to Eaton Apothecary that such witnessed destruction took place. This must be apart from the evidence destruction system implemented by the Massachusetts Department of Health.
- Specific instructions from the Police Department about how it wants to manage the controlled substances. For example, the Police Officer will take the controlled substances back to the station on the day of the collection, and then would like to have the witnessed destruction take place that week. Or, that arrangements must be made for the immediate transport of the medications to the witnessed destruction. I would be happy to discuss the particulars and your requirements in this regard.

If you have any questions, please do not he sitate to contact me. I appreciate that this request is unusual and coming out of the blue! Thank you for considering the request. I will follow-up with a phone call towards the end of the week of February 11.

Unwanted Medication Collection – Role of Wellesley Police Department

- The primary responsibilities of the Police Officer at the collection event are to:
 - · Provide security.
 - Take possession of the controlled substances.
 - Transport the controlled substances to the Police Department evidence storage locker, and take whatever steps are necessary to store the medications in that locker.
 - Ensure witnessed destruction of controlled substances. This will require transporting them to the Haverhill Waste-to-Energy facility and watching the destruction.

The Department will be compensated for the time involved in carrying out these responsibilities, and will not be responsible for the cost of the witnessed destruction of the controlled substances.

- The Police Officer must be in uniform.
- During the collection:
 - The Eaton pharmacist will determine if a medication is a controlled substance. If it is a controlled substance, the Police Officer 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 Police Officer. A container for collecting the controlled substances will be provided - for example a five-
 - From that moment on, the controlled substances must stay in the sole physical possession of Police throughout the collection and until placed in the evidence storage locker and taken for destruction. At no time may the container of medications leave the physical possession of the Police Officer.
 - 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 Police. The Police Officer 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 Police Department, the inventory may be physically attached to the container of controlled substances, placed inside it, or carried separately.
 - Depending on the type of container that the Police Officer chooses for transporting and storing the controlled substances in the evidence storage locker, the Police Officer may also be required to initial over a seal securing the container of medications.
 - For security sake, Police will be asked to 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.
- 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: Police should be on-site no later than 9:30 a.m. on April 12 and must 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 Police Officer 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.

APPENDIX 6: Follow-up Memo to Police Confirming Collection Details

Date

Deputy Chief Bill Brooks Wellesley Police Department

RE: Confirming Participation in Eaton Apothecary Unwanted Medication Collection – June 7, 2008

Dear Deputy Chief Brooks,

As you know, Eaton Apothecary will be holding a public unwanted medication collection on Saturday, June 7, from 10 - 2, at its store on Washington St. Thank you for agreeing to the participation of the Wellesley Police Department in this event.

Specifically, police officers are required to:

- Provide security. The Police Officer must be in uniform.
- Take possession of the controlled substances.
- Transport the controlled substances to the Police Department evidence storage locker, and take whatever steps are necessary to store the medications in that locker.
- Ensure witnessed destruction of controlled substances. This will require transporting them to the Milford Waste-to-Energy facility and watching the destruction.

Police should be on-site no later than 9:30 a.m. on June 7 and must 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 Police Officer 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.

The Department will be compensated for the time involved in carrying out these responsibilities, and will not be responsible for the cost of the witnessed destruction of the controlled substances.

During the collection:

- The Eaton pharmacist will determine if a medication is a controlled substance. If it is a controlled substance, the Police Officer 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 Police Officer. A container for collecting the controlled substances will be provided - for example a five-gallon pail.
- From that moment on, the controlled substances must stay in the sole physical possession of Police throughout the collection and until placed in the evidence storage locker and taken for destruction. At no time may the container of medications leave the physical possession of the Police Officer.
- 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 Police. The Police Officer 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 Police Department, the inventory may be physically attached to the container of controlled substances, placed inside it, or carried separately.
- Depending on the type of container that the Police Officer chooses for transporting and storing the controlled substances in the evidence storage locker, the Police Officer may also be required to initial over a seal securing the container of medications.
- For security sake, Police will be asked to 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.

Off-site, after the collection:

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

If you have any questions, please do not hesitate to contact me. I look forward to working together.

Sincerely,

APPENDIX 7: APhA Guidance

APhA Provides Guidance on Proper Medication Disposal Use with Respect and Discard with Care

In response to a growing concern about the improper disposal of unused or expired medications and the recent media coverage about medication misuse, the American Pharmacists Association (APhA) recommends three simple steps that consumers should take to protect their families, community, and the environment:

- DO NOT FLUSH unused medications. Consumers were once advised to flush their expired or unused medications; however, recent environmental impact studies report that this could be having an adverse impact on the environment. While the rule of thumb is not to flush, the Food and Drug Administration (FDA) has determined that certain medications should be flushed due to their abuse potential. Read the instructions on your medication and talk to your pharmacist.
- 2. When tossing unused medications, protect children and pets from the potentially negative effects. APhA recommends that consumers:
 - Crush solid medications or dissolve in water (this applies for liquid medications as well) and mix with kitty litter or a solid kitchen substance, then place in a sealed plastic bag to reduce the risk of poisoning children and/or pets *before* tossing in the trash.
 - Remove and destroy ALL identifying personal information (prescription label) from the medication container.
 - Check for approved state and local collection programs or with area hazardous waste facilities. In certain states, you may be able to take your unused medications to your community pharmacy.
- 3. Talk To Your Pharmacist. Research shows that pharmacists are one of the most accessible healthcare professionals. As the medication experts on the healthcare team, pharmacists are available to guide you on how to properly dispose of your unused medications.

Medications play an essential role in our society, but medications are powerful. They should be used with respect and discarded with care. Following these simple guidelines can help protect your family and community, prevent the illegal diversion of unused medications, and minimize a potential negative impact on the environment.



Proper Disposal of Prescription Drugs

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

Actiq (fentanyl citrate)

Daytrana Transdermal Patch (methylphenidate)

Dura gesic Transdermal System (fentanyl)

OxyContin Tablets (oxycodone)

Avinza Capsules (morphine sulfate)

Baraclude Tablets (entecavir)

Reyataz Capsules (atazanavir sulfate)

Tequin Tablets (gatifloxacin)

Zerit for Oral Solution (stavudine)

Meperidine HCI Tablets

Percocet (Oxycodone and Acetaminophen)

Xyrem (Sodium Oxybate)

Fentora (fentanyl buccal tablet)

Note: Patients should always refer to printed material accompanying their medication for specific instructions.

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