How Unused Medicine can create an opportunity for patient education


Stevan Gressitt, M.D.

Maine Unused Drug Disposal Group
www.mainebenzo.org
History

- The Maine Benzodiazepine Study Group
  - Formed 2002
  - Legislative initiative proposed 2003 to reduce Prescription Drug Abuse from 1st Conference
  - Bipartisan, with Maine DRUG RETURN IMPLEMENTATION Group formed
Supporters:

- Maine Medical Association
- Maine Psychiatric Association
- Northeast Occupational Exchange
- Maine Benzodiazepine Study Group
- Maine Dental Association
- Maine Rivers
- Maine Children's Alliance
- Memorial University of Newfoundland, Faculty of Medicine, Psychiatry
- Theo Colborn, PhD
- Maine Osteopathic Association
- Maine Association of Substance Abuse Programs
- Dave Galvin, Hazardous Waste Management, King County, Washington State
- Abdelkrim Smine, PhD, Global Assistance Initiatives, USP
- Northern New England Poison Control Center
- Dominion Diagnostics
- Strong Environmental
- Charlotte Smith, Pharmecology
Authorizing Legislation, Public Law 2003, Chapter 679, An Act to Encourage the Proper Disposal of Unneeded Pharmaceuticals

STATE OF MAINE
122nd LEGISLATURE
FIRST REGULAR SESSION

Final Report of the
MAINE DRUG RETURN IMPLEMENTATION GROUP

March 8, 2005

Members:

Sen. John L. Martin, Chair
Katherine Bilotas
James Cameron
Douglas S. Carr
William M. Earle
Stevan Gressitt
Susanne P. Ketterer
Roy McKinney
Sally-Lou Patterson
Ann Pistell
James Toman
Final Law:

Maine Legislature Title 22: HEALTH AND WELFARE
Subtitle 2: HEALTH
Part 5: FOODS AND DRUGS
http://janus.state.me.us/legis/statutes/22/title22ch604sec0.html

§2700. Unused Pharmaceutical Disposal Program (CONTAINS TEXT WITH VARYING EFFECTIVE DATES)
(WHOLE SECTION TEXT EFFECTIVE 7/1/06)

1. Establishment; purpose. There is established the Unused Pharmaceutical Disposal Program, referred to in this chapter as “the program.” The purpose of the program is to ensure the safe, effective and proper disposal of unused pharmaceuticals. For purposes of compliance with federal law and regulation, the return of pharmaceuticals under this section is deemed to be for law enforcement purposes. [2003, c. 679, §1 (new); 2005, c. 297, §3 (aff).]

2. Administration. The program is administered by the Maine Drug Enforcement Agency, referred to in this chapter as “the agency,” established in Title 25, section 2955. [2003, c. 679, §1 (new); 2005, c. 297, §3 (aff).]

3. Return of pharmaceuticals. The agency shall create a system for the return of unused pharmaceuticals. The system must use prepaid mailing envelopes into which the unused pharmaceuticals are placed and returned to a single collection location. The prepaid mailing envelopes must be made available to the public at various locations, including, but not limited to, pharmacies, physicians' offices and post offices. The agency may randomly assess the toxicity of materials received under the program as long as the assessment results do not identify the patient, person who mailed the material, prescriber or pharmacy. [2003, c. 679, §1 (new); 2005, c. 297, §3 (aff).]
4. Disposal of pharmaceuticals. The agency shall ensure that only agency officers handle the unused pharmaceuticals received pursuant to subsection 3. The unused pharmaceuticals must be disposed of by the agency in a manner that is designed to be effective, secure and in compliance with local, state and federal environmental requirements, including the federal Resource Conservation and Recovery Act of 1976, as amended. [2003, c. 679, §1 (new); 2005, c. 297, §3 (aff).]

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter. [2005, c. 297, §1 (amd); §3 (aff).]

6. Rulemaking. The agency shall adopt rules to carry out the purposes of this chapter. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. [2003, c. 679, §1 (new); 2005, c. 297, §3 (aff).]

7. Contingency. The program must operate with funding solely from the fund provided in subsection 5. The program may begin operation for 2 years on July 1st of any year in which notice is given by April 1st by the director of the agency to the State Budget Officer that funding has been procured for the fund that is sufficient to operate the program for 2 years. [2005, c. 297, §2 (new); §3 (aff).]
What were justifications originally used:

1. To reduce childhood accidental poisonings
2. To reduce teenage “pharming” and household burglary
3. To reduce excessive accumulation amongst the elderly
4. To preclude environmental impact
Additional rationales

1. Pharmacoeconomic feedback and pharmacosurveillance for adherence, compliance and policy directions

Organizations with positions

- USP, John Gans
- ASCP
- MAPP
- MMA
- APA
- APHA
Which brings us to here for scope

But whatever your current position, the math is compelling:

1. Clinical researchers estimate patient compliance rates are still below 60% for most medicines – and with some diseases the figure plummets as low as 10% - 20%.

2. The National Health Care Purchasing Institute says non-compliance contributes to 125,000 deaths every year.

3. Meanwhile, it’s costing pharma companies six times more to gain a new customer than to retain a current one.
National Drug Intelligence Center

Doug Ross
NDIC Field Program Specialist

October 13, 2005
NDTS 2006

Maine Benzodiazepine Study Group

All Data courtesy of:
National Drug Intelligence Center
Johnstown, Pennsylvania

Portland, Maine
October 23-24, 2006
NDTS 2006 Prepublication

- Q1 Greatest Drug Threat
- Q2 Greatest Availability
NDTS 2006 Prepublication

- Q12a Pharmaceuticals contributing to violent crime
NDTS 2006 Prepublication

- Q12b Pharmaceuticals contributing to property crime
"Because that's where the money is."

- Easy to get from parents' medicine cabinet 62%
- Are available everywhere 52%
- They are not illegal drugs 51%
- Easy to get through other people's Rxs 50%
- Teens can claim they have a prescription if caught 49%
- They are cheap 43%
- Safer to use than illegal drugs 35%
- Less shame attached to using 33%
- Easy to buy over Internet 32%

(Parternership for a Drug-Free America, 2005 Partnership Attitude Tracking Study)
How Young Adults Obtain Prescription Pain Relievers for Nonmedical Use

In Brief

- In 2005, 12.4 percent of young adults aged 18 to 25 used prescription pain relievers nonmedically in the past year, and 1.7 percent met the criteria for past year prescription pain reliever dependence or abuse.

There has been a growing concern in both the law enforcement and public health arenas about the increase in the use of pharmaceutical drugs for nonmedical use, especially among young adults. The National Survey on Drug Use and Health (NSDUH) asks persons aged 12 or older questions related to their nonmedical use of prescription-type drugs, including prescrip-
Figure 1. Percentages of Reported Method** of Obtaining Prescription Pain Relievers for Their Most Recent Nonmedical Use in the Past Year among Persons Aged 18 to 25: 2005 NSDUH

- Got Them from a Friend or Relative for Free: 53.0%
- Prescriptions from One Doctor: 12.7%
- Bought from a Friend or Relative: 10.6%
- Bought from a Drug Dealer or Other Stranger: 4.8%
- Took from a Friend or Relative without Asking: 3.8%
- Got Them Some Other Way: 2.9%
- Prescriptions from More Than One Doctor: 1.3%
- Other Unknown or Invalid Source: 10.0%

Source: SAMHSA, 2005 NSDUH.

Figure 2. Percentages of Reported Method*** of Obtaining Prescription Pain Relievers for Their Most Recent Nonmedical Use among Persons Aged 18 to 25 Who Were Dependent on or Abused Prescription Pain Relievers in the Past Year: 2005 NSDUH

- Got Them from a Friend or Relative for Free: 37.5%
- Bought from a Friend or Relative: 19.9%
- Prescriptions from One Doctor: 13.6%
- Bought from a Drug Dealer or Other Stranger: 12.5%
- Took from a Friend or Relative without Asking: 6.3%
- Prescriptions from More Than One Doctor: 2.8%
- Got Them Some Other Way: 2.3%
- Bought on the Internet: 1.3%
- Other Unknown or Invalid Source: 1.9%

Source: SAMHSA, 2005 NSDUH.
Many doctors prescribe medicine without explaining its purpose, side effects, instructions for use, or even mentioning its name.

- 74% mentioned name of medicine
- 87% mentioned its purpose
- 66% did not mention how long to take the medicine
- 45% did not say what dosage to take
- 42% failed to mention the timing or frequency of doses
- 65% did not mention adverse side effects
“Adverse Drug Events Cause 700,000 Emergency Visits”

- The **five** most common drug classes implicated in ADE-connected hospitalizations were: anticoagulants, insulins, opioid-containing analgesics, oral hypoglycemic agents, and anti-neoplastic agents.

- Of the **18** medications most commonly involved in an ADE that led to an ED visit, **16** have been in clinical use for more than **20 years**.

- More than **80%** of the population in ‘04 reported using at least one prescription medication, nonprescription drug, or a dietary supplement and **30%** reported using five or more of those products.
Vanishing Vultures

Biodiversity 5(9), 3-7, 2004

The collapse of vulture populations in South Asia

Richard T. Watson, Martin Gilbert, J. Lindsay Oaks, and Mauris Firmani
R.T. Watson, M. Gilbert and M. Firmani
The Peregrine Fund
3968 West Flying Hawk Lane
Boise, Idaho 83709, USA
Email: mwatson@peregrinefund.org
J. Lindsay Oaks
Department of Veterinary Microbiology and Pathology
Washington Animal Disease Diagnostic Laboratory
Washington State University
Pullman, Washington 99164-7000, USA
Email: jloaks@vetmed.wsu.edu

Abstract. The catastrophic crash in vulture populations in South Asia has been caused by the non-steroidal anti-inflammatory drug diclofenac which results in renal failure. Sufficient diclofenac residues in carcasses can be consumed by vultures feeding on a recently deceased livestock carcass. Survival of at least three vulture species depends on removing diclofenac from the vultures' primary food source, dead domestic livestock, by controlling its veterinary use. Survival of one or more of these species also depends on species restoration, not effectively achieved through captive breeding and release. Efforts on both fronts are in progress, but time available for remedial action is short and the probability of success will be greatly improved by the immediate collection of vultures for captive-keeping.
RCRA

- [http://www.epa.gov/epaoswer/osw/facts.htm](http://www.epa.gov/epaoswer/osw/facts.htm)

**Hazardous Materials at Home**

Household hazardous wastes include paint, mineral spirits, batteries, and used oil. Hazardous wastes that are generated in the home are not regulated by the federal RCRA program.
Legislative History

- In 1965 the **Solid Waste Disposal Act** [Public Law (Pub. L.) 89-72] was enacted to improve solid waste disposal methods. It was amended in 1970 by the **Resource Recovery Act** (Pub. L. 91-512), which provided the Environmental Protection Agency (EPA) with funding for resource recovery programs. However, that Act had little impact on the management and ultimate disposal of hazardous waste. In 1976 Congress enacted the **Resource Conservation and Recovery Act** (RCRA, Pub. L. 94-580). RCRA established a system for managing non-hazardous and hazardous solid wastes in an environmentally sound manner. Specifically, it provides for the management of hazardous wastes from the point of origin to the point of final disposal (i.e., "cradle to grave"). RCRA also promotes resource recovery and waste minimization.
If a waste is a solid waste (by RCRA definition), it may be a "listed hazardous waste," as specifically defined in 40 CFR 261 Subpart D (Parts 261.30 through 261.35). If the waste meets the definition of a listed hazardous waste, based on the process or circumstances of generation, then documented generator knowledge may be enough for sufficient characterization to satisfy all disposal requirements. This applies to mixtures of listed hazardous waste and non-hazardous waste (per 40 CFR 261.3 [a] [2]), and also to a waste that is derived from a listed hazardous waste (per 40 CFR 261.3 [c] [2]). An example of a derived waste is the ash that remains after a listed hazardous waste that is burned.

Each individual listed hazardous waste is assigned one or more waste type designations, based on the criteria of being ignitable (I), corrosive (C), reactive (R), toxicity characteristic (E), acutely hazardous (H), or toxic (T). Based on these characteristics, EPA specifies four hazardous waste lists, described below.

<table>
<thead>
<tr>
<th>List Name Designation</th>
<th>40 CFR Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-specific Source Wastes</td>
<td><strong>F List</strong></td>
</tr>
<tr>
<td><strong>K List</strong></td>
<td>261.32</td>
</tr>
<tr>
<td>Discarded Commercial Chemical Products - Acutely Hazardous</td>
<td><strong>P List</strong></td>
</tr>
<tr>
<td><strong>261.33(e)</strong></td>
<td>Discarded Commercial Products - Hazardous</td>
</tr>
<tr>
<td><strong>U List</strong></td>
<td><strong>261.33(f)</strong></td>
</tr>
<tr>
<td>To determine if a specific waste is included in one of these lists, the lists provided in 40 CFR Part 261</td>
<td></td>
</tr>
</tbody>
</table>
Common P-Listed Pharmaceuticals:

- **Name**
- **No.**
- Arsenic trioxide, P012
- Epinephrine, P042
- Nicotine, P075
- Nitroglycerin¹, P081
- Physostigmine, P204
- Physostigmine salicylate, P188
- Warfarin >0.3%, P001
- Diispropylfluorophosphate, P041

¹ A federal exemption for nitroglycerin, in the form of finished dosages, was created in 2001, and has been adopted by some [many?, most?] states.
<table>
<thead>
<tr>
<th>Name</th>
<th>No.</th>
<th>Name</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral hydrate (CIV)(^2)</td>
<td>U034</td>
<td>Mitomycin C (chemo)</td>
<td>U010</td>
</tr>
<tr>
<td>Chlorambucil (chemo)</td>
<td>U035</td>
<td>Paraldehyde (CIV)(^2)</td>
<td>U182</td>
</tr>
<tr>
<td>Chloroform</td>
<td>U044</td>
<td>Phenacetin</td>
<td>U187</td>
</tr>
<tr>
<td>Cyclophosphamide (chemo)</td>
<td>U058</td>
<td>Phenol</td>
<td>U188</td>
</tr>
<tr>
<td>Daunomycin (chemo)</td>
<td>U059</td>
<td>Reserpine</td>
<td>U200</td>
</tr>
<tr>
<td>Dichlorodifluromethane</td>
<td>U075</td>
<td>Resorcinol</td>
<td>U201</td>
</tr>
<tr>
<td>Diethylstilbestrol</td>
<td>U089</td>
<td>Saccharin</td>
<td>U202</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>U122</td>
<td>Selenium sulfide</td>
<td>U205</td>
</tr>
<tr>
<td>Hexachlorophene</td>
<td>U132</td>
<td>Streptozotocin (chemo)</td>
<td>U206</td>
</tr>
<tr>
<td>Lindane</td>
<td>U129</td>
<td>Trichloromonofluoromethane</td>
<td>U121</td>
</tr>
<tr>
<td>Melphalan (chemo)</td>
<td>U150</td>
<td>Uracil mustard (chemo)</td>
<td>U237</td>
</tr>
<tr>
<td>Mercury</td>
<td>U151</td>
<td>Warfarin &lt;0.3%</td>
<td>U248</td>
</tr>
</tbody>
</table>

\(^2\) Chloral hydrate and paraldehyde are controlled substances regulated by the Drug Enforcement Administration and must be destroyed through a "witnessed destruction process".
Characteristic Wastes

- Waste that does not meet any of the listings explained above may still be considered a hazardous waste if it exhibits one of the four characteristics defined in 40 CFR Part 261 Subpart C — ignitability (D001), corrosivity (D002), reactivity (D003), and toxicity (D004 - D043).

  - **Ignitability** — Ignitable wastes can create fires under certain conditions, are spontaneously combustible, or have a flash point less than 60 °C (140 °F). Examples include waste oils and used solvents. For more details, see 40 CFR §261.21. Test methods that may be used to determine ignitability include the Pensky-Martens Closed-Cup Method for Determining Ignitability (Method 1010a) (PDF, 1 pp., 19 KB), the Setaflash Closed-Cup Method for Determining Ignitability (Method 1020b) (PDF, 1 pp., 17 KB), and the Ignitability of Solids (Method 1030) (PDF, 13 pp., 116 KB).

  - **Corrosivity** — Corrosive wastes are acids or bases (pH less than or equal to 2, or greater than or equal to 12.5) that are capable of corroding metal containers, such as storage tanks, drums, and barrels. Battery acid is an example. For more details, see 40 CFR §261.22. The test method that may be used to determine corrosivity is the Corrosivity Towards Steel (Method 1110a) (PDF, 6 pp., 37 KB).

  - **Reactivity** — Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water. Examples include lithium-sulfur batteries and explosives. For more details, see 40 CFR §261.23. There are currently no test methods available.

  - **Toxicity** — Toxic wastes are harmful or fatal when ingested or absorbed (e.g., containing mercury, lead, etc.). When toxic wastes are land disposed, contaminated liquid may leach from the waste and pollute ground water. Toxicity is defined through a laboratory procedure called the Toxicity Characteristic Leaching Procedure (TCLP) (Method 1311) (PDF, 35 pp., 288 KB). The TCLP helps identify wastes likely to leach concentrations of contaminants that may be harmful to human health or the environment. For more details, see 40 CFR §261.24.
OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

MAY 16 1991

Mark J. Schulz
President
Pharmaceutical Services, Inc.
Browning-Ferris Industries
757 N. Eldridge
Houston, Texas 77075

As I understand your letter, pharmaceutical products may be returned for many reasons, including, among others: 1) an oversupply at the dispenser, 2) expiration of the recommended shelf life, 3) a recall has been initiated by the manufacturer, 4) the product was received as a result of a shipping error, and 5) the product has been damaged. You state that, in general the dispensers of the pharmaceutical products do not know whether the returned products will be reused, reclaimed, sold overseas, or disposed (i.e., they are not able to determine whether these materials are solid wastes). Because the dispensers receive credit for the returned products (either because the products actually have real value to manufacturer or because such credits are part of a competitive marketing approach), the products have a monetary value to the dispensers and they would not normally assume such materials to be wastes.
Under our current regulations, such returned products are not considered solid wastes until a determination is made to discard these materials. The returned products themselves (being "commercial chemical products" under our classification system) are considered more product-like than waste-like (until a determination is made to dispose of them) because recycling by use/reuse is generally a viable option. If the underlying assumption is that the returned products will be recycled, until the manufacturer or wholesaler determines otherwise (assuming that this determination is beyond the ability of the dispenser), then those products managed within the reverse distribution system are not solid wastes until the manufacturer or wholesaler makes the determination to dispose of them. This view is based on our

Sylvia K. Lowrance
Director
Office of Solid Waste
(a) Inventory

Except as provided in subsection (c) of this section - (1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;
DISPOSAL OF CONTROLLED DRUGS
Public Response

“Take-Back” Programs

- Organized collections of unwanted medications in co-operation with a collection facility or event.
- Law enforcement must be present if controlled substances are collected.

Pilot and Existing Programs

Internationally –
- Australia, Several European Countries, Canada (Ottawa, British Columbia, and Prince Edward Island).

United States
- Florida, Indiana, California, and Washington.
DEA “Closed System of Distribution”

- **21 USC 844(a):** Illegal to possess a controlled substance unless one is the intended recipient.

- **21 CFR 1301.24:** Law enforcement agencies are exempt from the requirement of a DEA registration and thus are able to “receive” controlled substances from private individuals.

- **21 CFR 1307.21 (b):** Procedure for disposing of controlled substances. (this section may be amended to accommodate future disposal programs.)
Solutions and Recommendations

- **Additional research:**
  - To evaluate environmental impact / harm from wasted pharmaceuticals.

- **Continued collaboration:**
  - With community, law enforcement and drug prevention programs to provide secure collection and transportation disposal process.

- **Lessons learned from Pilot Programs:**
  - May provide alternatives to flushing of pharmaceuticals into the sewage system.
Why not the Pharmacy?
Drug Crime Is a Source of Abused Pain Medications in the United States

of 12,894 theft/loss incidents were reported in these states between 2000 and 2003. Theft/losses were primarily from pharmacies (89.3%), with smaller portions from medical practitioners, manufacturers, distributors, and some addiction treatment programs that reported theft/losses of methadone.

Over the 4-year period, almost 28 million dosage units of all controlled substances were diverted. The total number of dosage units for the six opioids is as follows:

- 4,434,731 for oxycodone
- 1,026,184 for morphine
- 454,503 for methadone
- 325,921 for hydromorphone
- 132,950 for meperidine
- 81,371 for fentanyl
Question: Can an individual return their controlled substance prescription medication to a pharmacy? Answer: **No**. An individual patient may not return their unused controlled substance prescription medication to the pharmacy. Federal laws and regulations make no provisions for an individual to return their controlled substance prescription medication to a pharmacy for further dispensing or for disposal. There are no provisions in the Controlled Substances Act or Code of Federal Regulations (CFR) for a DEA registrant (i.e., retail pharmacy) to acquire controlled substances from a non-registrant (i.e. individual patient). The CFR does have a provision for an individual to return their unused controlled substance medication to the pharmacy in the event of the controlled substance being recalled or a dispensing error has occurred.
Bad International Donations

Photos courtesy of PSF-CI
Bosnia, 1992-1996
17,000 tonnes of drugs to be destroyed
Disposal cost: US$ 34 million

Albania, 1999
65% of the drugs had an inadequate expiry date
50% of the drugs were completely useless

Estimate: 4,000 tonnes of drugs for less than 2 million inhabitants
Destructions hôpital provincial  Incinérateur
Hôpital provincial
Estimated destruction cost: 1,380,000 euros

Non Indonesian labels
✓ 73% of the drugs had non Indonesian labels
   English, Chinese, French, Russian, Japanese, Turkish, Spanish, Portuguese, Arabic, German, Pakistani, Korean, Dutch, Danish, Indian, Thai, ...

Waste management:
2 incinerators in operating condition in the Province of Aceh
   Military hospital of Banda Banda Aceh + Hospital of Meulaboh

Estimate: 1,150 cubic metres (345 tonnes) to be destroyed in October 2005
Report on the San Francisco Bay Area’s Safe Medicine Disposal Days

Organized by the Bay Area Pollution Prevention Group
August 2006

- Indiana
- Maine
- Colorado
- Florida
- Michigan
- Wisconsin
- California
- Washington
- Massachusetts
- Vermont
- Oregon

Appendix B: Examples of Regional Advertising
Product Stewardship for Waste/Unwanted Pharmaceuticals

- Product Stewardship Institute, Inc.
Drug Disposal Issues: A Clear and Present Danger
NASCSA 22nd Annual Conference
October 19th, 2006
Charlotte A. Smith, R. Ph., M.S.

Ideal National Consumer Drug Take-Back Program

- Easily accessible to all consumers
- Uses current infrastructure
  - Requires little additional IT development
- Tracks data
  - NO PERSONAL DATA - HIPAA
  - Name, strength, dosage form
  - Quantity
  - Pharmacy of origin
  - Manufacturer
  - Central repository of data owned and managed by participating pharma manufacturers
- Funding
  - Allocation to manufacturers of returned products
  - Sale of data to insurance industry, other interested parties
The Best of All Worlds

- Exploration of a variety of consumer take back models at the local level
- In parallel, development of a national program based on existing infrastructure of reverse distribution
- Proposed change in DEA language to be presented at the Maine take-back conference Oct 23 -24 – suggestions welcome
Proposed Changes in 21 CFR 1304.11 Inventory Requirements

Addition: (e)(iii) Exception. In the case of receipt of a controlled substance from a non-registrant or their agent, the name of the manufacturer must be included if available.
Proposed Changes in 21 CFR1304.22(e)(3) Records

Addition: (3) For each controlled substance in finished form received from a non-registrant (consumer or their agent.)

(i) The name of the substance.

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).

(iii) The number of dispensing containers of each such finished form received from the non-registrant or their agent, including the date of and number of containers in each receipt and the name and address of the person from whom the containers were received.

(iv) Where possible, the manufacturer or distributor of record of the finished form.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

(vi) The number of the traceable common carrier label.
Proposed Changes in 21 CFR1304.33(f) Reports to ARCOS

Addition: (f) Exceptions.

(i) A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(ii) A reverse distributor who receives controlled substances from a consumer or their agent.
Proposed Changes in 21 CFR1307.21(d) Procedure for Disposal

Addition: (d) Nothing in the above procedures shall prevent a consumer from mailing an unwanted, unused controlled substance which has legally been in their possession or the possession of their agent to a DEA approved reverse distributor for the purpose of destruction as authorized.
SUMMARY

- Regulations regarding accessibility to controlled substances have continuously evolved over time.
- It is time to take the next step to provide an environmentally sound, easily accessible, secure system to remove unwanted controlled substances from the legitimate consumer marketplace.
- Reverse distributors provide the logical infrastructure for this activity.
Process Overview
Proposed Consumer Rx Returns Model

Reverse Distributors
Incinerators

Manufacturers

Retail Pharmacies

Wholesalers

Adapted by permission from Capital Returns, Inc.
Win-Win-Win Scenario

- Responsible consumers have a solution for the environmentally sound disposal of unused/unwanted prescriptions
- Diversion potential is lessened by removing unused/unwanted Rx from homes
- Environmental burden is reduced by stopping drain and landfill disposal (RDs could be monitored relatively easily for appropriate disposal technologies)
- Manufacturers would receive previously unavailable but extremely valuable data on drug compliance and usage
- Insurance companies and other interested parties could purchase data on unused Rx’s and develop feedback loops for greater compliance and outcomes analysis
- Reverse Distributors gain another source of revenue and provide total closed loop processing for the pharma industry
Reverse Distribution & Designing a National Consumer Rx Returns Program (and previous 8 slides)

October 23, 2006
Mary Hendrickson, RPh, MBA
Director of Quality & Regulatory Affairs
Capital Returns, Inc.
Mary.Hendrickson@CapitalReturns.com
Potential Returns Process Scenarios

1. Customer needs to return product
   - Kit contains:
     - Prepaid postage
     - Instructions
     - Form
     - Container (envelope or box)

RETURN OPTIONS

#1
Request Returns Kit* via web

#2
Call 1-800# and request Returns Kit*

#3
Return product to participating retail pharmacy

#4
Return product to local law enforcement agency

#5
Return to distributor via direct mail
2. Initial Accounting for returned product

Customer fills out form, including:
- Name of each drug returned
- Reason for return for each drug
- Percent of drug used
- Zipcode

Per HIPPA, no name is required.
3rd Annual Patient Compliance & Adherence USA Congress
Nov 30 – Dec 1, Philadelphia

 PROCESSING OPTIONS

#1
Ship product directly to incineration site and process in bulk.
Data collected = lbs incinerated

#2
Consolidate product and send to qualified, third-party processor for processing
- Data collection services paid by interested parties.
- Product manifested for incineration.
- Consumer forms entered in separate database from physical returns data.

- 3 slides courtesy of Dawn Bland
Inside a RD
Unused and Expired Medicines Registry

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Pharmaceutical Waste: Unused Medicine Return
October 23, 2006

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### Unused & Expired Medicines Registry

**Anonymous Return Form (Current)**

**INSTRUCTIONS:** Please complete this form by getting the information directly from your prescription labels, pill bottles, or medicine packages. If you need more space, use another form or make a blank copy of this form. 1. Write your zip code. 2. Write the date of return. 3. Write the name of each medicine you are returning. 4. Write the strength or dosage of each medicine. 5. Write the number of pills, capsules, tablets, or amount of liquid of each medicine. 6. Check box with '✓' for where you got each medicine. 7. Check box with '✓' for a reason you are returning each medicine. 8. If the medicine is returned because of a side effect, please write down the side effect or any comments in this space.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>List medicine(s) from pill bottle or package.</td>
<td>Write the strength of the medicine (e.g., 30 mg)</td>
<td>Write approx. number of pills or capsules or amount of liquids you are returning</td>
<td>Doctors Office</td>
<td>Pharmacy</td>
</tr>
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</tbody>
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8. Indicate side effect or other comments
### Unused & Expired Medications Registry

#### Most Simplified Version (No Personal Identifiers)

<table>
<thead>
<tr>
<th>Zip Code</th>
<th>Brand or Generic Name</th>
<th>Strength</th>
<th>Quantity</th>
<th>Why Unused?</th>
</tr>
</thead>
<tbody>
<tr>
<td>04401</td>
<td>Atenolol</td>
<td>25 mg</td>
<td>30</td>
<td>Expired</td>
</tr>
<tr>
<td>04401</td>
<td>Baclofen</td>
<td>10 mg</td>
<td>9</td>
<td>Discontinued</td>
</tr>
<tr>
<td>04412</td>
<td>Buspar</td>
<td>10 mg</td>
<td>84</td>
<td>Discontinued</td>
</tr>
<tr>
<td>04457</td>
<td>Cephalexin</td>
<td>500 mg</td>
<td>27</td>
<td>Expired</td>
</tr>
<tr>
<td>04412</td>
<td>Chloral hydrate</td>
<td>500mg/5ml</td>
<td>95 ml</td>
<td>Death</td>
</tr>
<tr>
<td>04457</td>
<td>Clarinex</td>
<td>5 mg</td>
<td>17</td>
<td>Discontinued</td>
</tr>
</tbody>
</table>
What You Can Do

Follow “Kloka Listan” (Stockholm County Council's “Wise List” of recommended drugs for common diseases). Always take cost-effectiveness and environmental impact into account when comparing medications that are equally safe and suitable for the purpose.

Prescribe starter packs.

Prescribe refill packs if available.

Encourage patients to return unused medications to the pharmacy.

Inform patients of the importance of even returning used estrogen patches to the pharmacy and avoid flushing them down the toilet, since most of the estrogen remains in the patch after use.

Do not prescribe more medications than can be used; if in doubt, repeating the prescription is preferable.

Review and regularly reassess the patient's total consumption of medication in order to reduce waste.

Learn more about which drugs have a large environmental impact by using this website and by asking for information from the pharmaceutical companies' representatives.

Last updated: 2006-05-19
A BILL FOR
SB0116LRB094 0679 3 DRJ 36895 b
1 AN ACT concerning health.
2 Be it enacted by the People of the State of Illinois, 3represented in the General Assembly:
4 Section 1. Short title. This Act may be cited as the Unused Medicine Disposal Act.
5 Section 5. Legislative findings and purpose. The General Assembly finds that there are insufficient procedures in place in Illinois for the safe disposal of unused or expired medications. Unused or expired medications threaten the health and safety of the people of Illinois through pollution of the waterways and their entrance into illegal drug markets. It is in the best interest of all the people of Illinois that a statewide system be put into place for people to safely dispose of unused or expired medicines.
6 Section 10. Unused Medicine Task Force. (a) The Unused Medicine Task Force is created. The task force shall be composed of the following members or their designees: the Lieutenant Governor; the Director of the Environmental Protection Agency; the Director of Aging; the Director of Public Health; an individual representing pharmacists; and an individual representing a law enforcement agency. The Lieutenant Governor shall be the chairman of the task force. (b) The task force shall meet for the first time no later than 90 days after the effective date of this Act. (c) Task force members are not entitled to compensation for performing their duties, other than necessary travel expenses.
7 Section 15. Statewide unused medicine pilot plan. (a) The task force shall develop a statewide unused medicine pilot plan. At a minimum, the plan shall include the following: (1) An assessment of solutions and programs currently available in private industry. (2) A statewide procedure for unused or expired medicine disposal that may include the use of prepaid mailing envelopes. (3) A method by which units of local government may assist in disposing of unused medicine. (4) A plan for educating residents of Illinois on when and how to dispose of their unused medications. (5) A budget for implementing the unused medicine pilot plan. (b) The task force shall submit the pilot plan to the Governor and the General Assembly by March 31, 2006.
8 Section 99. Effective date. This Act takes effect upon becoming law.
Bill Status of SB0116  94th General Assembly

Short Description:  UNUSED MEDICINE DISPOSAL ACT

Senate Sponsors
Sen. Iris Y. Martinez

Last Action
DateChamber Action  3/18/2005SenateRule 3-9(a) / Re-referred to Rules
Statutes Amended In Order of Appearance

New Act

Synopsis As Introduced
Creates the Unused Medicine Disposal Act. Creates the Unused Medicine Task Force, composed of the Lieutenant Governor, the Director of the Environmental Protection Agency, the Director of Aging, the Director of Public Health, an individual representing pharmacists, and an individual representing a law enforcement agency. Requires the task force to develop a statewide unused medicine pilot plan, to include: (1) an assessment of solutions and programs currently available in private industry; (2) a statewide procedure for unused or expired medicine disposal that may include the use of prepaid mailing envelopes; (3) a method by which units of local government may assist in disposing of unused medicine; (4) a plan for educating residents of Illinois on when and how to dispose of their unused medications; and (5) a budget for implementing the unused medicine pilot plan. Requires the task force to submit the pilot plan to the Governor and the General Assembly by March 31, 2006. Effective immediately.
A Legal Guide to Safely and Successfully Conducting a Collection Event for Unwanted Prescription Medications
According to the NSDUH survey, over 15 million Americans misused psychotherapeutics and pharmaceuticals in 2005, including about 2.5 million Americans who misused pharmaceuticals for the first time, outpacing new initiates for marijuana and cigarettes. “The illicit use of synthetic drugs such as methamphetamine and otherwise-legal prescription drugs,” the President warned, “has become a severe and troubling problem, both at the national level and in affected communities.”

One of the most common sources of illicit pharmaceuticals is from the home medicine cabinet. In many cases, large amounts of unused and expired pharmaceuticals are readily accessible to potential abusers through theft, diversion, or criminal resale. In most jurisdictions, no sanctioned mechanism exists to collect and dispose of unused pharmaceuticals, forcing legitimate users to stockpile unused medicine or dispose of them in an environmentally unsafe manner. “Greater educational efforts are needed regarding quick and safe disposal of unused and unneeded medications,” an Administration official recently observed.

- Results from the 2005 National Survey on Drug Use and Health: Detailed Tables; Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies; September 2006.
- Testimony before the House Government Reform Committee Subcommittee on Criminal Justice, Drug Policy, and Human Resources; Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control; July 26, 2006.
One strategy we support is the development of a national-program that would oversee the collection and disposal of all unused pharmaceuticals. By ridding medicine cabinets of unused medicines, we would significantly reduce the availability of pharmaceuticals for illicit diversion, provide a mechanism for disposal more environmentally sound than “hush and flush”, and remove a significant source of accidental and lethal poisonings among children.

The data gathered from sampled returns will be valuable for analyzing waste in existing prescribing and compliance practices, generating significant savings for the national healthcare system.

Such a program would incorporate a mail-back and/or drop-off framework that permits residents to return pharmaceuticals to an alternative secure repository.
Conference document recommendations

- We recommend:
  - Establishing a pilot mail-back program before instituting a national program; steps prudent to benchmark outreach, participation, volume, return and disposal practices.
  - Following evaluation, a standardized unused medicines collection, disposal, and educational program should be established nationwide.

- To ensure this program remains self-funded and reduces the burden on local jurisdictions, we propose a nominal 25 cent fee be assessed to each filled prescription.
We believe the effectiveness of an unused medicines disposal program will be resounding and can be measured through:

- A reduction in and crime related to household prescription theft and diversion,
- A reduction of medication-related accidental poisonings among children,
- A decrease in new initiates of abused pharmaceuticals,
- A reduction in medication errors among the elderly from excess stored medicines,
- A reduced environmental impact from improperly disposed medicines
- A reduction in donation of inappropriate medicines following disasters

We recognize that excess pharmaceuticals pose a national health, safety, and environmental threat that must be combated with a standardized program. We offer our assistance in developing such a system and encourage your thoughtful review of our recommendation.
EPA Competition

- EPA Aging Initiative announces Requests for Proposals for Prudent Disposal of Unwanted Medications.

- The EPA is accepting proposals to develop alternative stewardship approaches to disposal, including "mail back" or "take back" pilot demonstrations. Such pilot projects would include not only the prudent disposal of the unused medications but also an inventory of the types and quantities of drugs returned. Inventory data could prove useful to the medical community in altering its prescribing practices to reduce the incidence of leftover or unused medications.

- EPA intends to award up to three awards for a total of approximately $225,000-$300,000.

- Proposals are due by September 29, 2006
How and Why to benefit

- Branding
- Perception as a leader in collaborative effort as opposed to confrontational
- Significant and unique data collection opportunity
- Process can identify specific prescriptions to address adherence
- Improve patient safety, and curtail bad international donations
3rd Annual Patient Compliance & Adherence USA Congress
Nov 30 – Dec 1, Philadelphia

- Photos courtesy of Maine State Attorney General’s Office, Jim Cameron Collection, Stevan Gressitt
For further information

- Stevan Gressitt, M.D.
- Maine Unused Drug Disposal Group
- 314 Clark Road
- Unity, Maine, 04988
- 207-441-0291
- gressitt@uninets.net
- With thanks to Northeast Occupational Exchange,
  and the University of Maine Center on Aging