POISON Help
1-800-222-1222

Texas Panhandle Poison Center

TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER
at Amarillo

1501 South Coulter
Amarillo, TX 79106

Business: (806) 354-1630
FAX: (806) 354-1667

April 24, 2009

Dear Texas State Board of Pharmacy Officials,

We, at the Texas Panhandle Poison Center (TPPC), have been interested in implementing a medication take-back program for several years. We have encountered significant barriers in conducting this activity, but feel so strongly that this is necessary that we continue to push forward. At this time, we are attempting to address the barriers that exist at the State level, specifically that a lawful mechanism for collecting previously dispensed medications for destruction through a take-back program does not exist.

We have reviewed the Texas Administrative Code, Title 22, Part 15, Chapter 303, Rule §303.1 regarding the destruction of dispensed drugs and although this rule provides guidance for destruction of drugs dispensed to patients in health care facilities or institutions, and guidance for drugs returned to a pharmacy; it does not provide any regulatory guidance for the collection of drugs through a take-back program.

I discussed this matter with Mr. Robert Santana, Head of Compliance, on April 16th and he provided helpful information and offered that we could petition the Board to amend the Rule. Thus, we at TPPC are submitting the attached proposed amendment to the Rule for your consideration.

In developing this proposal, we utilized portions of the currently existing rule from both part (a) drugs dispensed to patients in health care facilities or institutions and part (b) drugs returned to a pharmacy to develop a part (c) drugs collected through drug collection programs.

Approval of our proposal would greatly assist our current efforts to conduct a medication take back program. However, we are cognizant of the fact that while we have ready access to resources such as licensed pharmacists, other organizations who share interest in getting these drugs "off the streets" may not have access to such resources. Therefore, our proposal also includes a section for collection and destruction by public health officials. We understand that our proposal may be overly simplistic and we our open to modifications that may be required.

Our goal is to work expeditiously with the Board to put mechanisms in place that will promote the safe and secure return of unused drugs for destruction. The TPPC receives calls daily regarding poisonings that occur due to the presence of unused (and improperly stored) medications. Notably, we have had two cases in which children have had near-death experiences after ingesting unused Tessalon Perles. In addition, our Network receives calls daily regarding teens who are "Pharming" (i.e. scavenging the medicine cabinets of parents and family members) for drugs that might provide them with a high.

We do not feel that it is in the interest of the public for TPPC to postpone this activity any longer simply because there are no standards in place. We are actively pursuing the facilitation of activities and we are pleading for your assistance.

We have contacted the Texas Commission on Environmental Quality regarding destruction methods compliant with their regulations and have also contacted the U.S. Drug Enforcement Administration regarding federal regulations and the barriers resulting from the Controlled Substances Act. We are making every effort to conduct this activity in a responsible manner. Attached you will find a white paper, *Safe Disposal of Unused Controlled Substances/* that provides a comprehensive look at this topic and summarizes activities that have been conducted in other states as well as barriers. A website has also been launched: www.takebacknetwork.com.

If you have further questions, please do not hesitate to contact us. We greatly appreciate your time, effort, and consideration.

Sincerely,

Jeanie Jaramillo, PharmD
Managing Director
806-354-1611

Dr. Shu Shum, MD
Medical Director
806-354-1630

Proposed amendment to TAC, Title 22, Part 15, Chapter 303, Rule 303.1

Request is to combine parts of 303.1 part (a) and 303.1 (b) to create a 303.1(c) to read similar to:

Rule 303.1 Destruction of Dispensed Drugs

(c) Drugs collected through drug collection programs.

1. Destruction by a pharmacist. A pharmacist, if licensed by and in good standing with the Texas State Board of Pharmacy, is authorized to collect and destroy dangerous drugs and controlled substances that have previously been dispensed to a patient and are brought to a drug collection program, providing the following conditions are met:

    A. The drugs are inventoried by the pharmacist. The following information shall be included on this inventory:
        i. Date and location of collection program
        ii. Name, strength, and quantity of the drug(s)
        iii. Method of destruction
        iv. Contact information and signature of overseeing pharmacist and/or pharmacist that is destroying the drugs
        v. Signature of the witness(es)
    B. The signature of the overseeing pharmacist and/or pharmacist that is destroying the drugs may be on a cover sheet attached to the inventory and not on each individual inventory sheet, provided the cover sheet contains a statement indicating the number of inventory pages that are attached and each of the attached pages are initialed by the overseeing pharmacist and/or pharmacist destroying the drugs and witness(es).
    C. The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.
    D. The actual destruction of the drugs is witnessed by one of the following:
        i. A second licensed pharmacist in good standing with the Texas State Board of Pharmacy
        ii. A commissioned peace officer
        iii. An agent of the Texas State Board of Pharmacy
        iv. An agent of the Texas Department of Human Services, authorized by the Texas State Board of Pharmacy to destroy drugs
    E. If the actual destruction of the drugs is conducted at a location other than the facility or institution, the overseeing pharmacist and witness(es) shall retrieve the drugs from the facility or institution, transport, and destroy the drugs at such other location.

2. Transfer to a waste disposal service for destruction. A pharmacist, if licensed by and in good standing with the Texas State Board of Pharmacy, is authorized to facilitate the collection of dangerous drugs and controlled substances that have previously been dispensed to a patient for destruction by a waste disposal service, provided the following conditions are met:
    A. The waste disposal service is in compliance with applicable rules of the Texas Commission on Environmental Quality and the United States Environmental Protection Agency relating to waste disposal.
    B. The drugs are inventoried by the pharmacist. The following information shall be included on this inventory:
        i. Date and location of collection program
        ii. Name, strength, and quantity of the drug
        iii. Method of destruction
        iv. Contact information and signature of overseeing pharmacist
        v. Signature of the witness(es)
    C. Drugs should be separated based on controlled vs. non-controlled categorization. Non-controlled drugs may be stored, transported, and disposed of in a suitable container. Controlled substances and those that cannot be identified, should be handled as follows:
        i. The pharmacist seals the container of drugs in the presence of a witness as specified in subparagraph 1(D) above and
        ii. Utilizes tamper resistant tape to seal the container in such a manner that any attempt to reopen the container will result in the breaking of the tape; and
        iii. The signature of the pharmacist is placed over this tape seal
        iv. The sealed container is maintained in a secure area until transferred to the waste disposal service by the pharmacist
    D. A record of the transfer of all collected drugs to the waste disposal service is maintained and attached to the inventory specified in subparagraph (B) of this paragraph. Such record shall contain the following:
        i. Date of transfer
        ii. Signature of the pharmacist or health department representative who transferred the drugs to the waste disposal service
        iii. Name and address of the waste disposal service who receives the container(s)
    E. The waste disposal service shall provide the pharmacist with proof of destruction of the container(s). Such proof of destruction shall contain the date, location, and method of destruction of the container(s) and shall be attached to the inventory of drugs specified in subparagraph (B) of this paragraph.
3. Destruction by a public health official. Public health officials may petition the Texas State Board of Pharmacy for authorization to collect and destroy medications in an effort to prevent poisonings, misuse, and abuse. Such a request shall include:
    A. Proposed date, time, and location of event

B. Contact information and qualifications of public health official(s)
C. Security measures that will be taken on-site to prevent diversion
D. Plan for on-site destruction of drugs or use of waste disposal service (plan must include, at a minimum, the standards detailed in (c)1 or (c)2.)

4. Record retention. All records required in this subsection shall be maintained by the pharmacist representative for two years from the date of destruction.

Safe Disposal of Unused Controlled Substances /

Current Challenges and Opportunities for Reform

Prepared for:
King Pharmaceuticals, Inc.

Prepared by:
Sharon Siler
Suzanne Duda
Ruth Brown
Josette Gbemudu
Scott Weier
Jon Glaudemans

Avalere®

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EXECUTIVE SUMMARY

Disposal of unused prescription drugs,

and controlled substances in particular, is a complicated issue. Unused drug take-back programs are emerging across the country as one strategy for reducing drug abuse, accidental poisoning, and flushing drugs into the water supply. Current laws and regulations regarding controlled substances, however, limit these programs from accepting all drugs without strict oversight from law enforcement.

SIGNIFICANT BARRIERS

The Controlled Substances Act and Drug Enforcement Agency regulations dictate who can handle controlled substances, and are two of the most significant challenges today facing efforts to dispose of unused drugs. The law and regulations prohibit pharmacies, providers, and hospitals from collecting controlled substances that have already been dispensed to consumers. There is an exception that allows law enforcement officers to accept controlled substances, but because of the added burden of ensuring a law enforcement presence at take-back events, most programs are not currently accepting controlled substances from consumers.

U.S. Postal Service rules that do not allow consumers to mail prescription drugs present another challenge. Unless the Postal Service grants a waiver, communities exploring mail-back options for unused controlled substances cannot collect them.

Other important barriers include regulations that govern how hazardous waste is treated and disposed, the process by which drug disposal instructions are included in drug labels, state pharmacy laws, and rules that govern unused drugs that belong to consumers living in residential facilities or hospice.

CRITICAL SUCCESS FACTORS

A safe and effective controlled substances disposal system should have the following attributes:

Consumer Convenience. Attractive and accessible options to collect unused controlled substances from consumers.

Legal and Regulatory Feasibility. Without means to legally collect controlled substances, take-back programs will not be able to offer comprehensive solutions.

Program Sustainability. Even if legal barriers are resolved, a disposal system will need a compelling business case and adequate funding to succeed.

Effective Outreach and Education. Participation by all stakeholders will hinge on education on the benefits of proper disposal and available options.

REFORM PATHWAYS

Leaders at the local, state, and federal level will each have to shoulder some of the responsibility for achieving the goals of a controlled substances disposal system. The federal government is well-suited to take a leadership role in aligning the states toward a single national priority, while states and localities can implement solutions based on local values and preferences that differ around the country.

INTRODUCTION

Proper disposal of unused prescription drugs

has become an important public health issue in the United States as rates of prescription drug abuse, accidental poisoning, and the incidence of drugs found in the drinking water have gained the nation's attention. Due in part to growing media coverage of the issue, U.S. consumers are eager to learn how they can prevent leftover prescription drugs from falling into the wrong hands or polluting the environment. Although some of the relevant issues — especially regarding disposal of controlled substances — are fraught with complications, it is clear that consumers want clear-cut disposal options and that guidance on this topic will be well-received by the media and the public alike.

This white paper seeks to create forward momentum by charting a path to a safer, more efficient, and more secure drug disposal system — one that will garner support from a wide range of stakeholders, while also contributing to meaningful reductions in drug diversion and pollution.

SOURCES OF UNUSED MEDICATION

3 PERCENT (2.8 MILLION POUNDS) OF PRESCRIPTION MEDICATIONS GO UNUSED BY U.S. CONSUMERS.

Consumers may have leftover pharmaceuticals for many reasons. Some patients fail to complete the full course of their medication because they have allergic reactions or changes in symptoms, dosage requirements, or treatment protocol. Patients may also be reluctant to continue taking a medication if they begin feeling better or if they do not want to endure unwanted side effects. In addition, some patients die due to life-ending morbidities while on medication, potentially putting loved ones in charge of disposing of their unused prescriptions.

Despite increasing awareness of disposal issues, there have been no definitive studies of how many prescription drugs go unused each year in the United States. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that 3 percent (2.8 million pounds) of prescription medications go unused by U.S. consumers and that 7-13 percent (1.5 million pounds) goes unused by patients in long-term care facilities.[1]

Recent data collection efforts, however, suggest that the percentages may be higher. The Teleosis Institute in California collected data on unused drugs from July 1 to December 31, 2007, and reported that of the prescription drugs collected, consumers did not use nearly 45 percent of what they were prescribed.[2] Teleosis, and others, are also collecting data on the types of medications consumers return unused:

MEDICATION	PERCENTAGE OF TOTAL DRUGS COLLECTED
Central nervous system agents	22.62%
Nutritional products	14.29%
Psychotherapeutic agents	12.51%
Gastrointestinal agents	8.99 %
Cardiovascular agents	8.77%
Respiratory agents	6.00%
Anti-infective medicines	6.00%
Alternative medicines	5.69%
Hormones	4.60%
Immunologic agents	2.85%

Particularly noteworthy in these recent data collection efforts is how few opioids consumers are returning to take-back programs, perhaps saving medications for a "rainy day." Teleosis reported that controlled substances accounted for only 2.15 percent of the total drugs returned.[3] There are several factors that could be contributing to this, not least of which is that most take-back programs do not accept opioids because of the regulatory complications that go along with handling controlled substances.

In recent years, the Drug Enforcement Administration (DEA) has stepped up its efforts to combat prescription drug abuse, especially its oversight of physicians who prescribe opioid analgesics, or painkillers. To thwart illegal diversion of prescription drugs, from May 2001 to January 2004, DEA launched more than 400 investigations of physicians, pharmacies, manufacturers, and wholesalers and arrested nearly 600 individuals.[4] In fiscal year 2007, DEA investigated 224 physicians, which amounts to less than 1 percent of all doctors.[5]

This increased attention to prescribing habits has had a chilling effect on physicians.[6] Several surveys indicate that nearly half of physicians knowingly undertreated pain in their patients for fear of investigation and prosecution.[7] It is, perhaps, not surprising then, that opioids do not appear at the top of the list of the drugs most frequently returned to drug disposal programs.

RISKS OF KEEPING UNUSED DRUGS

Although there are options for disposing of unused drugs, many consumers keep drugs in their possession because they do not want the drugs to go to waste or do not know how to dispose of them properly. Keeping medication in the home poses several risks related to diversion, accidental overdose, and consumption of spoiled substances.

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The presence of unused drugs in the household is likely contributing to growing rates of prescription drug abuse among Americans, particularly teenagers. A 2004 survey found that 20 percent of people ages 12 and older misused psychotherapeutic drugs during their lifetime, and 2.5 percent had done so in the past month. Prescription drug misuse was highest in young adults ages 18 to 25, with a rate of misuse of 14.5 percent among those individuals.[8] Types of prescription drugs frequently abused include pain relievers, tranquilizers, stimulants, and sedatives; OxyContin and Vicodin are especially popular among teens.

Many teens erroneously believe that it is safer to use prescription drugs than street drugs, and they report that these drugs are easier to

obtain than street drugs.[9] Nearly 60 percent of people ages 12 and older obtain prescription painkillers for free through friends or family.[10] This behavior poses a serious public health problem and is contributing to the steady uptick in poison-related deaths in the United States. In 2004, 20,950 people died of drug poisoning.[11]

A study by the Partnership for a Drug-Free America of seventh through twelfth graders found that 40 percent of respondents believe using prescription drugs is safer than using illegal drugs. In addition, 29 percent think that pain relievers are not addictive, and 62 percent of teens who abuse prescription pain relievers said they do so because they are easily accessible through parents' medicine cabinets.[12] The second most common type of drug abuse after marijuana was prescription drugs. Five of the six drugs most frequently abused by twelfth graders were prescription drugs or cough and cold medicines, as found in a 2006 study.[13]

The growing rates of prescription drug abuse are driving demand for a comprehensive and sensible drug disposal program. Parents, in particular, are becoming increasingly aware of this issue, largely because the White House Office of National Drug Control Policy (ONDCP) National Anti-Drug Media Campaign and other large-scale awareness efforts are encouraging them to safeguard and properly dispose of unused drugs.

CURRENT DISPOSAL PRACTICES

Research indicates that consumers lack guidance on how to dispose of their leftover medication. A 2006 survey of 301 patients at an outpatient pharmacy found that fewer than 20 percent had ever been given advice from a healthcare provider about medication disposal. The same survey found that more than half of patients reported storing unused and expired medications in their homes, while more than half flushed unused medication down the toilet, and only 22.9 percent reported returning unused medication to the pharmacy for disposal.[14]

Earlier research yielded similar findings. A 1996 survey of 500 callers to a U.S. poison information center found that only 1.4 percent of callers returned medications to a pharmacy, while 54 percent reported disposing of medications in the garbage, 35.4 percent reported flushing medications down the toilet or sink, 7.2 percent reported that they did not dispose of medications, and only 2 percent said they used all medications before expiration. The same study also surveyed 100 pharmacies and found that only 5 percent of the pharmacies had consistent recommendations for their customers on drug disposal. In addition, 25 percent of the pharmacies said questions on drug disposal were handled by individual pharmacists only on consumer request.[15]

As evidenced by this research, consumers depend on three primary disposal methods for unused medication: flushing them down the toilet, throwing them in the trash, and returning them to the pharmacy. Each of these methods deserves closer examination to understand the relevant advantages and disadvantages:

Flushing. This method, which the ONDCP recommends for several prescription drugs, including a number of controlled substances, is a convenient way to ensure that drugs are permanently removed from the home and cannot be diverted.

Despite its convenience, this approach nevertheless raises potential environmental concerns, especially in light of research from the United States, Canada, and Europe that found trace pharmaceuticals in surface, ground, and drinking water. In 2002, the U.S. Geological Survey conducted the first national study of organic wastewater contaminants and found human and veterinary drugs — including hormones, steroids, and personal care product ingredients — in 80 percent of the 139 streams tested in 30 states. Antibiotics and prescription drugs were among the most frequently detected chemicals.[16] It is unclear what amount is entering the water through human excretion of ingested medicines or from flushing. Scientists are currently exploring this very question; however, of the studies on pharmaceuticals in the environments that have been completed, no negative effects to human health were discovered.[17]

The Environmental Protection Agency (EPA) has yet to issue guidelines for testing for pharmaceuticals in water supplies. As a result, state and local wastewater and public and private water suppliers do not test for these compounds. Nevertheless, these environmental concerns raise important issues and deserve to be addressed in a comprehensive and sensible drug disposal strategy. Notably, some local government and environmental groups have raised concerns over the White House guidance approach to flushing medications, and some states have posted their own guidelines that recommend against flushing or pouring medications down drains.

Consumers depend on three primary disposal methods for unused medication: flushing them down the toilet, throwing them in the trash, and returning them to the pharmacy.

Trash. Throwing unused drugs in the trash — much like flushing them down the toilet — is a convenient method for removing medications from the household. This method is also supported by ONDCP, provided consumers disguise the drugs or mix them with kitty litter, coffee grinds, or other undesirable substances.

Despite the convenience factor, this method is not foolproof and can lead to drug diversion. In addition, research indicates that pharmaceuticals in landfills may be leaching into groundwater and waterways

because of poorly engineered or unlined landfill sites. In fact, the EPA has stated that it expects that all landfills will eventually fail and leak.[18] In spite of technological improvements, it is unlikely that the risk of leakage from landfills can be eliminated. In the small number of cases where waste is disposed of in unlined landfills, pharmaceuticals could theoretically leach into groundwater and enter the drinking water supply.

As a result of these issues, throwing medication into the trash might be contributing to the same environmental concerns outlined in the flushing section.

Take-Back Programs. Programs that collect and dispose of unused drugs are gaining support as people wrestle with how best to dispose of various types of medication. Most take-back programs have emerged as a response to reducing the potentially negative effects on the environment of flushing drugs or disposing of them in landfills. Stemming the tide of drug abuse and diversion and preventing accidental poisonings is typically a secondary motivator.

With respect to controlled substances, however, consumer return options are more limited because of DEA regulations that prevent pharmacists from taking back drugs from consumers. In fact, the DEA specifies that only law enforcement officials can receive returned controlled substances from consumers. Most community and state take-back programs do not accept controlled substances from consumers because of this constraint.

Despite the promise of these programs, they are currently hampered by numerous challenges that impede their overall effectiveness and sustainability. Among these obstacles are laws that prevent providers and pharmacies from accepting returned controlled substances, lack of adequate and sustained funding, and competing demands and priorities that can limit commitment and collaboration from community stakeholders.

Given the difficulty of implementing these programs, it is not surprising that they are somewhat rare. And those that do exist often are offered infrequently or at locations, such as household hazardous waste collection facilities, that can make them inconvenient for consumers.

SCOPE OF PAPER

The purpose of this paper is to determine optimal strategies for consumer-initiated disposal of unused and unwanted drugs. This paper does not address how best to change consumer behavior to take advantage of these systems, but it does seek to identify disposal methods that will pose the fewest barriers in terms of convenience and difficulty.

Once systems are in place to help consumers safely and efficiently dispose of drugs, additional research will be needed to uncover social marketing practices that can convince consumers that they should, indeed, take advantage of drug disposal programs. New methods will also be needed to heighten consumer understanding of the fact that keeping unwanted medications in homes carries more risk than benefit, especially with regard to potential for overdose, expiration, and diversion.

Also, this paper does not contemplate drug disposal issues for hospitals or other healthcare facilities where medications are the property of the facility, and not the patient. In nursing homes or hospices, medications remain the property of the patient, and the staff is merely custodians. Because the drugs never become patient property, hospitals do not have to contend with many of the issues regarding return of controlled substances that nursing homes or hospices do. The requirements for returning controlled substances are discussed later in the Current Landscape section. Hospitals have separate channels for returning unused drugs, typically through a reverse distributor, that handles the disposal. Nursing homes and hospices, however, cannot accept unused drugs from patients because the law prohibits anyone but the patient to whom the drug was prescribed from taking possession of it. As such, nursing homes and hospices are grappling, much like consumers, with the most appropriate way to dispose of unused drugs.

METHODOLOGY

To better understand the issues related to

disposal of controlled substances and to inform potential solutions to the problem, Avalere Health reviewed the literature on federal regulations, policies, and guidelines that govern disposal of pharmaceuticals, particularly controlled substances. The literature review also included materials from existing efforts to collect and dispose of unused drugs from consumers.

Additionally, Avalere interviewed more than 20 public- and private-sector stakeholders across the country invested in the safe collection and disposal of unused or expired pharmaceuticals. Specifically, interviewees included participants from eight statewide or community take-back programs of varying models. These interviewees ranged from employees of solid and hazardous waste departments to nonprofit organizations to law enforcement. Avalere also interviewed representatives of key industry groups including national associations representing state controlled substances regulators, hospices, pharmacies, reverse distributors, national chain pharmacies, and regional coalitions focused on pollution prevention. Officials representing the regulatory arm of the federal government were also interviewed.

To conduct the interviews, Avalere developed and used structured interview guides tailored for each stakeholder group. The interviews explored a number of topics:

- Issues contributing to the large amounts of unused/expired pharmaceuticals
- Benefits to developing a collection and disposal system
- Operational and regulatory barriers related to collecting and disposing controlled substances
- Potential broad and sustainable solutions to the problem
- Infrastructure, stakeholders, and funding streams needed to support those potential solutions

Additionally, Avalere participated in a national stakeholder dialogue led by the Product Stewardship Institute (PSI), which focuses on fostering partnerships between government and private-sector stakeholders to reduce the health and environmental impacts of consumer products. PSI is hosting a series of four multi-stakeholder meetings to evaluate the feasibility of developing product stewardship approaches for the collection and disposal of unused pharmaceuticals.

The literature review, interviews, and participation in PSI's dialogue meetings provide the basis for this report's findings.

CURRENT LANDSCAPE FOR DRUG DISPOSAL PROGRAMS

Take-back programs are emerging to address drug abuse and diversion, accidental poisoning, and environmental problems by providing consumers with a safe and environmentally sound option for disposing of unused or expired drugs. Take-back programs are state or community-driven initiatives focused on safely collecting and disposing of unwanted over-the-counter, prescription, and in certain cases, veterinary medications.

COLLECTION

ONLY 22.9 PERCENT OF CONSUMERS REPORTED RETURNING UNUSED MEDICATION TO THE PHARMACY.

Two collection models have emerged: drop-off and mail-back/ship-back. Both of these options are limited by current laws and regulations concerning controlled substances, so some programs accept only non-controlled drugs, while others are experimenting with creative solutions to allow for collections of all medications—including controlled substances. In either model, collection events are typically organized by a collaboration of many stakeholders.

Drop-off Models. Under this model, individuals can drop-off their unused medications either at permanent collection sites or one-day events. Based on the literature review, more than 30 permanent and one-day take-back programs are operating in the United States; the majority of these are permanent sites. This figure (overall number of existing programs) could very well be an under-representation of the actual amount of take-backs, as new programs are constantly being launched and because a systematic tracking system for take-back programs is just now getting underway.[19]

Permanent collection programs provide ongoing, year-round drop-off services for consumers at either one or multiple predefined locations, generally at pharmacies, police stations, or household hazardous waste (HHW) facilities. The most widely used drop-off sites for permanent collections are pharmacies and police stations. Also, depending on the scale of the project, permanent collection programs operate multiple drop-off sites throughout a defined service area. Entities organizing permanent collection programs range from nonprofit organizations focused on consumer or environmental issues, to counties and municipalities, to state boards of pharmacy. With the exception of very few programs, permanent collection programs do not generally accept controlled substances because of the limitations imposed by the Controlled Substances Act and accompanying DEA regulations.

PROGRAM SPOTLIGHT: Washington State Pharmaceuticals From Households: A Return Mechanism (PH:ARM)	
BRIEF DESCRIPTION	PH:ARM pilot began in 2006. Consumers deposit unused drugs in secure drop boxes in pharmacies. Controlled substances are not allowed. Once collected, drugs are moved to secure storage facilities operated by participating pharmacies. Drugs are transported for incineration by a reverse distributor licensed by the state board of pharmacy and the DEA.
COLLECTION SITE(S)	Group Health Cooperative clinical pharmacies and Bartell Drugs retail pharmacies.
COLLECTING CONTROLLED SUBSTANCES	No
ORGANIZERS & PARTNERS	Interagency Resource for Achieving Cooperation, King County Hazardous Waste Management Program, Snohomish County Solid Waste Management Division, Seattle-King County Public Health, Northwest Product Stewardship Council, Washington Citizens for Resource Conservation, Pacific NW Pollution Prevention Resource Center, Washington Department of Social and Human Services-Aging and Disabilities Services, Washington State Department of Ecology (Solid Waste and Financial Assistance), Washington Board of Pharmacy, Group Health Cooperative, Bartell Drug Company.
COSTS	Projected cost of statewide program is $3.3 million or $5.60 per pound collected.
OUTCOME	As of May 2008, PH:ARM collected more than 10,000 pounds of unused pharmaceuticals.

PROGRAM SPOTLIGHT: La Crosse County, Wisconsin	
BRIEF DESCRIPTION	In June 2007, the La Crosse County Solid Waste Department became the first permanent collection site in Wisconsin. The county developed a unique strategy for disposing of unwanted pharmaceuticals, specifically controlled substances. Employees from the department are conditionally deputized by the county sheriff to receive controlled substances from individuals. County residents are then able to drop off any unused medication at the hazardous waste facility. Under supervision by the department's deputized staff, residents drop off their medication through a funnel into a gallon drum of solvent that dissolves the medications. The program is funded through a tax levy, grants, and fees charged to non-area residents/businesses.
COLLECTION SITE(S)	County hazardous materials facility.
COLLECTING CONTROLLED SUBSTANCES?	Yes
ORGANIZERS & PARTNERS	La Crosse County Solid Waste Department, La Crosse County Sheriff's Office, La Crosse area local pharmacies, Franciscan Skemp Medical Center, La Crosse area U.S. Fish & Wildlife office.
COSTS	The total annual cost is estimated at $12,000-$15,000.
OUTCOME	As of May 2008, La Crosse County collected 8,500 pounds of unused pharmaceuticals.

Unlike permanent collections, one-day take-backs are regional or local collection events held only occasionally. One-day events may take the form of communitywide or citywide collection drives that occur simultaneously across different locations throughout a selected geographic region. These collection events are hosted in a variety of venues including pharmacies, police stations, HHW facilities, senior centers, parks, and hospitals; law enforcement officials, nonprofits, and state environmental or health agencies typically work together to organize one-day take-back events. Many one-day take-back events collect controlled substances along with other medications. Because these events are time-limited, they do not require the long-term commitment from law enforcement officers that permanent collection sites do; therefore, one-day events are able to secure a law enforcement presence at a reasonable cost.

PROGRAM SPOTLIGHT: Northeast Recycling Council (NERC)	
BRIEF DESCRIPTION	NERC is a nonprofit collaboration among 10 states (CT, DE, ME, MA, NH, NJ, NY, PA, RI, VT) devoted to advancing an environmentally sustainable economy by promoting source and toxicity reduction, recycling, and the purchasing of environmentally preferable products and services. Through grants from the Community Pharmacy Foundation, the EPA, and the U.S. Department of Agriculture (USDA), NERC is working with retail pharmacies around the United States to encourage the development of unwanted medication collections. NERC has organized one-day events in nine states (ME, NH, VT, MA, CT, NY, PA, VA, WV).
COLLECTION SITE(S)	One-day collection pilots in pharmacies, senior centers, and HHW facilities.
COLLECTING CONTROLLED SUBSTANCES?	Yes
ORGANIZERS & PARTNERS	Nonprofit organization that is composed of 10 Northeast states.
COSTS	NERC events range in costs. For example, a program held in conjunction with a blood drive in Vermont cost just over $4,000, while an event at a CVS pharmacy in Massachusetts cost nearly $8,000.
OUTCOME	NERC drafted guidance detailing approaches and best practices for conducting a replicable take-back program, as well as case studies from many of its one-day events.

Mail/Ship-back Models. In a mail-back program, consumers send their unused drugs to a central location via the United States Postal Service (USPS), while a ship-back program uses a private carrier, such as UPS or FedEx. There are two programs currently operating in this capacity across the country. Maine in partnership with USPS conducts a statewide mail-back program, and Capital Returns, a Wisconsin-based reverse distributor, operates a ship-back pilot program.

In both programs, participants who use the services are expected to put the pharmaceuticals in a specified mailer before sending. The Maine program provides prepaid mailing envelops that are available at pharmacies, physician offices, and post offices. The Maine take-back program accepts controlled substances, while the Wisconsin program does not. Law enforcement officers at the Maine Drug Enforcement Agency receive the

mailed-in controlled substances, fulfilling the requirements of the Controlled Substances Act. To minimize the likelihood of receiving controlled substances, Capital Returns encourages individuals to call a toll-free number to describe the exact medications they plan on mailing.

PROGRAM SPOTLIGHT: Maine Mail-back Pilot	
BRIEF DESCRIPTION	Launched in May 2008, the pilot offers a free mail-back option for consumers aged 65 and older. A total of 1,800 envelopes will be available in 7 pharmacies in 4 counties. The pilot is currently funded through a grant from the EPA Aging Initiative designed specifically to assist older adults and caregivers. The pilot will be expanded to all age groups in late 2008 or early 2009, when 7,200 mailers will be available statewide.
COLLECTION SITE(S)	Consumers can pick up envelopes at participating pharmacies.
COLLECTING CONTROLLED SUBSTANCES?	Yes
ORGANIZERS & PARTNERS	University of Maine Center on Aging, Maine Benzodiazepine Study Group, Drug Disposal Group, Maine DEA, USPS, Rite Aid Pharmacies, Miller Drug Pharmacy, Maine Department of Environmental Protection, Maine Department of Health and Human Services, Community Medical Foundation for Patient Safety, National Council on Patient Information and Education.
COSTS	Maine is supporting this pilot with $300,000 in grant funds, half from EPA, and half from state appropriations.
OUTCOME	Not measured yet.

PROGRAM SPOTLIGHT: Wisconsin Ship-back Pilot	
BRIEF DESCRIPTION	Launched in May 2008, the pilot program offers a ship-back option for consumers via UPS.
COLLECTION SITE(S)	Consumers must call Capital Returns to receive a prepaid and prelabeled envelope.
COLLECTING CONTROLLED SUBSTANCES?	No
ORGANIZERS & PARTNERS	Waukesha and Winnebago counties, University Extension-Solid and Hazardous Waste Education Center, Wisconsin Department of Natural Resources, EPA, Department of Agricultural Trade and Consumer Protection, Illinois-Indiana Sea Grant Program
COSTS	$72,625 for six-month pilot.[20]
OUTCOME	Not measured yet.

DISPOSAL

There are several options for disposing drugs collected through take-back programs: hazardous waste incineration, solid waste incineration, hazardous waste landfill, or solid waste landfill. Most take-back programs treat and destroy non-controlled medications as hazardous waste, whereas controlled substances, if collected, are turned over to law enforcement for witnessed destruction as required by the DEA.

Consumer options for returning unused controlled substances are limited.

A number of respondents cited reasons why hazardous waste incinerators are the optimum method currently available for disposal: high burn temperature and effective pollution control systems to deal with air emissions and residue from the incinerated medications. At least one program is taking advantage of a waste-to-energy facility. The Capital Returns ship-back pilot transfers all collected medications to a facility in Indiana where the steam generated from incineration is used to help power the city of Indianapolis.[21]

It is important to note that the DEA requires that a licensed physician, pharmacist, mid-level practitioner, or a state or local law enforcement

officer witness the disposal of controlled substance and that the drugs be destroyed beyond recovery. If a take-back program is collecting controlled substances, it should arrange for disposal that meets these requirements. Most programs turn the collected controlled substances over to the law enforcement officers present at the event.

COSTS

The interviews and literature revealed that existing programs capture and measure operational costs in different ways. There are, however, certain categories of costs that are universal for all programs: staffing, equipment/supplies (including mailers in mail-back/ship-back models), advertising, and disposal.

The table below describes and links the cost drivers to examples of their attendant expenses:

CATEGORY	COST DRIVERS	EXPENSES
STAFF	Required staff includes greeters, data entry personnel, a site supervisor, a hazardous waste company, pharmacists, and law enforcement if controlled substances are accepted.	Law enforcement personnel average $45/hour. Pharmacists average $50 hour.[22]
SUPPLIES & EQUIPMENT	Programs will need to purchase and maintain tools for counting medications, reference documents for researching unknown or unlabeled medications, tables, chairs, laptops, and hazardous waste containers. These costs may be nominal depending on the sophistication of collection vessels and whether the tables, chairs, and laptops used are borrowed.	Large metal drop boxes could cost about $650 each plus additional bucket costs. [23]
MAILERS	Prepaid mailers or mailing labels	Prepaid mailers used by the Maine program cost approximately $4 to mail.
ADVERTISING	The advertising costs are determined by the marketing strategies and tactics. A number of programs reported purchasing newspapers, television, and radio advertisements, sending press releases, and posting fliers.	NERC one-day programs ranged from $100 to $1,000, depending on each program's strategy.
DISPOSAL	Costs associated with hazardous waste disposal are linked to the transportation of non-controlled substances for destruction, the tracking of medications from the stage of collection to destruction, and incineration.	Two programs reported averaging about $2.00-2.50 per pound for disposal. NERC found that one-day events held outside of HHW events averaged about $23 per gallon for disposal and nearly $294 for transportation fees. For events held in conjunction with HHW events, disposal averaged $12 per gallon and no transportation fee.

Existing programs do not systematically measure the same operational costs because some programs benefit from donated services or items. For example, some programs received in-kind donations from partners. In Clark County, Washington, participating pharmacies and county public programs absorb all costs of the program so that consumers can return their unwanted medications at no fee. Additionally, in Illinois, the state EPA will fund transportation and disposal of non-controlled medicines collected through county-organized collections. In each of these cases, the costs reported by these programs may underestimate the actual costs because of an undercount of in-kind services.

FUNDING

A combination of public and private sources fund take-back programs, such as federal and state environmental agencies, the USDA, and private grants. With respect to federal funding, the EPA issued $300,000 in grants in 2006 to the Maine mail-back program and to the St. Louis, Missouri, take-back program. EPA's Office for Children's Health Protection funded the federal grant, which was set aside for financing take-back programs as part of the agency's efforts to work jointly with the DEA in ensuring compliance with federal and state laws and regulations.[24] The EPA also has a number of grants that, although not strictly reserved for funding take-back programs, support state and community efforts to address waste reduction, pollution prevention, and source reduction. For example, an EPA grant created the Great Lakes Regional Collaboration to focus on pollution prevention recommendations for emerging contaminants, such as pharmaceuticals. Working through the Collaboration, the Illinois-Indiana Sea Grant Program developed a toolkit for organizations seeking to implement drug take-back programs.[25] The USDA also provided funding to the Northeast Recycling Council to determine mechanisms for incorporating pharmaceuticals into HHW collection.

State governments and local municipalities are also financing take-back programs. Specifically, the state EPAs of Illinois, Maine, and Florida offered grants to local take-back programs. State and county services also help to defray certain costs of take-back programs. In a permanent collection program in Kendall County, Illinois, the local police department provided in-kind donations for use of the police station building and officer time to run the collection program.

Non-governmental funding comes in the form of private grants. The PH:ARM, for instance, receives funds from the Russell Family Foundation, the Public Information and Education fund of the Puget Sound Action

Team, Group Health Cooperative, and the Bartell Drug Company in addition to public funds received from the Snohomish County Solid Waste Management Division and Seattle Public Utilities.

STAKEHOLDER PERSPECTIVES

In considering a solution for opioid disposal, stakeholders have distinct and sometimes opposing perspectives on the proper course of action. Because of the broad range of interested stakeholders, designing a comprehensive solution will be no easy task and a "one size fits all" solution will likely not be feasible to accommodate the various needs and desires of all stakeholders that touch the issue.

Pharmaceutical Manufacturers. While there are some pharmaceutical manufacturers emerging as leaders in drug disposal efforts, manufacturers individually have said very little.[26] The Pharmaceutical Research and Manufacturers of America (PhRMA), a membership association of large pharmaceutical and biotechnology companies, has participated in several stakeholder dialogue meetings on unused drugs and pharmaceuticals in the environment across the country, and maintains that drugs appear in drinking water primarily from human excretion — not from flushing or pouring drugs down drains.[27] As such, PhRMA does not see consumer take-back as an appropriate strategy to reduce drugs in drinking water.[28] PhRMA recently joined the SMARxT Disposal campaign, a joint effort with the American Pharmacists Association and Fish and Wildlife Service, which seeks to educate consumers that disposing unwanted medication in the trash is a safe and effective means of removing drugs from the home, and poses no measureable threat to the environment.[29]

In response to producer responsibility or product stewardship models, PhRMA opposes manufacturer funding of take-back programs, and instead proposes that communities implementing the programs take care of the funding.[30]

Pharmacies and Pharmacists. In general, pharmacies and pharmacists are supportive of encouraging proper disposal of unwanted or expired medications in an effort to decrease drug abuse and diversion; however, they have some concerns that pharmacies do not have the resources to absorb the costs of such a program "without having to pass it on to the consumers."[31] In interviews and research, chain drug stores as well as smaller community pharmacists supported the reimbursement of pharmacists participating in take-back programs or paybacks for the costs incurred in arranging for disposal of the collected drugs. [32]

Additionally, pharmacies and pharmacists felt that there were a number of public health, safety, and logistics reasons that pharmacies were not the most appropriate sites for permanent collection of unwanted drugs from consumers. First, they suggested that an expansion of the waste disposal programs already run by the state, counties, and municipalities would be a better option to collect pharmaceuticals than implementing an entirely new program solely for collection and disposal of drugs. Second, they argued that bringing unused drugs back into the pharmacy creates safety risks. The purity and integrity of the drugs that consumers return cannot be verified, and pharmacies do not want to expose their staff or their customers to drugs that may be contaminated or hazardous. Third, they noted pharmacies have very little storage space, and could not maintain the space needed for drop boxes in addition to the space required for regular storage of drugs dispensed to patients. Lastly, they proposed that take-back programs be funded not by industry, but rather by states or grant programs. Pharmacies pay state taxes and other fees to the state, such as license and other business fees, and those monies support public waste disposal programs, which the members argue are the more appropriate means by which consumers should dispose of unwanted and expires medications.[33]

Hospices. Most patients served by hospices are at the end of life and typically in need of high doses of prescription medications to manage pain, including opioids. As such, when many patients die, large quantities of opioids and other controlled substances remain unused and cannot be returned to a pharmacy for re-dispensing. One study estimates that hospice patients waste nearly $200 million worth of unused medications each year.[34] Medicare conditions of participation require hospices to have policies and procedures in place for disposal of controlled substances that are left in patients' homes, but federal regulations do not dictate specific disposal methods.[35] DEA rules prevent hospice workers from removing unused controlled substances from the patients' homes, and historically, many hospices have instructed deceased patients' families to flushed unused medications.[36]

Among our interviewees, there was some discrepancy in opinion about whether it was in fact legal for hospices to remove drugs from deceased patients' homes. Because hospices are not required to register with DEA, the same restrictions placed on other DEA registrants, like pharmacists or practitioners, do not apply. However, because it is illegal under the Controlled Substances Act for anyone other than the person for whom the medication was prescribed to have possession of a prescribed

controlled substance, most hospices entrust disposal of the medication to the family, rather than risk violating the law by taking the patients' unused drugs into their possession.[37]

Hospices agree that there needs to be a better solution to the problem of unused drugs, and controlled substances in particular. Hospices think that flushing unused medications is not necessarily the most appropriate means of disposing of drugs for environmental reasons, and because of the high volume of unused controlled substances, hospice organizations are generally supportive of drug recycling options. For drugs that are individually packaged and unopened, hospices feel strongly that these drugs should be re-dispensed or donated to other patients.

CRITICAL SUCCESS FACTORS

In the current environment,

a system for disposal of unused opioids is burdensome on many of the stakeholders and communities that seek to implement comprehensive solutions. For a safe and effective opioid disposal system to successfully meet the varied goals of all involved stakeholders, the following factors are critical:

1. CONSUMER CONVENIENCE

To facilitate the greatest consumer participation levels, an opioid disposal system must be convenient, common sense, and economical. Options for disposal should be appealing and accessible to consumers, and should reduce as many barriers to participation as possible, such as cost to participate. Many of our interviewees said reaching the goal of improved consumer convenience was achievable with some changes to the current system.

"Consumer convenience is paramount. Returning unused drugs should be routine—just another part of the health-care process."

Enhancing the Drop-off Model. To make the drop-off model more convenient, programs should consider collection locations that are familiar, comfortable, and easily accessible to consumers. Drop-off locations that are connected to sites that consumers regularly associate with prescriptions or healthcare (e.g., pharmacies, hospitals, clinics, physicians' offices) may be the most convenient collection points in areas where those facilities are within close proximity to consumers' homes and workplaces. In urban areas, consumers may not view police stations or household hazardous waste facilities as ideal collection locations for a number of reasons. Consumers may be unfamiliar with hours of operation, disinclined to travel to distant locations, or feel uneasy about interacting with police officers — all of which may act to dissuade consumers from participating in disposal programs.

In rural areas, however, there may only be one pharmacy available to consumers, while police stations, fire stations, or similar sites may be more prevalent in communities. Assessing optimal locations for drop-off sites should be a case-by-case determination — a single approach is not likely to meet the needs of every community.

For all locations, drop-boxes should be easily accessible to consumers. Some pharmacy drop-off programs house the boxes behind the pharmacy counter, while others position the drop-box in a location where pharmacists never have to physically touch the returned drugs. Because DEA regulations and state board of pharmacy rules restrict pharmacists from taking possession of dispensed drugs from consumers, programs should be careful to arrange the drop-off site to avoid jeopardizing pharmacists' licensure status. Many programs work with state boards of pharmacy to ensure that their model complies with all relevant laws and regulations.

Disposal programs should also consider establishing permanent drop-off locations, as opposed to holding sporadic events. One-day or occasional events can be very inefficient, levels of consumer participation can be hard to gauge, and consumer expectations are difficult to maintain. In the San Francisco Bay area, the cost of drugs disposal days held over one

week averaged $175 per consumer, for a total of $87,000.[38] They also noted that consumers returned to the collection locations after the events seeking out disposal options that were no longer available. Additionally, recycling drives for other consumer products, like electronics, have reported exceeding capacity and long wait times. Collections on the first day of a three-day electronics collection event in Minnesota in 2007 overwhelmed event organizers forcing the cancellation of the second and third days of collections.[39] Consumers turned out in droves, and many left frustrated by the lack of traffic control and reported two-hour wait times.

Permanent drop-off programs present more convenient options by offering more consistent hours of operation and continuous opportunities for disposal.

Enhancing the Mail/Ship-back Model. The mail/ship-back pilot programs underway may offer more convenient disposal options to consumers, in that consumers do not have to travel to a pharmacy, police station, or household hazardous waste treatment facility to dispose of their unused medications. In Maine, consumers pick up the mail-back envelopes at the pharmacy where their prescription is dispensed and they place the envelopes in their mailboxes — requiring no additional travel. The Wisconsin pilot, however, requires that participating consumers deposit the envelope containing unused drugs in a UPS box, which presumably requires some additional travel to a UPS drop-off location.

In expanding mail/ship-back pilots, stakeholders should consider the following to boost consumer convenience:

+ **Availability.** Making mailers widely available to consumers at pharmacies, doctors' offices, post offices, and other retail locations that sell or dispense medications (e.g., grocery stores, large discount stores) may help to facilitate participation. There are some drawbacks to offering mailers at so many locations. First, to ensure adequate and constant supply, it is probable that more mailers than necessary would need to be manufactured. This is likely to increase costs associated with a mail-back program. Second, with limited oversight of who is taking the mailers, mail-back programs run the risk of receiving unwanted materials, i.e., not unused drugs. Third, consumers may misplace or lose mailers if they do not use them shortly after receiving them.

- **Packaging.** Mail/ship-back programs can provide the mailers to consumers, as in Maine and Wisconsin, or programs could opt for consumers to use their own packaging. Capital Returns, the reverse distributor participating in the Wisconsin pilot, recommends that consumers use the mailers provided by the project to enable better tracking of packages sent for disposal and so that consumers do not have to pay for their own packaging. Additionally, when programs supply the mailers, they can ensure that the packaging conforms to USPS and DEA rules regarding mailing prescription drugs, especially controlled substances. Permitting consumers to use their own packaging, however, may be more convenient for consumers if they are not required to travel to a post office, pharmacy, or other location to pick up the mailers. Conversely, some consumers may view being required to purchase their own packaging as an inconvenience. Mail/ship-back programs should carefully weigh these options, and may want to consider holding focus groups or town hall meetings to determine which methods consumers prefer.
- **Cost.** The type of packaging required can drive the costs associated with mailing unused drugs for disposal. For example, in the Maine mail-back program, the mailers cost $3-$4 because of the weight of the padded envelopes.[40] UPS, FedEx, or another commercial carrier may be a less expensive option, particularly if programs can make some arrangement for lower shipping costs based on volume.

One option for addressing these considerations is for health plans and pharmacy benefits managers (PBMs) to send mailers to consumers. Plans and PBMs have access to data on when consumers fill prescriptions, including the provider's dosing instructions, and the number of pills dispensed. With this information, plans and PBMs could determine when a patient should be completing the medication, and could send a mailer at that time. This method could also help payers become more knowledgeable about patients' medication adherence behaviors, as well as providing information on wasted medications.

2. LEGISLATIVE AND REGULATORY FEASIBILITY

There are a number of federal and state laws and regulations that take-back programs currently must comply. Some of these act as barriers to

creating a comprehensive and streamlined collection and disposal solution for unused or unwanted drugs. Laws and regulations dealing with controlled substances present the most significant challenges, and hazardous waste disposal requirements are also difficult to navigate. Better coordination among regulatory agencies at the federal and state level is critical to ensure a consistent strategy and messaging regarding disposal of unused drugs, including opioids. Currently, federal and state agencies offer inconsistent and sometimes contradictory guidance on proper drug disposal, resulting from differences in interpretation and incompatible laws. Working in a more collaborative manner to resolve misinterpretations, inconsistencies, and contradictions among all laws can facilitate developing a feasible legal and regulatory framework that satisfies the needs of all stakeholders. To enable a convenient, efficient, and effective system, the following policy changes should be explored:

"DEA has legitimate concerns, but our pilot is trying to demonstrate that we can collect unused drugs in a safe and secure way."

Controlled Substances Act and DEA Regulations. The DEA enforces the Controlled Substances Act (CSA) and its accompanying regulations. Many states also have agencies charged with oversight of controlled substances that focus on reducing the risk of diversion.[41] Controlled substances are grouped into five "schedules" and include illegal drugs as well as medications like Ambien, oxycodone, and codeine.[42] The CSA and DEA regulations create a closed distribution system to limit opportunities for diversion of controlled substances. When controlled substances, specifically Scheduled II and III products, are in the system — from manufacturers to distributors to dispensers — they are tracked and accounted for at every turn. Once dispensed, controlled substances are outside the closed system and may not re-enter. The DEA prohibits the transfer of that medication from the consumer back to the pharmacist, doctor, reverse distributor, or anyone else registered with the DEA to handle controlled substances.[43] The DEA permits only two exceptions:

- Consumers may return controlled substances to manufacturers in the case of recalls or dispensing errors.[44]
- Controlled substances may be taken into possession by law enforcement officials.[45]

In effect, no one else except for the patient can legally take possession of a prescription for a controlled substance. Because of the prohibition or because law enforcement officers have to be present to receive any returned controlled substances, many take-back programs have opted not to collect them.

There is a provision in DEA's regulations that covers drug disposal. As it now exists, 21 CFR § 1307.21 directs non-registrants (e.g., consumers) to apply to the local DEA Special Agent in Charge for authorization and instructions to employ one of four options for disposal:

- Transfer to a DEA registrant that is authorized to possess the substance;
- Delivery to a DEA agent or to the nearest DEA office;
- Destruction in the presence of a DEA agent or other authorized person; or
- Some other means the local Special Agent in Charge deter mines to ensure the substance does not become available to unauthorized persons.

Amending this section to include more disposal options for consumer and other stakeholders would facilitate expansion of feasible solutions. The DEA is working to promulgate regulations to allow DEA-registered reverse distributors to accept controlled substances mailed from consumers for disposal.[46] This option would allow DEA to rely on a trusted source to receive the drugs, document and inventory all controlled substances received, and ensure that all drugs collected are sent directly for disposal and not mistakenly returned into the supply of drugs available to be dispensed to patients.

This type of change will give consumers an alternative to flushing controlled substances, but might contravene the principle of consumer convenience by requiring consumers to dispose of their unwanted medications in two different ways: by mail for controlled substances and by some other means for all other drugs.

State Board of Pharmacy Laws and Regulations. State boards of pharmacy oversee licensing of pharmacists as well as handling and dispensing of prescription medications. Because federal law and all state laws dictate that controlled substances, once dispensed, can only be in the possession of the patient, pharmacists are almost always prohibited from taking physical possession of a controlled substance after it leaves the pharmacy. There are two very limited exceptions to this, discussed above.

This restriction makes it virtually impossible within the confines of existing law for pharmacists to be the sole participants in take-back programs that accept controlled substances. Instead, most programs use

pharmacists' services to identify whether a medication is a controlled substance, to inventory the product, and to hand it over to a law enforcement officer for permanent custody. Even this level of participation may be construed as violating the prohibition on pharmacists "taking possession" of controlled substances, so take-back programs have worked closely with state boards of pharmacy to ensure pharmacists that participate do not jeopardize their licensure.

Federal Hospice Regulations. Current federal rules require hospices to have a policy for disposal of controlled substances "maintained in the patient's home when those drugs are no longer needed by the patient."[47] State regulations echo this requirement. New Medicare rules will go into effect in December 2008 that expand hospices' responsibilities around disposal of controlled substances. Under the new rules, when controlled substances are first ordered, hospices must provide a copy of their drug disposal policies to the patient and/or family and discuss the options with the patient and/or family.[48]

Because hospice patients tend to be using pain medications at the time of their death, there are often large amounts of unused controlled substances present in hospice patients' homes. As DEA regulations prohibit anyone other than the patient from taking possession of prescribed controlled substances, hospice workers cannot remove the unused drugs from patients' homes. Accordingly, the only disposal option for most of these drugs is for family members to flush them down the toilet.

USPS Rules on Mailing Prescription Drugs. Until a few years ago, USPS rules prohibited consumers from mailing prescription drugs under any circumstances. When Vioxx was withdrawn from the market in 2004, USPS revised its rules to allow consumers to mail recalled drugs directly back to manufacturers using mailers pre-paid and pre-addressed by manufacturers.[49] This is still the only permissible consumer use if the mail for prescription drugs; however, manufacturers, pharmacies, and authorized dispensers may mail prescription drugs.[50]

USPS is currently working with state and local pilot programs to enable consumers to mail unused drugs, including controlled substances, to law enforcement entities. The first program, which began in Maine in May 2008, allows consumers to mail unused drugs to the Maine DEA. USPS also specifies the packaging and labeling requirements for mailers containing controlled substances, which dictate that the mailers must have no markings indicating that they contain drugs, the medications must remain in their original containers, and the mailers must be secure to prevent the drugs from being damaged.[51]

To successfully implement DEA's rumored regulation that would allow consumer to return unused controlled substances to reverse distributors through the mail, USPS rules may again have to be changed to allow consumers to mail unused controlled substances to reverse distributors for disposal.

RCRA and EPA Regulations on Hazardous Waste. The Resource Conservation and Recovery Act (RCRA), enforced by the EPA, outlines the regulatory scheme for the disposal of hazardous waste from municipalities and industries.[52] RCRA does not regulate household waste, which would include any unused pharmaceuticals in the possession of an individual. It does regulate facilities that generate, transport, treat, store, or dispose of hazardous waste. Some prescription and over-the-counter medications must be treated as hazardous waste if they are disposed of by facilities. Examples of drugs specifically listed as hazardous wastes include nitroglycerin, nicotine patches, and Coumadin. Other drugs may require treatment as hazardous waste if they are flammable, reactive, can corrode, or are toxic.[53]

The EPA does not allow the take-back of waste household pharmaceuticals through reverse distributors, which manage unwanted pharmaceuticals for healthcare facilities, such as pharmacies and hospitals.[54] The drugs collected by reverse distributors are either returned to manufacturers or are sent for disposal. The EPA has made clear, however, that at the time of collection the drugs are not considered waste because they still may have some financial value.[55] The reverse distributor, not the facility from which the unused drugs are collected, determines whether the unwanted drug is waste, and therefore, becomes the waste generator.[56] Because reverse distributors cannot accept any waste, they cannot accept pharmaceutical waste from households.

While EPA has primary authority to develop regulations to implement RCRA, there are provisions that permit EPA to delegate this authority to states that wish to administer and enforce their own hazardous waste programs. The state programs must be at least as stringent as the federal requirements. Most states have authorized the hazardous waste program and may have more strict requirements; however, most state hazardous waste laws maintain the exemption for household waste.[57]

While household hazardous waste is exempt from federal regulations, questions remain about whether drugs returned by consumers in a take-back program maintain their exempt status if a collection is held at a regulated facility, like a pharmacy.

One way that EPA has simplified the regulatory requirements for collection and recycling of widely manufactured consumer products is

the Universal Waste Rule. Currently, this rule covers batteries, pesticides, mercury-containing equipment, and lamps. By streamlining the requirements related to accumulation time limits, tracking, and transportation, for example, the Universal Waste Rule hopes to make it easier for companies to establish collection programs and participate in manufacturer take-back programs.

Adding pharmaceuticals to the products covered by the Universal Waste Rule could facilitate greater participation in local and state drug disposal programs. In fact, EPA is considering this policy change. In its spring 2008 semiannual regulatory agenda, EPA announced that it intends to propose a rule to add pharmaceuticals to "facilitate pharmaceutical take-back programs so that these wastes can be properly managed," among other purposes.[58] The proposed rule should be published in December 2008.

MATERIALS ADDED UNDER UNIVERSAL WASTE RULE	STATES
AEROSOL CANS	California, Colorado
ANTIFREEZE	Louisiana, New Hampshire
BALLASTS	Maine, Maryland, Vermont
BAROMETERS	New Hampshire, Rhode Island
CATHODE RAY TUBES (CRTS)	Maine, New Hampshire, Rhode Island
ELECTRONICS	Arkansas, California, Colorado, Connecticut, Louisiana, Michigan, Nebraska, New Jersey
OIL-BASED FINISHES	New Jersey
PAINT & PAINT-RELATED WASTES	Texas
HAZARDOUS WASTE PHARMACEUTICALS	Michigan

EPA encourages states to adopt similar Universal Waste Rules, but this is optional as the requirements are less stringent than current RCRA requirements. Almost all states have implemented some version of the Universal Waste Rule, and some have chosen to add products to their rules, including pharmaceuticals. [59]

FDA Risk Mitigation Strategy and Drug Labels. The Food and Drug Administration works with manufacturers to craft the disposal instructions that appear on the labels of around a dozen controlled substances. Through this "risk mitigation" strategy, the FDA and manufacturers have determined that flushing down the toilet or pouring down the drain is the most appropriate manner for disposal of these certain drugs to limit the opportunities for accidental overdose or intentional abuse.

FDA worked with ONDCP to craft the 2007 consumer guidance on drug disposal. While ONDCP recommended disposing of most drugs in the trash, it did note that FDA recommended that certain drugs be flushed down the toilet. The following table lists these drugs and the disposal instructions on their labels

CATEGORY	CLASS / INDICATION	DISPOSAL INSTRUCTIONS
ACTIQ (FENTANYL CITRATE)	Opioid / Treatment of breakthrough pain in cancer patients	Flush down toilet
DAYTRANA TRANSDERMAL PATCH (METHYLPHENIDATE)	Central nervous system stimulant /ADHD	Flush down toilet or place in household trash in a lidded container
DURAGESIC TRANSDERMAL SYSTEM (FENTANYL)	Opioid / Management of persistent, moderate to severe pain	Flush down toilet
OXYCONTIN TABLETS (OXYCODONE)	Opioid / Management of moderate to severe pain	Flush down toilet
AVINZA CAPSULES (MORPHINE SULFATE)SULFATE)	Morphine sulphate / Relief of moderate to severe pain	Flush down toilet
BARACLUDE TABLETS (ENTECAVIR)	Antiviral / Treatment of chronic Hepatitis B	Flush down toilet
REYATAZ CAPSULES (ATAZANAVIR SULFATE)	Protease inhibitor / Treatment of HIV	Community take-back programs, where available, or place in unrecognizable, closed container in household trash.[60]
TEQUIN TABLETS (GATIFLOXACIN) (STAVUDINE)	Antibiotic / Treatment of lung, sinus, skin, urinary tract infections, and certain sexually transmitted diseases	Flush down toilet
ZERIT FOR ORAL SOLUTION (STAVUDINE)	Nucleoside Reverse Transcriptase Inhibitor / Treatment of HIV	Flush down toilet or pour down drain
MEPERIDINE HCL TABLETS	Narcotic / Relief of moderate to severe pain	Flush down toilet
PERCOCET (OXYCODONE AND ACETAMINOPHEN)	Opioid / Relief of moderate to moderately severe pain	Flush down toilet
XYREM (SODIUM OXYBATE)	Central nervous system depressant / Prevention of catalepsy in patients with narcolepsy	Pour down drain
FENTORA (FENTANYL BUCCAL TABLET)	Opioid / Treatment of breakthrough pain in cancer patients	Flush down toilet

Capt. Jim Hunter, R.Ph., M.P.H., Senior Program Manager on FDA's Controlled Substance staff, explained these precautions in recent consumer guidance, using a fentanyl patch, an adhesive patch that delivers pain medicine through the skin, as an example. Fentanyl exposure can cause severe breathing problems and lead to death in babies, children, pets, and even adults. "Even after a patch is used, a lot of the drug remains in the patch," said Hunter, "so you wouldn't want to throw something in the trash that contains a powerful and potentially dangerous narcotic that could harm others."[61]

As drug disposal programs become more widespread and available to consumers, and if DEA proposes to allow consumers to mail unused controlled substances to reverse distributors, FDA may need to revisit its risk mitigation strategy. Drug labels that include disposal instructions may also need to indicate that there are options beyond flushing available to consumers.

3. PROGRAM SUSTAINABILITY

Even if the above legal and regulatory challenges are resolved, there are additional obstacles that may stand in the way of establishing a comprehensive solution for opioid disposal. Among these is the problem of articulating a compelling value proposition for participation and sustaining adequate funding.

Incentives for Consumers. Take-back pilot programs typically rely on education and outreach to drive consumer participation; however, participation rates are difficult to project and are sometimes much lower than expected. One reason for low consumer turnout may be that some individuals believe there is little chance for abuse of their unused drugs — and they may be right if they have no children, teenagers, elderly adults, or pets present in the home. Alternatively, some patients may be reluctant to part with the drugs because they think the drugs may be useful to them sometime in the future, or because they do not want to dispose of a potentially expensive product for which they will not get a refund. Ensuring that programs are convenient and well advertised can certainly help, but some people simply may never be motivated to participate, not seeing the personal value proposition in disposing of their unused drugs.

For these people, additional incentives may help secure broader participation. One option for encouraging broader consumer participation is to offer consumers something of value in exchange for returning unused drugs. For example, consumers could be paid for returning unused drugs, similar to the return deposits historically offered for glass bottles

and aluminum cans. Alternatively, pharmacies or other retail stores could offer discounts on future purchases or other in-kind benefits, similar to the loyalty cards that are widely used today by many retailers, including some pharmacies. While a "benefits" program may be less attractive to consumers than straight cash, it can offer a meaningful opportunity for pharmacies and retailers to increase sales and build customer loyalty.

Incentives for Collection Locations. Hosting a take-back program undoubtedly creates costs for collection locations, but it also provides them an opportunity to mitigate these costs by increase customer traffic and, possibly, sales. Additionally, collection locations may be able to generate goodwill in their communities by offering take-back services.

Pharmacists, in particular, may be reluctant to participate in take back programs because of the added responsibility and burden that participation in these programs would bring. Several pharmacists interviewed suggested that ensuring that they are compensated for their time is critical to promoting their participation in these programs. How pharmacists should be compensated depends in part on the nature of their responsibilities. For example, if a pharmacist is participating in a one-time take-back event, compensation could be paid on an hourly basis. However, if the disposal program is a permanent feature in the pharmacy and pharmacists are taking back unused medications during the regular course of their business, fee-for-service (FFS) — in effect, a reverse dispensing fee — might be a more viable compensation structure. If compensation is based on a FFS model, it may be appropriate to pay a higher fee for taking back medications like opioids that will likely require with special inventory and disposal protocols.

"The funding right now isn't sustainable. Some kind of national or industry-sponsored infrastructure would help maintain the momentum we're seeing in our state and across the country."

Incentives for Reverse Distributors. Because of their expertise in managing pharmaceutical returns to manufacturers on behalf of providers and other institutions, reverse distributors may seem well-suited to participate in a consumer take back program. Indeed reverse distributors sometimes choose to participate in take-back programs for philanthropic reasons or to generate goodwill, but integrating consumer returns into their core business may present some challenges. The reverse distribution business model derives value from managing a high volume of products and is dependent in part on refunds or credits offered by manufacturers. To make it worthwhile for reverse distributors to participate in take-back programs, the programs would need to be able to reliably collect large quantities of unused drugs on an ongoing basis. Even then, reverse distributors' interest in participating may be limited because products returned by consumers are generally ineligible for manufacturer refunds or credit. Unless reverse

distributors can refine their business model to create value from consumer-returned products, their incentive to participate in take back programs will likely remain largely philanthropic.

Funding. In the absence of a market-driven business model for deriving private value from consumers' unused drugs, funding for take-back programs would need to come from public sources or philanthropy. General tax revenue is one possible source of funding, but it may not be reliable because it is subject to regular review and revision by states or the federal government. A more targeted funding system, such as charging a disposal fee at the time of purchase, offers greater transparency to consumers. Tires and automobile oil are examples of products for which consumers are accustomed to paying disposal fees. Likewise, consumers could be charged a disposal fee when picking up a prescription, with revenues from the fee directed to fund take-back programs and other costs associated with proper disposal of unused drugs. One criticism of such a fee might be that it could inhibit access to necessary medications, particularly at a time when consumers are regularly facing higher out-of-pocket costs for health-care products and services, including prescription drugs. In addition, some may argue that a disposal fee should not be charged on all drugs that are purchased, only on those that are disposed of instead of consumed. Charging consumers a fee when they bring back unused prescriptions, however, would likely discourage participation in take-back programs.

To avoid charging direct fees to consumers, some other options merit exploration. In an effort to promote great patient compliance with medication regimens and disposal instructions, health plans could craft an arrangement with manufacturers whereby plans would condition final payment for drugs prescribed to their members on notification that the patient completed the doses or returned the unused portion for disposal. Under this method, manufacturers would have a direct financial incentive to promote disposal programs, and ensure that there are sufficient options available to consumers. This method would require some coordination with the collection locations and patients as well, so that plans could receive the required notification.

Another possible funding method is direct fees to industry as a whole. In other countries that operate disposal programs, it is drug manufacturers, pharmacies, and drug wholesalers — not consumers — that are assessed a disposal fee. This producer responsibility or product stewardship model used for drug take-back programs in Canada, Australia, and Europe is currently gaining support, and is the preferred funding model in legislation in New York, Washington, and Oregon.[62] For example, the

quantity of drugs collected is the basis for manufacturer fees in British Columbia, Canada. Although imposing an assessment on manufacturers to fund take back programs may seem more palatable than charging consumers directly, it is likely that the cost would still be passed on to the consumer through higher drug prices. The best way to keep program costs low is by designing and operating an efficient take-back program. Fortunately, the experience in British Columbia suggests that it is possible to operate a large-scale take-back program on a relatively small budget, with limited impact on manufacturer business costs or consumer drug prices.

4. EFFECTIVE EDUCATION AND OUTREACH

Deploying an organized and effective education and outreach effort is an important step for ensuring broad stakeholder confidence and participation in a disposal system. Individuals and groups impacted by the development of a comprehensive disposal system will become more aware of the issues surrounding unused or expired pharmaceuticals (e.g., drug diversion, accidental poisoning, and environmental concerns) and the benefits of designing a sustainable disposal system. Education plus outreach will also help inform interested parties, both from the public and private sector, about ways to address the multitude of issues resulting from unsafe disposal of pharmaceuticals and consequently, broader participation and collaboration by different stakeholders in the design and use of a disposal system.

Education and outreach operations should be directed toward key stakeholders and their constituents, whose involvement and participation in the development and use of a disposal system will shape its overall success. These vital stakeholders include:

- Consumers (parents, teens/children, consumer-focused groups)
- Healthcare professionals (doctors, nurses, physician assistants, nurse practitioners, health educators)
- Pharmacies and pharmacists
- Hospice
- Federal agencies (DEA, EPA, CMS, SAMHSA, ONDCP)
- State and local government officials (law enforcement, municipal waste, state and local health departments, state boards of pharmacy)

It is important to customize both the educational content and method that information is delivered when directing such efforts to various stakeholders.

Consumers. Consumer investment in a pharmaceutical disposal system depends on whether there is a clear value proposition associated with its use. It is paramount to inform consumers through a number of mechanisms that their participation may yield aggregate benefits. These benefits include cleaner waterways and reduced opportunities for illicit diversion of pharmaceuticals into the black market, as well as more direct benefits such as decreased accidental poisoning. Not all consumers are familiar with the pharmaceutical disposal topic or take-back programs. This fact makes it important to provide information that is easily digestible, conveys the main facets of a disposal system, and attempts to level everyone's knowledge base.

"We get calls from school districts, nursing homes, coroners' offices, health departments, and businesses across our county. There's a real demand for our program."

To facilitate consumer outreach on a broader scale, educational materials should be disseminated to all age groups including children/teens, parents, and the elderly, especially those living in assisted living facilities. Information directed toward parents should explicitly issue warnings about the potential hazards to children of leaving unused pharmaceuticals around—notably controlled substances—as well as the options for disposal. Educational content for children/teens should promote disclosure to parents if and when medication dosages are complete and if leftover drugs remain. Information that is provided to the elderly should encourage open dialogue between them and their caretakers about the options that may be used for drug disposal.

All this content can be disseminated in many forms and through various grassroots channels such as TV commercials, newspaper ads, radio ads, local press releases, and pamphlets/flyers.

Healthcare Professionals. Individuals generally value their provider's input on a range of clinical and health-related issues. Providers may serve as an ideal gateway for educating consumers about the safety benefits of a frequently used disposal system. Before doing so, providers themselves need to be just as informed about the upside of creating and sustaining a system. This message can be delivered through professional associations and journals.

Pharmacies and Pharmacists. Pharmacies and pharmacists play an integral role in developing a disposal system, and having their full support and participation is vital for establishing a workable system, especially if the collection sites are located in pharmacies. Working with industry associations that represent these groups could be an effective and efficient tactic for educating a broad set of pharmacists and pharmacies. The associations may help inform their constituents on the value of contributing to the solutions development process. Some pharmacies are already invested and involved in conducting pharmaceutical collections that are available regionally and locally. Enabling others to learn from these pharmacies that have taken a leadership step could encourage wider participation.

Hospice. Although the exact amount is uncertain, hospice, both inpatient and outpatient, may generate large quantities of leftover medications following patients' deaths. As required by Medicare Conditions of Participation (COP) for Coverage, all hospices must have a drug disposal policy. The new COPs also require hospices to share these policies with patients and/or their families and discuss disposal options when controlled substances are first ordered. Educational efforts aimed at hospices should seek to inform these policies and provide advice for discussing drug disposal issues with patients and/or their families. Educating all hospices on safe disposal techniques, possibly through their national associations, may better enable them to offer consistent recommendations.

Federal Agencies and Regional/Field Offices. Outreach to the following federal agencies should be conducted: DEA, EPA, CMS, SAMHSA, and ONDCP. This effort should focus less on the education of these entities and more on outreach to solicit participation in the development process, which requires demonstrating and articulating the value and necessity of a system. Outreach should be directed to the regional and field offices of these federal agencies, where applicable, as well. From the onset, the relevant departments within these offices should be encouraged to exercise some level of commitment because their input and perspectives on issues regarding funding, infrastructure, and design of the system are essential. The involvement of these entities in the process would spur fruitful dialogue about the legal and regulatory landscape governing pharmaceutical collection and disposal and how it may be improved moving forward.

State and Local Government. Inviting various government stakeholders to openly discuss what their role should be in building a disposal system is the first step in ensuring adequate and committed participation from the public sector. Stakeholders representing state and local governments should be part of this dialogue, including representatives from law enforcement, municipal waste, state and local health departments, and state boards of pharmacy. Periodic conferences are one way to focus on this issue and may be a strategy for gathering all of the appropriate governmental and private bodies to discuss their role in building and sustaining an effective system.

Conducting a broad, efficient, and effective educational and outreach effort is imperative for spreading the message about the benefits of an unused opioid disposal system and also for fostering collaboration between stakeholders interested in building a comprehensive system that meets the needs of all involved.

INCONSISTENT DISPOSAL ADVICE LEAVES CONSUMERS WITHOUT CLEAR GUIDANCE

The White House Office of National Drug Control Policy recommends flushing certain drugs and combining all others with undesirable substances, like coffee grounds or kitty litter, and placing them in the trash.

The SMARxT Disposal campaign, sponsored by the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America, cautions against flushing or pouring drugs down the drain.

The Food and Drug Administration recommends flushing certain narcotic pain relievers and other controlled substances for safety reasons.

The Environmental Protection Agency stated at a Senate hearing that "it is important that the public understand that the toilet is not a trash can for unused medications."

MODELS FOR REFORM

System reform is no easy task,

and an issue as complex as disposal of controlled substances calls for involvement of many different agencies at the federal, state, and local levels — some of which have not historically had interaction. American federalism demands a shared responsibility of all levels of government. This dynamic federalist system can yield different results, however, depending on who is at the helm. The federal government may be better suited to take a leadership role in aligning the states toward a single national priority on an issue, as well as redistributing resources as a result of its access to a broader tax base. On the other hand, states and localities may be better equipped to take the reins when local values and preferences truly differ around the country and dictate distinctions in public policy.[63]

PATHWAYS TO SUCCESS FOR CONTROLLED SUBSTANCES DISPOSAL SYSTEM

There are three possible pathways to achieve reform on disposal of controlled substances. Each relies on leadership and execution by local, state, and federal leaders, but differs in the responsibilities each assumes.

Pathway 1: Local Leadership, State and Federal Execution. In essence, this pathway is how the drug disposal landscape is currently being shaped. Local pharmacies, senior centers, law enforcement, and community groups within a defined geographic region are responding to an important public health problem created by the presence of unused drugs by implementing drug disposal programs. Local leaders are integral members of their communities, understand the local values and priorities, and can take quick action to meet the evolving needs of their community.

This pathway, often termed "grassroots," can lead to widespread reform, but typically change is effected slowly. For example, the substance abuse treatment movement that occurred nationally in the 1970s and 1980s can be traced back to the founding of Alcoholics Anonymous in 1935, several decades before.[64]

Local efforts may also lack adequate funding needed to sustain disposal programs on a continual basis. Funds from municipal coffers or from private grants are drawn from a relatively small pool of dollars that have to be apportioned carefully. If local priorities shift, funding for disposal programs could dry up, leaving consumers without safe options to dispose of controlled substances they want to remove from their homes.

Coordination and communication between local efforts is crucial to ensure that lessons learned are shared, and to foster a sense of community among programs scattered across the country. To drive change on a national level, local leaders will need to achieve a certain level of consensus on the approaches that can best achieve the goals of the critical success factors. Local leaders speaking with one voice and a unified agenda are more likely to get the attention of state and national policymakers. Without principles, priorities, or best practices that can be replicated, what may emerge could be a patchwork of drug disposal programs that bear no relation to one another — and that could have little hope of evolving into a national movement towards proper disposal.

There are some organizations that currently exist that could serve as the convening body for bringing together local leaders: the U.S. Conference of Mayors, the National Association of Counties, the National Association of City and County Health Officials, the National Association of Drug Diversion Investigators, the Community Anti-Drug Coalitions of America,

and the National Sheriffs' Association are examples of such organizations that have a stake in the public health of consumers, and could be good starting points for initiating dialogue among local leaders seeking to drive change on a larger scale.

Pathway 2: State Leadership, Federal Execution. Past reform efforts on other healthcare issues have taught valuable lessons in how to structure a reform movement to achieve the best outcome for all interested stakeholders. One of the major principles of federalism is that states act as "laboratories" for experimentation, testing out various policy approaches to determine which work best and could be implemented on a national scale. This theory, of course, hinges on sharing and applying lessons learned. Examples of unsuccessful results derived from the laboratory theory scatter recent history of policy reform:

Medicare Part D Prescription Drug Benefit. Part D emerged after most states had already implemented pharmacy assistance programs; however, some key elements of the Medicare program were not derived from the state programs. Namely, the coverage gap, or "doughnut hole," and the dual-eligible enrollment presented new and somewhat divergent programmatic aspects, and not based on the lessons learned in the states.

State Children's Health Insurance Program (SCHIP). Despite objective success of the SCHIP program in reducing the number of uninsured children the states, federal reauthorization of the program in 2007 failed. Ideological disagreements about program design and the role of government in healthcare kept the legislation from moving forward. After two vetoes, Congress and the President agreed to an 18-month extension in December 2007.

A handful of states have recently or are currently exploring legislative options to enable consumer drug disposal. The only state successful in this venture thus far is Maine, which passed a law in 2003 to establish a mail-back program for consumers' unused prescription drugs. New York and Washington both considered legislation in 2007 and 2008 to require pharmaceutical manufacturers to establish and fund programs to collect and dispose of unwanted drugs. Neither bill passed. Also in 2007, California and Pennsylvania considered requiring retailers of prescription drugs to have collection and disposal options in place for consumers. Again, neither of these provisions passed; however, California did enact an amended

version of the bill that required the California Integrated Waste Management Board to develop model collection and disposal programs by the end of 2008.

Currently, most of these states are looking to Maine's mail-back pilot and Washington's PH:ARM program as models ripe for expansion to the national stage. As more states implement options for consumer drug disposal programs, however, new models may emerge as leading contenders for national solutions. To exchange lessons learned and to build consensus on the needed reforms, state leaders — like local leaders — must also seek to foster communication and collaboration. Organizations that exist to bring state leaders together, such as the National Conference of State Legislatures, the National Governors' Association, the National Association of State Boards of Pharmacy, and the National Association of State Controlled Substances Authorities.

Pathway 3: Federal Leadership, State and Local Execution. For every failed attempt at national reform, there is also a success story. Take, for example, welfare reform in the mid-1990s. Based on guidance and study design well-defined at the federal level, states implemented true experiments to test various approaches to welfare reform — complete with hypotheses, control groups, and data collection. The outcomes of the experiments were the launching pad for a new way of thinking about effective welfare policies, and led to sweeping change on a national scale.[65]

Federal leadership on drug disposal will be a complex venture, as several agencies have interests in the issue — agencies that are not accustomed to collaboration. The DEA and the ONDCP should be at the center of this dialogue, as they will have valuable perspectives on the unique complications around the handling of controlled substances. Without absolute support from these agencies, a disposal system for controlled substances could face serious legal hurdles and obstacles for success.

Consultations with federal agencies like the EPA and Department of Health and Human Services (HHS) would enhance input on the public health concerns related to poisoning and environmental effects of drug disposal. To the extent that a mail-back program is considered, consultations must take place with representatives from the U.S. Postal Service. HHS, and in particular, CMS, will be able to assist in the system design from a payer's perspective. Representatives from HHS may have insight as to incentives for consumers to participate or ways that payers can encourage participation. The FDA may also have ideas as to how to facilitate disposal through the drug labeling and approval process, the SAMHSA, and the National Institute on Drug Abuse would offer significant contributions to

the discussion of how to structure the disposal solutions to best combat drug abuse issues.

To foster alliance and cooperation among disparate stakeholders on a discrete issue, the federal government has explored a number of mechanisms, including national coordinators, panels, commissions, and White House conferences.

COORDINATOR OFFFCES	PANELS AND COMMISSIONS	CONFERENCES
Office of National Drug Control Policy (ONDCP) (1988 – present)	National Panel of Consultants on the Conquest of Cancer (April 1970 – December 1970)	White House Conference on Mental Health (June 7, 1999)
Office of the National Coordinator for Health Information Technology (ONC) (2004 – present)	President's Cancer Panel (1971 – present)	White House Conference on Teenagers (May 2, 2000)
Office of National AIDS Policy (ONAP) (1993 – present)	White House Commission on Complementary and Alternative Medicine Policy (March 2000 – March 2002)	White House Conference on Aging (December 11-14, 2005)

Each type of collaboration has merits and limitations. For example, if a national coordinator office is placed in the White House, like ONDCP, it may have better access to the president and may have greater visibility with the press and the public; however, it may not have the support of the federal agencies and it may not sustain across administrations. Conversely, if an agency houses a national coordinator office — ONC is within HHS — the agency secretary may be able to make progress without needing presidential approval at every turn, but the office may be constrained by limited funding and staffing.

Panels and commissions are advantageous for engaging a wide range of experts on an issue — from the public and private sectors, and they tend to generate substantial press coverage. One downside, however, is that follow-up activity is usually necessary to carry out their recommendations. A White House conference can be an effective means of

spotlighting an issue and catalyzing executive-level and regulatory action; however, they typically are one-time events that the press and public eventually lose interest.[66]

No matter the mechanism used to bring together federal stakeholders, leadership from DEA and ONDCP will be critical to bring about changes in the laws and regulations related to handling and disposal of controlled substances.

WHICH PATHWAY WILL LEAD TO SUCCESS?

Judged against the four critical success factors — consumer convenience, legislative and regulatory feasibility, program sustainability, and effective education and outreach — the relative merits and limitations of these three pathways to reform comes into sharper focus. While none is likely to appear the clear winner in all cases, stakeholders pursing drug disposal reform will want to contemplate how conducive each pathway is to achieving success on these four objectives.

	LOCAL LEADERSHIP, STATE AND FEDERAL EXECUTION	STATE LEADERSHIP, FEDERAL EXECUTION	FEDERAL LEADERSHIP, STATE AND LOCAL EXECUTION
CONSUMER CONVENIENCE	More familiar with community needs Potential for faster deployment of solutions	Larger funding base could mean more options for collection	Should implement flexible solutions to allow state and local leaders to best meet their own needs
LEGISLATIVE & REGULATORY FEASIBILITY	Grassroots reform often unorganized and slow	Potential for patch-work of disparate policies to emerge	Setting federal priorities can help state and localities develop uniform or consistent policies
PROGRAM SUSTAINABILITY	Limited funding through grants and small tax base	Larger funding pool, but competes with other state priorities	Wields strongest influence over funding streams, private sector participation
EFFECTIVE EDUCATION & OUTREACH	Closer ties to local participants in take-back programs and consumers	Can tap into existing public health educa-tion and outreach programs aimed at key stakeholders	Can use visibility with public and press to reach broad audience

CONCLUSION

Communities across the country

are exploring options for collecting and disposing unused medications from consumers. Take-back programs have emerged as one possible strategy to prevent drug abuse, accidental poisoning, and harmful disposal practices such as flushing. However, because of the barriers that exist in today's regulatory environment, these programs cannot offer comprehensive solutions that include collection of controlled substances.

The broad range of stakeholders that are needed to formulate workable solutions are beginning to engage in substantive and productive dialogue, but there is more work to be done. By contemplating the critical success factors and the possible reform pathways, stakeholders can begin to create systems for controlled substances disposal that attract sustained consumer and industry participation and demonstrate value to their communities.

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ENDNOTES

1 Buzby, Mary E., Merck & Co, Inc., PhRMA Pharmacueticals in the Environment (PIE) Task Force. "Pharmaceuticals in the Environment – PhRMA PIE Perspective." May 22, 2007. www.dtsc.ca.gov/AssessingRisk/PPCP/upload/04_Buzby.pdf.

2 Teleosis Institute. "Green Pharmacy Program – Preliminary Data Report." www.teleosis.org/pdf/GreenPharmacy_FullPreliminaryReport.pdf.

3 Ibid. Teleosis rejected controlled substances; they do not collect them because of limitations contained in DEA regulations. See the Regulatory Barriers section below for further discussion of the DEA regulations.

4 Raffanello, Thomas W., Special Agent in Charge, Miami Division, U.S. DEA, statement before the U.S. House of Representatives Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, 108th Congress, 2nd session, February 2, 2004.

5 Reiterman, Tim. "Prescription Drugs Diverted." Los Angeles Times. May 18, 2008. http://articles.latimes.com/2008/may/18/local/me-drugs18.

6 Libby, Ronald T., "Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Pain Killers." The Independent Review. Spring 2006.

7 Potter, Michael et al., "Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians in the UCSF/Stanford Collaborative Research Network," Journal of Family Practice (2001): 148; Weissman, David E. et al., "Wisconsin Physicians' Knowledge and Attitudes about Opioid Analgesic Regulations," Wisconsin Medical Journal 90 (1991): 671.

8 "Results from the 2005 National Survey on Drug Use and Health: National Findings." Department of Health and Human Services. SAMHSA. Office of Applied Studies.

9 "Teens and Prescription Drugs: An Analysis of Recent Trends on the Emerging Drug Threat." February 2007. Office of National Drug Control Policy. Executive Office of the President. www.mediacampaign.org/teens/brochure.pdf.

10 "Results from the 2005 National Survey on Drug Use and Health: National Findings." Department of Health and Human Services. SAMHSA. Office of Applied Studies.

11 "Unintentional Poisoning Deaths." February 9, 2007. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm.

12 "The Partnership Attitude Tracking Study (PATS): Teens in Grades 7 through 12, 2005." May 16, 2006. Partnership for a Drug-Free America." www.drugfree.org/Files/Full_Teen_Report.

13 Johnston, L.D., et al., "Teen Drug Use Continues Down in 2006, Particularly among Older Teens; But Use of Prescription-Type Drugs Remains High." December 21, 2006. University of Michigan News and Information Services: Ann Arbor, MI. www.monitoringthefuture.org/pressreleases/06drugpr.pdf.

14 Seehusen, DA and J. Edwards. "Patient practices and beliefs concerning disposal of medications." Journal of the American Board of Family Medicine 19 (2006):542-547.

15 Kuspis DA, and EP Krenzelok. "What happens to expired medications? A survey of com munity medication disposal." Veterinary and Human Toxicology 38 (1996):48–49.

16 Buxton, Herbert T. and Dana W. Kolpin, "Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants in U.S. Streams." U.S. Geological Survey. June 2002. http://toxics.usgs.gov/pubs/FS-027-02/index.html.

17 EPA. "Pharmaceuticals and Personal Care Products – Frequent Questions." www.epa.gov/ppcp/faq.html; Schwab, Bradley W., et al. "Human pharmaceuticals in U.S. surface waters: A human health risk assessment," Regulatory Toxicology and Pharmacology 42 (2005):296-312; Webb, Simon, et al. "Indirect human exposure to pharmaceutcals via drinking water," Toxicology Letters 142 (2003):157-167; Schulman, Lisa et al. (2002) "A human health risk assessment of pharmaceuticals in the aquatic environment," Human & Ecological Risk Assessment, 8 (2002): 657-680; Christensen, F.M. (1998) "Pharmaceuticals in the environment – A Human Risk?," Regulatory Toxicology & Pharmacology, 28 (1998): 212-221.

18 U.S. EPA, 53 Fed. Reg. 33345 (August 30, 1988).

19 Unused & Expired Medicines Registry, maintained by the Community Medical Founda tion for Patient Safety. http://www.comofcom.com/Abstract8.pdf.

20 Winnebago County Board of Supervisors, Solid Waste Management Board. Open Ses sion Minutes, August 1, 2007, p. 4. www.co.winnebago.wi.us/countyclerk/docs/swm070801.pdf.

21 Waukesha County, New Mail Back Pilot Medicine Collection Program—Frequently Asked Questions. www.waukeshacounty.gov/uploadedFiles/Media/PDF/Parks_and_Land_Use/Recycling/Medicine%20Pilot%20FAQ.pdf.

22 Rubinstein, Lynn. "Operating Unwanted Medication Collections- A Legal and Safe Approach." Northeast Recycling Council. www.iisgcp.org/unwantedmeds/updatedToolkitMaterials/3.1NERCadvisory.pdf.

23 Jeppesen, Stan. "Pharmaceuticals from Households: A Return Mechanism (PH:ARM); A Washing ton State Pilot Program to Return Medications for Proper Disposal." Presented at National Conference on Drug and Chemical Diversion, Houston, TX, June 6-8, 2006. www.deadiversion.usdoj.gov/mtgs/drug_chemical/2006/drugdisposal_sj.pdf.

24 Testimony of Benjamin H. Grumbles, Assistant Administrator for Water, EPA, before the Transpor tation Safety, Infrastructure Security and Water Quality Subcommittee of the Environment and Public Works Committee (2008): http://www.epa.gov/ocir/hearings/testimony/110_2007_2008/2008_0415_bhg.pdf. It is unclear whether this EPA grant is renewable.

25 The toolkit is at www.iisgcp.org/unwantedmeds/.

26 King Pharmaceuticals, Roche, Alpharma, Johnson & Johnson, AstraZeneca, and Pfizer are partici pating in the PSI national stakeholder dialogue process.

27 Wood, Leslie, Director of State Police, PhRMA. "Recommendations for an Effective Drug Take Back Program – Structure and Funding." Presented at meeting of Oregon Pharmaceutical Take Back Stakeholder Group, Salem, OR, May 11, 2007. http://blog.oregonlive.com/pdxgreen/2007/11/Phrmareport.pdf.

28 Ibid.

29 SMARxT Disposal: A Prescription for a Healthy Planet. www.smarxtdisposal.net/.

30 Oregon Pharmaceutical Take Back Stakeholder Group. "Final Report." July 1, 2007. p. 78.

31 Letter from Lis Houchen, National Association of Chain Drug Stores to Janet Gillaspe, Oregon Association of Clean Water Agencies, April 21, 2008 (on file with author) ("NACDS letter").

32 Ibid.; interviews on May 1, 2008, and May 8, 2008.

33 NACDS letter, supra note 32.

34 Hauser, Joshua M., Lex Chen, and Judith Paice. "Down the Drain: The Cost of Medications Wasted in Hospice." Journal of Pain and Symptom Management. May 2006. This study focused on one hospice and found that the total number of medications wasted by 51 patients who died at home totaled 4,762 mL, 2,495.5 tablets, and 67 patches. The average cost of wasted medications per patient was $109 (if purchased as generics) and $206.59 (if purchased as brand name).

35 42 C.F.R. § 418.96(b).

36 Interview on May 29, 2008.

37 Interviews on May 29, 2008, and June 13, 2008.

38 "Report on the San Francisco Bay Area's Safe Medicine Disposal Days." August 2006. www.p2pays.org/ref/40/39862.pdf.

39 Collins, Bob, Minnesota Public Radio. "Stunned by turnout, organizers cancel e-waste effort." November 16, 2007. http://minnesota.publicradio.org/display/web/2007/11/16/recycle/

40 Thompson, Virginia, EPA Region 3. "Pharmaceuticals in the Environment." June 1, 2008. www.epa.gov/reg3wapd/npdes/pdf/2008npdesmeeting%20presentations/NPDES%20States%20Meeting%206-2-08%20%5BRead-Only%5D.pdf.

41 See the National Association for State Controlled Substances Authorities website for a list of these state agencies. http://www.nascsa.org/Folder5/memstates.htm.

42 See the DEA Diversion Control Program's website for a list of controlled substances. www.deadiversion.usdoj.gov/schedules/schedules.htm.

43 DEA Diversion Control Program – General Questions and Answers. www.deadiversion.usdoj.gov/faq/general.htm.

44 See 21 CFR § 1307.21; DEA Diversion Control Program – General Questions and Answers: www.deadiversion.usdoj.gov/faq/general.htm; USPS Publication 52 – Hazardous, Restricted, and Perishable Mail, Section 48 Controlled Substances and Drugs: http://pe.usps.gov/text/pub52/pub52c4_008.html#NL508_52.

45 21 CFR § 1301.24.

46 Letter from Mark Caverly, DEA Office of Diversion Control, to Stephen M. Kearney, USPS. April 15, 2008 (on file with author).

47 C.F.R. § 418.96(b).

48 Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs: Hospice Conditions of Participation. 73 Fed. Reg. 32088, (June 5, 2008) (to be codified at 42 C.F.R. part 418).

49 Interview on May 15, 2008. See USPS Publication 52 – Hazardous, Restricted, and Perishable Mail, Section Controlled Substances and Drugs. http://pe.usps.gov/text/pub52/pub52c4_008.html#NL508_52.

50 Domestic Mail Manual 601.11.11.2, 601.11.11.5.

51 USPS Operational Test Agreement Template (on file with author), DMM 601.11.11.4.

52 RCRA hazardous waste regulations are at 40 CFR §§ 260-280.

53 As part of the Northeast Recycling Council's take-back project, PharmEcology Associates evaluated a list of medications collected and determined that approximately 10 percent of the collected medications – prescription and over the counter – should be should be considered hazardous waste. Rubinstein, Lynn, "Operating Unwanted Medication Collections- A Legal and Safe Approach." Northeast Recycling Council. 2006. http://www.nerc.org/documents/operating_unwanted_medication_collections_final_2006.pdf.

54 If the product has been designated as "waste," RCRA calls for the waste to be handled by a licensed hazardous waste firm.

55 U.S. EPA, letter from Alan S. Corson, Chief, Waste Characterization Branch, Hazardous and Industrial Waste Division, to Steven Wittmer, Merck, Sharp & Dohme, May 13, 1981. http://yosemite.epa.gov/OSW/rcra.nsf/Documents/F3001B817EF4265885256611005156D; U.S. EPA, letter from Sylvia K. Lowrance, Director, Office of Solid Waste, to Mark J. Schulz, Browning-Ferris Industries, May 16, 1991. http://yosemite.epa.gov/OSW/rcra.nsf/Documents/354FE6A290ED95E1852565DA006F04A1.

56 TDC Environmental. Household Pharmaceutical Waste: Regulatory and Management Issues. August 2004. www.tdcenvironmental.com/HouseholdPharmWasteMgtIssuesFinal.pdf.

57 EPA RCRA State Authorization: http://www.epa.gov/epaoswer/hazwaste/state/index.htm.

58 EPA. Semiregulatory Agenda. "Amendment to the Universal Waste Rule: Addition of Pharmaceuticals." Spring 2008. p. 119. www.epa.gov/lawsregs/documents/regagendabook-spring08.pdf.

59 EPA. "Universal Waste: Where You Live." www.epa.gov/epaoswer/hazwaste/id/univwast/statespf.htm.

60 In 2008, an update for Reyataz disposal occurred. Previous disposal instructions were to flush unused or expired medication down the toilet or pour it down the drain. See labeling revision dated December 21, 2007, for last version that directed consumers to flush. www.fda.gov/cder/foi/label/2007/021567s014lbl.pdf.

61 FDA. "How to Dispose of Unused Medicines" www.fda.gov/consumer/updates/drug_disposal062308.html (last visited November 10, 2008).

62 Introduced legislation: New York State Assembly Bill A840; Washington House Bill 2600. Oregon is contemplating legislation for the 2009 session.

63 Weil, Alan. "How Far Can States Take Health Reform?" 2008 Health Affairs. 27(3).

64 North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services. "Chapter 1: Foundations of Reform" State Plan 2003.

65 Hamilton, Gayle. "Moving People from Welfare to Work: Lessons from the National Evaluation of Welfare-to-Work Strategies." July 2002. www.mdrc.org/publications/52/summary.html.

66 Frieder, Miryam, et al. "Focusing Federal Efforts: A Review of Health-Related Offices, Commissions, Panels, and Conferences." Avalere Health. 2008.

Avalere Health LLC
1350 Connecticut Ave., NW
Suite 900
Washington, DC 20036

www.avalerehealth.net