

Pharmaceutical Take-Back Programs in Adult Care Facilities: A Pilot Project in Newberg, Oregon

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Today's Discussion:

1. Regulatory & Infrastructure Constraints
2. Program Design in Newberg
3. Paving the Way for Other Programs



Pharmaceutical Categories: Three Different Perspectives

What the Public Sees on the Label →	Prescription	Non-Prescription (over-the-counter)	
U.S. Drug Enforcement Administration (Controlled Substances Act, 1972) →	Controlled Substances (e.g., codeine, oxycodone, percocet & ritalin)	Non-Controlled Substances	
U.S. Environmental Protection Agency (Resource Conservation and Recovery Act, 1976 – RCRA) →	Non-Hazardous Pharmaceuticals	Hazardous Pharmaceuticals (e.g., nitroglycerin, warfarin, nicotine & epinephrine)	Non-Hazardous Pharmaceuticals



Regulatory Constraints



Controlled Substances Act

- 21 CFR §1301.11(a), § 802(11), and § 841(a) prohibit the transfer of dispensed, controlled substances from the patient to any other entity registered with the DEA to handle or manage controlled substances.
- 21 CFR §1301.24 Exempts law enforcement.

Controlled Substances Act, continued



- 💧 Therefore, successful, comprehensive take-back programs rely on the personal interest & commitment of Chief of Police or County Sheriff.
- 💧 Controlled substances may constitute between 5% and 15% of the items in your take-back program.



Resource Conservation & Recovery Act (RCRA)

applies to non-controlled substances

💧 Some pharmaceuticals are defined as “hazardous” under US EPA’s RCRA rules (adopted & enforced by Oregon DEQ)

- Arsenic Trioxide
- Wafarin/Coumadin
- Nicotine Patches
- Epinephrine
- Physostigmine
- Nitroglycerin
- Physostigmine salicylate

💧 These may constitute 10% of items collected during a take-back program





Resource Conservation & Recovery Act (RCRA)

- 💧 “Household” hazardous waste is exempt from RCRA, while hazardous waste from large, small, and conditionally exempt generators (CEGs) is not.
- 💧 Although DEQ has designated adult care facilities as “households” in October 2006 for these purposes, the Newberg program has chosen to treat collected items as though they came from CEGs.



Infrastructure Constraints

Comparison of Incineration Options

Questions	(1) Covanta in Brooks	(2) Metro South in Oregon City	(3) Clean Harbors in Marion County	(4) Picked up from one location by Clean Harbors
Accept controlled substances?	Yes	No	No	No
Accept waste defined as hazardous under RCRA?	No	Yes	Yes	Yes
Do solids have to be in their original containers?	No	No	Yes	No
What level of inventory is required?	Simple	Simple	None	Complex inventory of all active ingredients
Will items be incinerated?	Yes, on site	Yes, in another state	Yes, in another state	Yes, in another state
How are charges calculated?	By the pound: \$200/ton w/ \$30 minimum (<input type="checkbox"/> w/ evidence run)	By the pound \$1.10 / lb	By the pound \$2.50 / lb	By the gallon (5 gall min) \$ 97.50 / 5 gall pail + \$ 15.00 pail purchase + \$150.00 transport
One consolidated bill?	Yes	No: it's per generator	Yes	Yes
Have to schedule an appointment?	Yes	Yes	Yes	Yes
			Information as of December 2006	

Program Design in Newberg

- City of Newberg, Oregon (pop. 20,000)
- Focus in Phase 1 = adult care facilities
- Year-round program
- Collect & incinerate both controlled & non-controlled substances
- Pilot project launch 1st quarter of 2007
- “Mailbox-like” containers located indoors, in locked med rooms, bolted to the floor or wall, and locked.



**Contract
Pharmacies**



Oregon State Board
of Pharmacy allows pharmacies
to take-back non-controlled
substances from adult care
facilities and re-dispense them,
if the drugs are:

**Adult
Care
Facilities**

1. In unopened, tamper-evident packaging
2. Under the control of an adult care facility & contract pharmacist
3. With their original labeling
4. Stored under conditions meeting US pharmacopeia standards

*** It's the remaining pharmaceuticals that are destined for disposal that the Newberg take-back program addresses.**

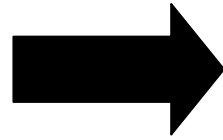
Disposing Controlled Substances: Piggyback on the City Police “Evidence Run”



Piggyback on the Quarterly Evidence Run



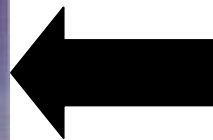
Mailboxes.com



ccbox.com



Covanta Marion, Inc.
Brooks, Oregon

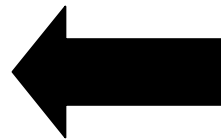
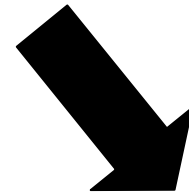
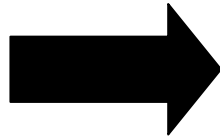


Newberg-Dundee Police Dept.

Similar Design for Non-Controlled Substances Component



Mailboxes.com



Funding for the Program

Department of Public Works

- **Program administrator & information officer reside here.**
- **Pay for collection/disposal of non-controlled substances**
- **Ongoing program costs (cardboard boxes & plastic liners)**

Newberg-Dundee Police Department

- **Pay for collection/disposal of controlled substances**

Facilities hosting collection containers

- a. Purchased the collection containers**

Paving the Way for Other Programs

- DEQ-approved protocols
- Trademarked logo

Formal Protocols – Approved by DEQ



Pharmaceutical Take-Back in the City of Newberg:

Protocols for Collection, Handling, and Transport of Pharmaceutical Waste in Adult Care Facilities

The City of Newberg will begin to collect pharmaceutical waste from adult care facilities during 2007. The purpose of this document is to establish procedures that will help protect the health and safety of program participants as well as the environment.

The Director of Nursing in each adult care facility currently has the responsibility to collect, document, and dispose of any pharmaceuticals after a patient discontinues their use. After documenting the type of medication, dosage, and amount remaining, the nursing staff has traditionally disposed of the pharmaceuticals by flushing them down the drain. The City and its program partners¹ have designed a pharmaceutical take-back program to give the nursing staff a more environmentally responsible alternative to flushing pharmaceutical waste², while continuing to protect the health and safety of staff, patients, and facility visitors.

The City's collection program will be offered year-round, and will collect both controlled and non-controlled substances from residents of adult care facilities in Newberg. First, this document describes the handling protocols for both controlled and non-controlled substances. It then describes funding, timelines, training opportunities, procedures to clean up spills, an inventory of necessary supplies, and key contacts common to both the controlled and non-controlled substances components of the program.

¹ A steering committee of 15 community leaders convened during 2004 to design this pharmaceutical take-back program. Committee members included the Mayor, Director of Public Works, and representatives from the local police department, hospital pharmacies, hospice, garbage collection franchise, and DEA office.

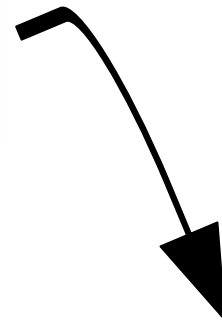
² Pharmaceutical waste is defined as any controlled, prescription, or over-the-counter pharmaceutical that is unwanted, unused, expired, or otherwise determined to be waste.

³ The Controlled Substances Act of 1970 identifies five "Schedules" or categories of controlled substances. Schedule I are illicit street drugs with no acceptable medicinal use in the United States. Schedules II through V are prescribed for medicinal use in the United States, and are categorized according to their potential for abuse and addiction. See <http://www.usdoj.gov/dea/psbs/scheduling.html> or Appendix A for a representative schedule of controlled substances. The U.S. Drug Enforcement Administration also has posters available of "The Most Abused Controlled Substances" that facilities can hang in the vicinity of the collection box as an their resource.

Trademarked Logo







Questions?



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