

NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

RETURN, REUSE & DISPOSAL OF UNUSED PHARMACEUTICALS

WORKING GROUP MEETING

NOVEMBER 4-5, 2010

Crystal Gateway Marriott

1700 Jefferson Davis Highway

Arlington, Virginia

This working group was convened with the ultimate goal of determining the feasibility of developing a model take-back law, guidance document or protocols relating to the return, reuse and disposal of unused pharmaceuticals. The participants, who represent groups working on the local, state and federal levels, were selected for their expertise and interest in various prescription drug issues, such as the return, reuse and disposal of these drugs.

Over the course of two days, the participants discussed and debated a variety of relevant issues including but not limited to the following:

- The different approaches to establishing a drug take-back program – the mail-back model, singular take-back events and ongoing drop-offs;
- Stakeholders and implications for each of those stakeholders;
- Funding obstacles;
- Disposal options and environmental impacts; and
- State and federal legislation and regulations.

The information contained in this document reflects presentations and discussions that occurred during the facilitated working group session.

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STAKEHOLDERS

Group	Stakeholders
Law Enforcement	Prosecuting Attorneys State Boards of Pharmacy (if the Board has enforcement authority) Attorneys General State Drug Enforcement Agencies Local Law Enforcement Agencies State Controlled Substance Authorities
Business/Industry and Their Affiliated Associations	National Community Pharmacists Association (NCPA) National Association of Chain Drug Stores (NACDS) National Association of Boards of Pharmacy (NABP) National Association of State Controlled Substance Authorities (NASCSA) Drug Manufacturers (Prescription and Over-the-Counter) Consumer Health Products Association (CHPA) Pharmaceutical Researchers and Manufacturers of America (PhRMA) Generic Pharmaceutical Association (GPhA) Bio-tech Companies Chemical Companies
Environmental Interests	Water Authorities Clean Air Authorities Waste Management Authorities Environmental Non-Governmental Organizations
Public Health	Health and Human Service Departments State Health Departments Local Boards of Health Substance Abuse Treatment Providers Boards of Pharmacy and Licensing Authorities Single State Authorities Poison Control Centers (National and Regional) Association of Food & Drug Officials (AFDO) National Associations Advocating for Public Health Interests
Education/Community Groups	Media Outlets Civic Groups (Elks, Rotary) Consumer Advocate Groups National Guard Community and Youth Groups

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Group	Stakeholders
Federal Agencies	Office of National Drug Control Policy (ONDCP) Environmental Protection Agency (EPA) Drug Enforcement Administration (DEA) Food and Drug Administration (FDA) Veteran’s Administration (VA) Department of Justice (DOJ)/Bureau of Justice Assistance (BJA) National Drug Intelligence Center (NDIC) Indian Health Services (IHS) Centers for Medicare and Medicaid Services (CMS)
Medical Community	Physicians and their Affiliated Associations – including but not limited to: <ul style="list-style-type: none"> • American Medical Association • Associations of Medical Specialties • State Medical Associations Pharmacists and their Affiliated Associations Veterinarians and their Affiliated Associations Osteopaths and their Affiliated Associations Dentists and their Affiliated Associations Nurses and their Affiliated Associations Long-term Care Facilities Individual Health Care Providers
Insurers	Medicare Medicaid Commercial Insurance Companies and their Affiliated Organizations State Insurers State Insurance Commissioners
International	The Partnership for Quality Medical Donations (PQMD) World Health Organization

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RETURN OPTIONS AND OPERATING PROGRAM EXAMPLES

	Take-Back Events
Key Components	<ul style="list-style-type: none"> • Obtaining necessary approvals, especially if controlled substances will be collected • Soliciting support of law enforcement agencies • Establishing convenient drop-off/collection sites • Arranging for proper disposal of items collected • Advertising and promotion of the event • Sampling returned items and extracting useful empirical data
Existing Program Examples	<p><u>Drug Enforcement Agency Take-Back Day</u></p> <ul style="list-style-type: none"> • On September 25th, 2010 the DEA sponsored a nationwide coordinated take-back day • There were over 4000 collection sites and nearly 3000 state and local law enforcement agencies participated • DEA maintained a website listing collection sites • A second take-back event is planned for April 30th, 2011 <p><u>Arkansas Tool Kit</u></p> <ul style="list-style-type: none"> • The State of Arkansas maintains a tool kit designed to guide law enforcement entities in their efforts to plan and carry out take-back events • The tool kit is available as a hard copy and online in an e-version • To date the kit has been distributed to more than 800 law enforcement agencies in the state • The kit includes guidelines for obtaining proper approval, securing collection containers and arranging destruction sites for the items collected
Concerns & Suggestions	<ul style="list-style-type: none"> • Early advertising and educating the public about up-coming events • Set the day as far in advance of the event as possible to ensure maximum participation • Promotional materials should be published in several languages as needed • Sporadic collection events have been shown to be more costly and less effective than other methods for collecting household waste; are take-back events cost efficient? • Demographic differences can make it difficult for all localities, regions and states to comply with a single set of parameters that govern a particular take-back event • Take-back events may not be a viable long-term option

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Concerns and Suggestions Continued	<ul style="list-style-type: none"> • Law-enforcement currently plays a pivotal role in take-back events; what is their capability and willingness to be involved – what are the potential impacts on local law enforcement in terms of staffing and capacity to store and transport collected medicines? • Law enforcement should not treat collections like evidentiary drugs; this will cut down significantly on paperwork • Should someone be gathering data on the types and quantities of drugs that are returned? • When should take-back events take place; should they take place on weekends when consumers are out running errands but law enforcement offices may be understaffed? • Cross-jurisdictional cooperation is key • Returns must be confidential • To ensure proper disposal, the DEA and/or other entities overseeing the event should coordinate with state agencies involved in waste management in advance of the event • Consumer reliance on take-back events may lead to the accumulation of unused and unneeded medications, which could be counter-productive to the goal of reducing abuse, misuse, diversion and accidental poisonings • As consumers often cannot distinguish between different types of medicines/drug products, take-back events should permit the return of all types of medicines (prescription and non-prescription as well as controlled and non-controlled substances) • Requiring consumers to separate controlled substances from non-controlled substances will decrease participation
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Mail-Back Programs	
Key Components	<ul style="list-style-type: none"> • Any mail-back program must complete an approval process that includes authorizations from both the United States Postal Service and the United States Drug Enforcement Administration • Generic looking, postage-paid mailers provided to pharmacies and other approved locations for distribution to consumers when prescriptions are dispensed • Mailers must have a law enforcement agency return address since the Controlled Substances Act prohibits consumers from directly sending controlled substances through the mail; this prohibition could be lifted or amended by the pending regulations that will implement the 2010 Secure and Responsible Drug Disposal Act (S 3397, P.L. 111-273)

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Key Components Continued	<ul style="list-style-type: none"> • If necessary, statutes/regulations should be amended to facilitate implementation of a mail-back program • As drug products (including controlled substances) are involved, a chain of custody must be followed from the time the recipient agency takes possession of the mailers until the contents of the mailers are destroyed • A law enforcement agency must have the responsibility for enforcing the provisions of the program and prosecuting any crimes associated therewith; a regulatory agency can have the responsibility for enforcement of the programs' provisions but may have to refer any cases involving criminal activity to the appropriate law enforcement agency
Existing Program Examples	<p><u>Maine Safe Medicine Disposal Program</u></p> <ul style="list-style-type: none"> • Pilot program began in 2008 • The program is funded by the EPA and an allocation from the "Fund for a Healthy Maine" • Postage-paid medicine return envelopes are distributed to selected pharmacies and organizations, at no cost to those entities or the consumers • Staff then give the mailers and instructions to those expressing interest • Consumers can put any drug products in the mailers – approximately 17% are controlled substances • The mailers are securely delivered to the Maine Drug Enforcement Agency where there are logged, catalogued and destroyed • Local law enforcement does not handle mailers and their contents • Maine has statutory authority to operate their mail-back program • Program approval process lasted approximately one year • The State prosecutes related crimes through their Attorney General's office • During the course of the pilot program 9,400 envelopes were distributed and 2,373 pounds of drugs were collected at an estimated wholesale price of \$572,772.35 • Currently, 20,000 mailers are available through a statewide network of participating pharmacies and partner sites • One of the greatest challenges is the success of the program; it is convenient and increasingly widely used, driving up mailing and disposal costs <p><u>Veteran's Administration Program</u></p> <ul style="list-style-type: none"> • The U.S. Postal Service and the Veteran's Administration implemented a pilot program limited to approximately 780,000 veterans living in Baltimore, MD, Washington D.C. and West Virginia

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<p>Existing Program Examples Continued</p>	<ul style="list-style-type: none"> • Through this program veterans are able to mail back outdated, unwanted medications • Federally approved facilities destroy the medicine, ensuring that the drugs do not end up in municipal waste facilities or in ground water stores • Veterans receive specially designed, postage-paid envelopes and instructions at the time each prescription is filled • Expired and unused prescriptions can be placed in the envelopes and dropped off in USPS collection boxes or at Post Offices
<p>Concerns & Suggestions</p>	<ul style="list-style-type: none"> • Cooperation and collaboration is pivotal for a successful mail-back program; packaging and mailers must have U.S. Postal Service approval and the DEA must also sign off on the program • Program officials must set up a post office box for returns • Program approval process can be lengthy • Some law enforcement entities have concerns about a mail-back approach, including but not limited to the following: <ul style="list-style-type: none"> - mail-back is not secure enough to prevent diversion unless there is a comprehensive mailer tracking system in place - the cost of operating such a tracking system as well as other costs associated with large scale mail-back are unknown and may prove too costly for some communities to participate, especially given the current economic environment - local agencies lack the jurisdiction to prosecute potential offenses involving diversion and can therefore not make up any potential gaps in U.S. Postal Service enforcement authority • Prosecution for diversion may be a problem in states that do not have a statewide law enforcement agency dedicated to enforcing/prosecuting drug-related crimes or if the mailers are transported across state lines • Generic-looking mailers should be used to discourage theft and subsequent abuse and/or diversion • A system using mailers may not be effective in situations where a person is sending a large volume of medicines, perhaps after a long illness or the death of a family member • The USPS is very supportive of mail-back programs and it is in their financial interest to make sure the programs are successful and secure • Mail-back programs are an appealing option for rural areas (where drop-offs can prove inconvenient for residents) and for specific populations with limited mobility (seniors and other persons who are homebound) • Mail-order pharmacies have already set a precedent for delivering large quantities of prescription drugs through the mail

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Concerns & Suggestions Continued	<ul style="list-style-type: none"> • There should be an toll free or package tracking number so that consumers can confirm delivery and receipt of the mailers by the take-back program • There should be protocols in place for the mail back of sharps waste (sharps are medical waste that includes any device used to lacerate or puncture the skin) • In terms of ongoing terrorism threats, mass mail-backs could result in a big increase in false alarms as packaging breaks and pharmaceuticals leak out
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On-Going Drop-Offs	
Key Components	<ul style="list-style-type: none"> • Establishment of permanent drop-off sites equipped with some type of secure receptacle • Drop-off sites must be convenient and well-advertised to encourage and support use throughout a region or community • Drop-off sites should list which drug products can be deposited as well as those that cannot; sites should have specific postings listing prohibited items (i.e. mercury thermometers, sharps, glucometers) • Common drop-off locations are at law enforcement agencies and community pharmacies; established and secure protocols must be followed at all drop-off locations • Drop-off points at law enforcement agencies can accept both controlled and non-controlled substances but pharmacy drop-off locations are generally not permitted to accept controlled substances • Use of tamper-resistant/tamper-evident seals on collection containers and proper tracking and record-keeping (from the point of collection through disposal) to prevent diversion and provide confirmation that all collected medicines are ultimately destroyed • Establishment of a method of disposal for the collections
Existing Program Examples	<p><u>Washington State Medicine Return Initiatives</u> (Please see www.takebackyourmeds.org for more information and a list of collection sites)</p> <ul style="list-style-type: none"> • There are currently 14 Bartell Drugs community pharmacies and 25 Group Health Cooperative clinical pharmacies collecting pharmaceuticals

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<p>Existing Program Examples Continued</p>	<ul style="list-style-type: none"> • State and local agencies were unable to get a waiver for these pharmacies to collect controlled substances, but security protocols were designed as if controlled substances would be collected (see http://www.takebackyourmeds.org/pdf-files/pharm-final-report) • Protocols for the Bartell Drugs and Group Health Cooperative programs were reviewed and approved by the WA State Board of Pharmacy • Since October 2006, Bartell Drugs and Group Health have securely collected and disposed of approximately 60,000 pounds of medicines without any known incidence of diversion • Throughout the state there are currently more than 50 law enforcement take-back programs spread across 12 of 39 counties • The Thurston County Sheriff and Snohomish County Sheriff respectively reported collecting 1200 and 1800 pounds of medicine from January through September 2010 • The established protocol for collection at Bartell Drugs pharmacies includes: <ul style="list-style-type: none"> - individuals returning drugs must show the drugs to a pharmacist - the pharmacist then tells the consumer which drugs they can take and directs the consumer to take controlled substances to a law enforcement agency -medicines are deposited in a tamper-proof, steel container that is bolted to the floor/counter or cabled to the wall - two keys (held by two different staff members) are required to open each drop box -each box or bucket of collected medicines is sealed with tamper-resistant materials and then securely stored and tracked through the point of final disposal -there is no counting or sorting of collected pills; medicine returns are tracked in bulk (by box, bucket or other similar container) • Disposal costs are approximately one dollar per pound; this includes transportation and disposal at a hazardous waste incinerator through a WA statewide blanket contract available to both government entities as well as non-profits • Two WA counties have local ordinances prohibiting trash disposal of unused medications, due to their designation as hazardous waste under the federal Resource Conservation and Recovery Act (RCRA) or WA State's hazardous waste provisions • Police are encouraged to keep collected drug products separate from evidentiary drugs
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<p>Existing Program Examples Continued</p>	<ul style="list-style-type: none"> • A 2006 survey of King County residents showed that 74% of residents would be willing to return unused drugs to a convenient location; 84% said they would return their unwanted medicines to a secure drop box at their pharmacy (see http://www.zerowastewashington.org/images/pdfs/med-survey-summary.pdf) • A 2009 statewide survey of WA households found that 64% of respondents said they were “likely” to drop off unused or expired medications for free disposal if the location was convenient (45% responded they would be “very likely” to do so); 55% of respondents said they would be likely to use a free mailer to dispose of unused or expired medications (40% responded they would be “very likely” to do so) (see http://www.takebackyourmeds.org/pdf-files/wa-or-pharm-survey-report)
<p>Concerns & Suggestions</p>	<ul style="list-style-type: none"> • Which drop-off location should be used – pharmacies, law enforcement agencies or a combination of both? • A pharmacy protocol can provide pharmacists with the opportunity to discuss medication compliance with their patients • Pharmacists may have reservations due to the public’s potential concern that returns to pharmacies will be re-dispensed to patients • Pharmaceutical collection points operate under varying guidelines and standards, making some more conducive to counting and cataloging what consumers are returning; conducting counts and cataloging returns should be a voluntary (not mandatory) process • There is value in gathering empirical data about the types of medicines that are collected as this information can lead to changes in prescribing practices, etc. • Pharmacists may be more likely to participate if they are following the direction of or a mandate from the National Association of Boards of Pharmacy and/or their respective state boards of pharmacy • Some people are never going to be comfortable with a law enforcement protocol, despite any efforts to promote anonymity of returns • Law enforcement should not treat collections like evidentiary drugs; this will cut down significantly on paperwork • Address security concerns with respect to the drop boxes • Take relevant Health Insurance Portability and Accountability Act (HIPAA) issues into account through protocols that protect patient information found on medicine packaging

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Concerns & Suggestions Continued	<ul style="list-style-type: none"> Drop-off programs that collect all types of medicines (both prescription/non-prescription and controlled/non-controlled) are the best option for consumers as they are typically not aware of the distinctions between different drug products
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DISPOSAL

Key Points & Concerns

- Total agreement on this issue may be irrelevant because of the vastly different regulatory schemes in each of the states.
- Arkansas uses the “Drug Terminator,” a 50 gallon drum used to incinerate collected medicines; one concern is that the Terminators create a lot of residual waste (dioxins) and air-based contamination and they may require special licensing in some states because they are technically incinerators.
- If standardized disposal procedures are implemented, they must take into account state and local government authority regarding environmental protection; under the federal Resource Conservation and Recovery Act (RCRA), state and local governments are authorized to adopt more stringent requirements for the disposal of toxic materials than the standards provided in federal law; a number of states have adopted more stringent standards for the disposal of pharmaceutical waste.
- Disposal standards and procedures may necessarily differ in states that have RCRA authority.
- Proper disposal is important but it is also important to set realistic goals, given funding constraints and legal obstacles.
- There needs to be more scientific research to help determine the safest and most practical disposal method(s).
- When federal/national groups conduct nationwide take-back days, should they be required to follow individual state standards when disposing of the collected drugs?
- Is it actually more expensive to use an environmentally safe disposal method?
- Solid waste incineration is one of the cheaper disposal methods but is it as effective or as protective of public health interests as some of the other established methods?
- If there are more full time drug return programs operating, the market may drive down the per pound price of incineration.

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- Due to current federal regulations, destruction/disposal of controlled substances from end-user/consumer take-back programs and long-term care facilities is more complicated than the destruction/disposal of other pharmaceutical products, due in part to the requirement for a witnessed burn.
- Pharmaceutical waste from clinical/business sources (i.e. hospitals, pharmacies, doctor's offices) is currently transported and disposed of by companies (reverse distributors and pharmaceutical waste disposal vendors) that utilize hazardous waste incinerators, solid waste incinerators and medical waste incinerators depending on the characteristics of the pharmaceuticals and application of relevant federal, state and local laws/regulations; end-user/consumer take-back programs and long-term care facilities should have the ability to utilize these same services, giving them a full range of disposal options.
- Should we be using Geiger counters to detect radioactive medicines of a certain age?
- If disposal is not effected in a manner that is environmentally sound and considerate of public safety concerns, certain groups will cease their support of drug take-back programs.
- Disposal should afford equal protection to public health concerns and the environment.
- Keeping drug residue out of this country's water resources is an important consideration; there are also concerns over deteriorations in air quality resulting from certain combustion and incineration methods.

FUNDING

Key Points & Concerns

- Funding is needed for all aspects of this issue...program implementation and sustainability, research and disposal.
- The public wants take-back programs and they have proven successful; unfortunately, success means more individuals are participating, which means increased operating expenses.
- Drug companies and insurers can set a positive example by helping to fund take back programs.
- Grants are an option but in many cases, the lengthy grant-writing process and un-sustainability of grants outweighs the funds being offered.
- Sustainable funding is key but it has proven much easier to secure funding for a startup or a pilot project than for long-term implementation.
- It is important to factor in costs saved when determining the cost of a program, such as the costs associated with overdoses, car crash injuries and the personal property damage associated with motor vehicle accidents, drug court costs, accidental poisonings, etc.

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LEGISLATIVE OPTIONS AND REGULATION THROUGH OTHER MECHANISMS

Key Points & Concerns

- A number of states have introduced legislation to create statewide take-back programs, and many others may wait to do so until after the release of the federal regulations that will implement the Secure and Responsible Drug Disposal Act of 2010 (S. 3397).
- Those regulations, in addition to the language of S. 3397, will significantly impact the types of take-back programs states are able to implement.
- At this point in time the DEA, which is the agency responsible for drafting the regulations, does not know how those regulations will affect individual states.
- Will the forthcoming federal regulations for S. 3397 set the stage for a model take back law states or other entities can follow?
- DEA's main concern is promoting the safest and most secure way to perfect the processes involved in medicine take-back.
- Differences in state laws, geography and demographics necessitate the availability of options in any comprehensive federal-level legislation.
- The "producer responsibility" or "product stewardship" approach is one funding model that has been successful in other countries and that some states are weighing as an option.
- Model legislation should allow for creative funding options.
- Legislation should be very clear as to which entities have certain responsibilities with regard to operating a take-back program.
- Should model legislation focus on implementation or authorization?
- Is it possible and/or practical to require instructions as to proper disposal to accompany every prescription upon dispensation?
- Should the Centers for Medicaid Services (CMS) provide patients with mailers when their prescriptions are filled?
- Could the Food and Drug Administration institute a requirement that mailers be sent along with drugs that have specific disposal requirements?
- The "Consumer Medication Information" that accompanies prescriptions could include safe disposal guidelines.

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NEXT STEPS

- As this is an issue with ever-changing parameters, there must be constant engagement by relevant parties to ensure there is a sustained effort to develop and implement long-term successful take-back programs.
- Compiling relevant existing materials on drug take-back programs, including but not limited to legislation, protocols, guidance documents, statistics, studies, news articles and memoranda.
- Creation of a website that will display information about take back days, drop off sites and mail back options all across the country.
- Convene a second meeting of this working group, with some additional representatives, particularly from the pharmacy profession and the pharmaceutical industry.
- Continue to explore ancillary yet relevant subjects such as prescribing practice reform and alternative disposal methods.
- Drafting of a model law and/or guidance document on drug take-back programs, taking into account the existing operating programs and all relevant federal laws and regulations.
- Research and evaluate the effect of take-back programs on the levels of pharmaceutical waste found in the environment.

RESOURCES

The links listed below are for information purposes only. These resources provide a variety of relevant information on the topic of return, reuse and disposal of unused pharmaceuticals. The content of the websites is maintained by external sources and The National Alliance for Model State Drug Laws cannot account for the accuracy and timeliness of the information/data provided.

Office of National Drug Control Policy – Proper Disposal of Prescription Drugs:
http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

Drug Enforcement Administration – Office of Diversion Control – Drug Disposal:
http://www.deadiversion.usdoj.gov/drug_disposal/index.html

Drug Enforcement Administration Take Back Resources:
http://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html

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Environmental Protection Agency – Disposal of Pharmaceuticals and Personal Care Products:
<http://www.epa.gov/ppcp/projects/disposal.html>

Environmental Protection Agency – Best Management Practices for Unused Pharmaceuticals at Health Care Facilities:
http://water.epa.gov/scitech/wastetech/guide/unusedpharms_index.cfm

Washington State Medicine Return Program Information:
<http://www.takebackyourmeds.org/>

Safe Medicine Disposal for Maine:
<http://www.safemeddisposal.com/>

Arkansas Toolkit
http://www.productstewardship.us/associations/6596/files/TakeBack_Toolkit.pdf

Arkansas Prescription Pill Take Back Initiative:
<http://www.artakeback.org/>

Washtenaw County, Michigan – Medication Disposal Information:
http://www.ewashtenaw.org/government/departments/environmental_health/recycling_home_to_xics/medication_disposal/frontpage

New Hampshire Department of Environmental Services – Unwanted Medicine Collection Events Recommended Standard Operating Procedures:
http://des.nh.gov/organization/divisions/water/dwgb/dwssp/medsafety/documents/sop_unwanted_med_collection.pdf

Product Stewardship Institute Resources on Pharmaceuticals:
<http://productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=181>

The Drug Take-Back Network:
<http://www.takebacknetwork.com/>

Teleosis Institute – Green Pharmacy Program:
<http://www.teleosis.org/gpp-program.php>

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Northeast Recycling Council, Inc – Holding an Unwanted Medication Collection for Community Pharmacies:

http://www.nerc.org/documents/unwanted_medication_collection_quick_guide_11_08.pdf

Pharmacy Society of Wisconsin – Establishing an Unwanted Medication Collection Program:

<http://www.pswi.org/government/disposal.pdf>

Oregon State University - Pharmaceutical Take Back Stakeholder Group Final Report:

http://oracwa.org/downloads/drugtakeback-rpt_0907.pdf

Illinois-Indiana Sea Grant Program – Disposal of Unwanted Medicines – A Resource for Action in Your Community:

<http://www.iisgcp.org/unwantedmeds/index.html>

Report on the San Francisco Bay Area's Safe Medicine Disposal Days:

<http://www.p2pays.org/ref/40/39862.pdf>

The American Medicine Chest Challenge:

<http://www.americanmedicinechest.com/>

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