

US EPA Pretreatment Webcast Series

Management of Unused Pharmaceuticals and the Proposed Universal Waste Rule

September 22, 2009



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Samantha Lewis, **US EPA**

Charlotte A. Smith, **PharmEcology Services**

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Today's Speakers

- **Lisa Lauer** (US EPA) - Addition of Hazardous Pharmaceutical Wastes to the Federal Universal Waste Program
- **Samantha Lewis** (US EPA) - Health Care Industry Study Management and Disposal of Unused Pharmaceuticals
- **Charlotte Smith** (PharmEcology Services) - Pharmaceutical Waste: Issues & Impact

Addition of Hazardous Pharmaceutical Wastes to the Federal Universal Waste Program

Lisa Lauer, US EPA

Office of Resource Conservation and Recovery

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What Is the Universal Waste Rule?

- The universal waste rule (UWR) - 40 CFR 273 - streamlines hazardous waste management standards for federally designated universal wastes (UW)
- So, what does this mean?
 - A universal waste **is still a hazardous waste**, but the generator requirements are simplified in order to:
 - Promote the collection of these wastes;
 - Promote the proper recycling, treatment or disposal of these wastes; and
 - Reduce the burden on businesses

www.epa.gov/osw/hazard/wastetypes/universal/index.htm

Current Federal Universal Wastes

- Batteries, pesticides, mercury-containing equipment (MCEs), and lamps
- Why are these wastes special?
 - Compared to other hazardous wastes, they are relatively low-risk during accumulation and transport
 - Frequently generated in a wide variety of settings
 - Present in significant volumes in non-hazardous waste management systems (e.g., households)

Proposal to Add Hazardous Pharmaceutical Wastes to UWR

- FR notice published December 2, 2008: 73 FR 73520
- Comment period closed March 4, 2009
- Applies to Resource Conservation and Recovery Act (RCRA) hazardous pharmaceutical wastes
 - P and U listed wastes (see 40 CFR 261.33(e) and (f))
 - Characteristic wastes
 - Ignitability, corrosivity, reactivity and toxicity (see 40 CFR 261.21-24)
- Proposed rule applies to pharmacies, hospitals, doctors' and dentists' offices, ambulatory care centers, outpatient care centers, residential care facilities, vet clinics and other facilities that generate this type of waste

www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.pdf

Why Is This Rule Important to POTWs?

1. Discourages the sewer disposal of pharmaceutical wastes by health care facilities
 - Rule Goal: improve the management of hazardous pharmaceutical wastes
 - Rule Goal: decrease the amount of pharmaceutical wastes being disposed of in municipal solid waste streams (sewer)
 - Encourage the management of non-RCRA hazardous drugs as UWs

Why Is This Rule Important to POTWs?

(cont.)

2. Encourages drug take-back programs

– Household hazardous wastes are excluded from RCRA

- Once consolidated, take-back programs often manage household pharmaceutical wastes in compliance with full RCRA subtitle C regulations
 - Note: some states/local regulators **require** that collected household hazardous wastes be managed as hazardous wastes

Proposed Requirements for Handlers of UW Pharmaceuticals

(As compared to current hazardous waste
generator requirements)

- Increased accumulation threshold
- No EPA ID number for small quantity handlers of universal waste
- Increased on-site storage time
- Basic training requirements
- Transporters
 - No EPA ID number and manifest requirement

Comments Received

- States – 15
- Municipalities – 6
- POTW Facilities – 10
- Federal Agencies – 2
- Hospitals – 6
- Reverse Distributors – 4
- Waste Management/Consulting Services – 16
- Trade associations – 16
- NGOs – 2
- Miscellaneous Comments

POTWs

- **Commenting POTWs supported the rule**
 - Des Moines Water Works
 - The Oregon Association of Clean Water Agencies
 - Corvallis Public Works
 - McMinnville, Oregon - Pretreatment Coordinator
 - Salem, Oregon - Public Works Director
 - Gresham, Oregon – WW Services Manager
 - The Association of Metropolitan Water Agencies (AMWA)
 - King County Wastewater Treatment Division
 - The American Water Works Association (AWWA)
 - The National Association of Clean Water Agencies (NACWA)
 - Supports in principle but more outreach and education is needed
 - Concern that many may mistakenly think that all pharmaceutical waste will need to be managed as UW
 - Office of Resource Conservation and Recovery (ORCR) and Office of Water need to coordinate efforts

Public Comments

- Security Concerns – requests for additional/more stringent requirements
 - Tracking/manifest
 - Notification
 - Threshold/accumulation time decrease
 - Labeling
- Education and enforcement – more is needed for rule to be effective
- Reverse distribution – clarification of how the rule applies to reverse distributors

Public Comments (cont.)

- Definition clarifications
 - Controlled substances
 - Clarifying what is/is not included
 - Dual wastes
 - Recalls
 - Manufacturing/compounding residues
- Sorting
- Training
- General clarifications

Next Steps

- Development of final rule
 - Address comments
 - Drafting of preamble and regulatory language
 - Inter- and intra-agency review
 - *Projected* date for publication: April 2011
- Education
- Adoption by authorized states

Important Things to Note

If finalized:

- Adoption by authorized states
 - The rule immediately goes into effect only in un-authorized states and territories
- The UWR is optional
- DOES NOT supersede the regulations of the other federal agencies

Appendix: UW vs. Subtitle C (handlers)

	Universal Waste Requirements		Generator Requirements		
	Small Quantity Handler of Universal Waste (SQHUW)	Large Quantity Handler of Universal Waste (LQHUW)	Conditionally Exempt Small Quantity Generator (CESQG)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Quantity Handled by Category	accumulate < 5,000 kg (11,000 lb) on site at any one time	accumulate 5,000 kg (11,000) or more on site at any one time	generate ≤ 100 kg (220 lb) per month ≤ 1 kg acute per month	generate < 1,000 kg (2,200 lb) per month	generate ≥ 1,000 kg per month > 1 kg acute per month
EPA ID #	Not required	Required	Not required	Required	Required
On-Site Accumulation Limit	< 5,000 kg	No quantity limit	≤ 1,000 kg ≤ 1 kg acute ≤ 100 kg spill residue from acute	< 6,000 kg	No quantity limit

Appendix: UW vs. Subtitle C (handlers)

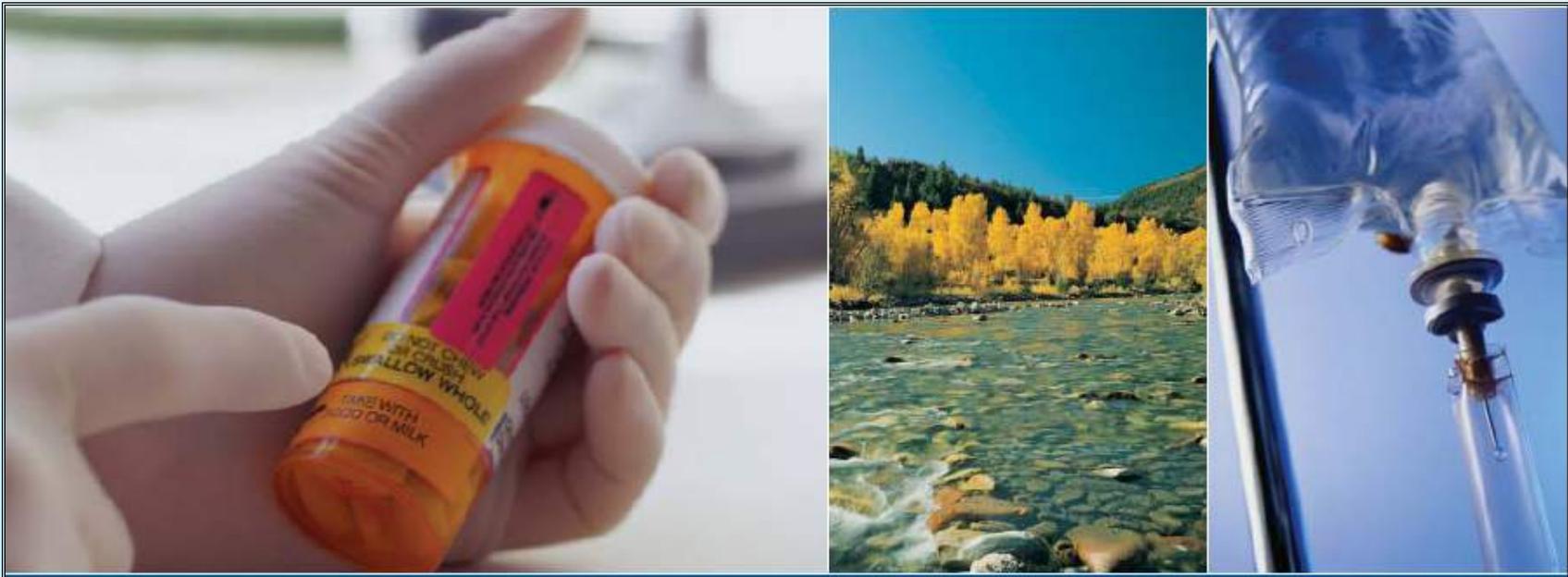
	Universal Waste Requirements		Generator Requirements		
	Small Quantity Handler of Universal Waste (SQHUW)	Large Quantity Handler of Universal Waste (LQHUW)	Conditionally Exempt Small Quantity Generator (CESQG)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Storage Time Limit (without a storage permit)	1 year, unless for proper recovery, treatment, or disposal	1 year, unless for proper recovery, treatment, or disposal	None	≤ 180 days or ≤ 270 days	≤ 90 days
Manifest	Not required	Not required, but must keep basic shipping records	Not required	Required	Required
Personnel Training	Basic training	Basic training geared toward employee responsibilities	Not required	Basic training	Full training

Appendix: UW vs. Subtitle C (transporters)

	Universal Waste Transporters	Hazardous Waste Transporters
Compliance with Department of Transportation (DOT)	yes	yes
EPA ID Number	none	yes
Allowance to Store up to 10 days at a Transfer Facility	yes	yes
Manifest Requirements	none	yes
Response to Releases	yes	yes, with more complex requirements

Questions?

Health Care Industry Study Management and Disposal of Unused Pharmaceuticals



Samantha Lewis, US EPA
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Where EPA Started...

Selected the Health Care Industry (HCI) because of:

- comments received on its Preliminary 2004 and 2006 CWA Section 304(m) Effluent Guidelines Programs Plans
- studies that investigated the presence and potential effects of pharmaceuticals in U.S. waters

Where EPA Started...

Goal of the Study is to:

- evaluate disposal practices for unused medications at health care facilities (HCFs) and
- identify best practices that avoid flushing

What EPA Did...

We have collected information on:

- Factors driving current disposal practices
- Identifying barriers to not flushing
- Estimate information on amount of unused pharmaceuticals currently disposed of via the drain
- Alternatives to drain disposal
- Information on best management practices (BMPs) and their costs
- Regional and demographic differences in disposal practices

What EPA Did...

Summer 2008

Publication of a Federal Register Notice (FRN) seeking comment on a potential survey for the industry :

www.epa.gov/fedrgstr/EPA-WATER/2008/August/Day-12/w18606.pdf

The survey was written to collect information on:

- Identifying alternatives to flushing
- Identifying ways to reduce waste generation
- Finding out how big is the problem (baseline)
- Identifying barriers to NOT flushing
- Identifying cost of BMPs
- Collecting demographic information

What EPA Did...

Outreach with about 700 stakeholders to solicit comments on the survey and to get background on the industry characteristics.

Stakeholders included:

- Industry Representatives
- Other Federal Agencies (Food and Drug Administration [FDA], Drug Enforcement Administration [DEA], Centers for Medicare & Medicaid Services [CMA])
- Other EPA Offices (Office of Solid Waste [OSW], Office of Air and Radiation [OAR])
- State and Local Governments
- Reverse Distributors
- Technology Vendors
- Waste Management Companies

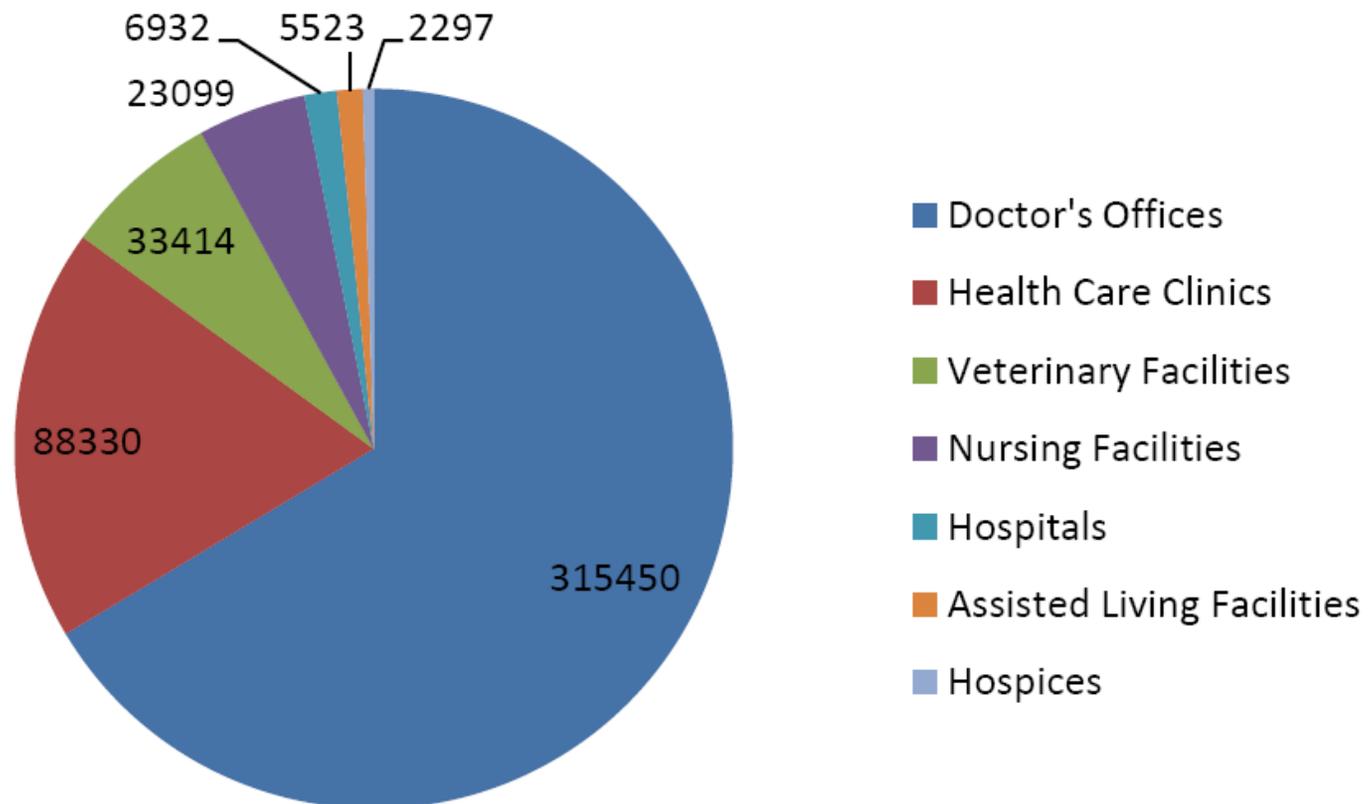
What EPA Did...

Site visits to observe unused medication disposal practices:

- 4 hospitals in 3 states (MD, MN, PA)
- 4 Long Term Care Facilities (LTCFs) in 3 states (DE, NJ, DC)
- a veterinary hospital in VA
- a long-term care pharmacy in MD
- a hospice in VA
- a clinic in VA
- a reverse distributor in WI, and
- a medical waste management facility in MD

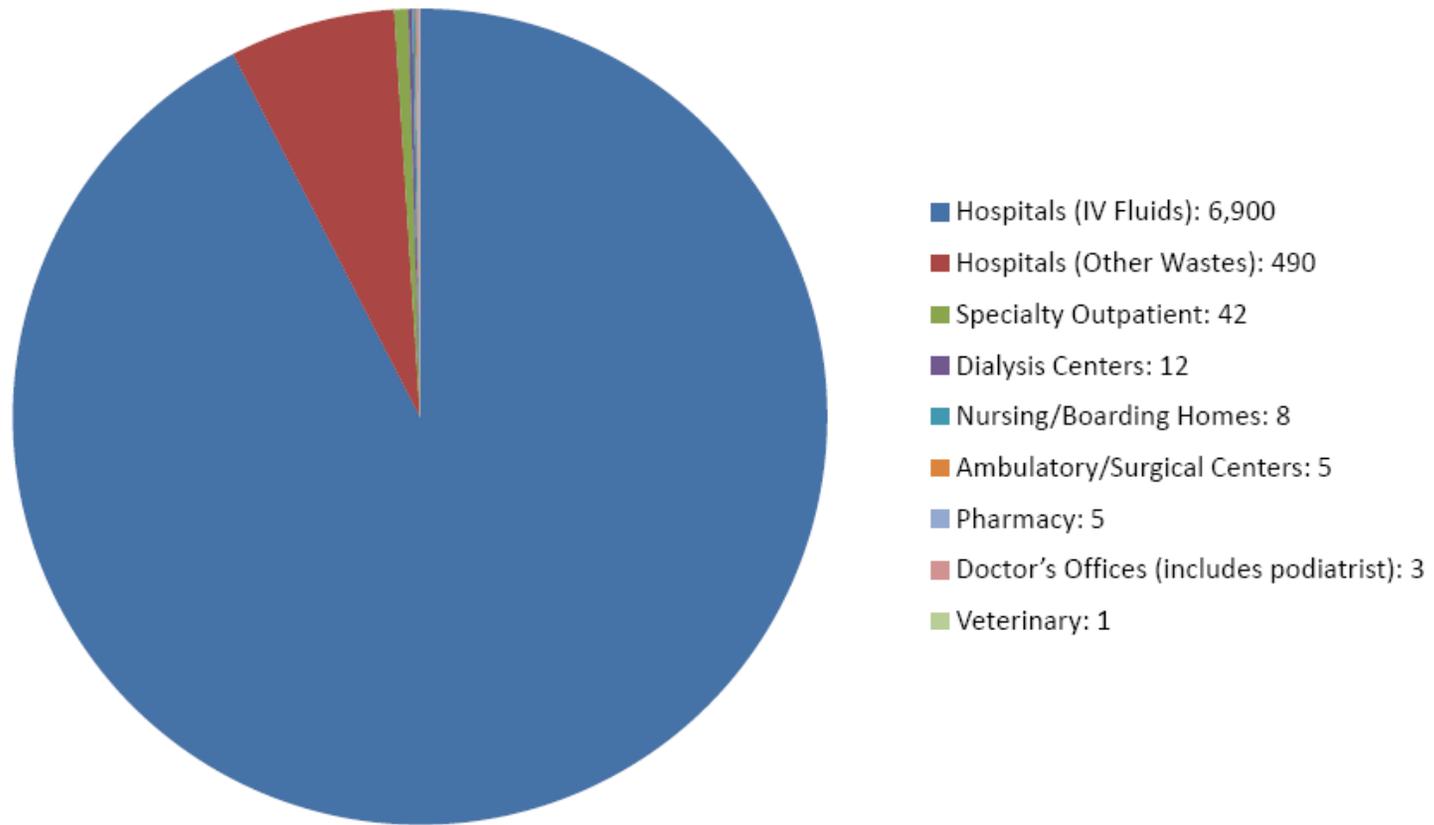
What EPA Learned...

Numbers and Types of Health Care Facilities Identified



What EPA Learned...

Estimated unused pharmaceuticals disposed each year by facility type in lbs/year (King County, WA)



What EPA Learned...

Stakeholder Outreach

- This sector is motivated to do the “right” thing, but need guidance on what is the best method for disposal
- LTCFs have more limited disposal options than hospitals and pharmacies because they are not DEA registrants
- Veterinarians are developing BMPs with our help
- Retail pharmacies do not dispose of unused pharmaceuticals in the drain
- Dentists do not dispose of unused pharmaceuticals in the drain

What EPA Learned...

Stakeholder Outreach (continued)

- EPA Office of Science and Technology (OST) worked with the DEA on their January 2009 FRN that sought input on relaxing licensing procedures
<http://edocket.access.gpo.gov/2009/pdf/E9-1056.pdf>
- Medicare Part D and other private health insurance Rx drug coverage programs can contribute to volume of unused medications
- CMS is working on an FRN to address medication dispensing requirements

What EPA Learned...

Comments from the Summer 2008 FRN:

- Few facilities track amounts of pharmaceuticals disposed to sewer
- Suggestions and changes to survey questions
- Industry receives conflicting information on disposal and guidance would be helpful

What EPA Learned...

Site visits:

- Estimates of the amount of unused pharmaceuticals disposed at a couple of facilities visited
- Observed Rx waste management practices
- Common industry disposal practices
- Challenges with generation and disposal
- Information about how facilities operate
- Awareness increased

What EPA Learned...

General BMPs

- Avoid Drain Disposal (LTICFs use Office of National Drug Control Policy [ONDCP] guidance)
- Do not send pharmaceuticals to autoclave
- Use Reverse Distributors
- Segregate wastes (Waste Disposal Company)

What EPA Learned...

Ways to Minimize Rx Waste Generation

- Inventory Control by Pharmacy
- Stock Rotation
- Unit dose packaging and reuse of untampered unit doses
- Order Rx in smaller quantities and doses
- Do not accept samples from manufacturers

What EPA Learned...

Hospitals with on-site pharmacies can reuse unused medications except when:

- Packaging has been tampered with
- Medication is expired

What EPA Learned...

LTCFs can return unused medications to LTC pharmacies for reuse except when:

- The medication is a controlled substance
- The medication is expired
- The medication is not in unit dose packaging or the packaging has been tampered with
- The medication has been paid for by private insurance or Medicare Part D. Too difficult to apportion credit back to both patient and insurance company

What EPA Learned...

Types of data gathered:

- Number of Hospitals by State – 2005
- Number of In-Scope Nursing and Residential Care Facilities by State – 2005
- Number of Establishments in 1998, 2002, and 2005 by North American Industry Classification System Based on County Business Patterns
- **Toxics Release Inventory and Permit Compliance System Facility Counts – 2004**
- **Concentrations of Pharmaceutical Compounds in Effluent from Two Norwegian Hospitals**
- Average Use of Disposal Practices Reported by Santa Barbara Hospitals, LTCFs, and Pharmacies

See Interim Technical Report on Unused Pharmaceuticals in the Health Care Industry: www.epa.gov/guide/304m/2008/hsi-tech-study-200809.pdf

What EPA Learned...

Types of data gathered: (continued)

Table 3-1. Concentrations of Selected Pharmaceuticals in Wastewater, Surface Water, and Groundwater

Compound	Therapeutic Family	Concentration (ug/L)				Reference ^{b,c}
		POTW Influent ^a	POTW Wastewater Effluent ^a	Surface Water	Ground-water	
Acetaminophen	Painkiller/anti-inflammatory	No data	No data	ND – 10,000	No data	AWWARF, 2007 ^b
Benzafibrate	Lipid regulator	0.6	0.2	0.015	0.027	Bren School, 2007 ^b
Caffeine	Stimulant	ND – 31	No data	No data	No data	Stephenson, 2007 ^c
		No data	No data	0.040 – 0.250		AWWARF, 2007 ^b
Carbamazepine	Anti-epileptic	ND– 0.7	ND – 0.7	0.0716		Bren School, 2007 ^b
Clofibric acid	Lipid regulator	ND – 0.34	ND	ND	0.27	Bren School, 2007 ^b
Diazepam	Central nervous system agent	No data	No data	ND – 0.00213	No data	AWWARF, 2007 ^b

See Interim Technical Report on Unused Pharmaceuticals in the Health Care Industry for full table: www.epa.gov/guide/304m/2008/hsi-tech-study-200809.pdf

What EPA Learned...

Types of data gathered: (continued)

Table 4-2. State Regulations for Pharmacy Services at Nursing Homes

State	How to Dispose of Controlled Substances?	How to Dispose of Non-controlled Substances?	Who Destroys Unused Meds?	Who Must Witness the Destruction?	How Soon Must Medications be Destroyed?	Under What Conditions are Medications Returned/ Donated?	Record Keeping and Labeling
Alabama	Destroyed on the premises (method not specified, but may include flushing or down the drain); or Collected by environmental agency providing disposal service	Destroyed on the premises (method not specified, but may include flushing or down the drain); or Collected by environmental agency providing disposal service	Pharmacist	Registered Nurse Controlled substances: a third witness (law enforcement official, management or supervisory personnel.)	30 days. Medications ordered to be used on an "as needed" basis: 90 days from purchase.	Unused legend drugs may be donated to a charitable clinic pursuant to state regulations.	Records must be completed and maintained by the facility that include facility information, date of destruction or collection, destruction method, prescription details (e.g., name and strength of drug, pharmacy, resident name), amount destroyed, and reason for destruction.

4-7

See Interim Technical Report on Unused Pharmaceuticals in the Health Care Industry for full table: www.epa.gov/guide/304m/2008/hsi-tech-study-200809.pdf

What EPA Learned...

Types of data gathered: (continued)

Table 6-1. POTW Removal Efficiencies for Specific Pharmaceuticals in Selected Studies

Compound	Therapeutic Family	POTW Treatment	Compound Removal (%)	Reference
Acetaminophen (paracetamol)	Painkiller/anti-inflammatory	Secondary treatment	0 – 100 ^a	Thomas, 2007
Alpha-ethinylestradiol	Steroid	Secondary treatment	>92	Drewes, 2006
		Reverse osmosis (lab-scale)	100% removal	Drewes, 2006

See Interim Technical Report on Unused Pharmaceuticals in the Health Care Industry for full table: www.epa.gov/guide/304m/2008/hsi-tech-study-200809.pdf

Schedule/Next Steps

- Publish Preliminary 2010 CWA Section 304(m) plan in Fall 2009, 60-day comment period follows
- Draft Guidance and BMPs
 - Work with EPA and Federal partners in developing this draft guidance
- Publish draft guidance and solicit comment by spring 2010
- Finalize guidance and summarize study activities in conjunction with final 2010 Plan

Questions?

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Pharmaceutical Waste: Issues & Impact



EPA Pretreatment seminar
September 22nd, 2009

Charlotte A. Smith, R. Ph., M.S., HEM
Director, PharmEcology Services
Waste Management Healthcare Solutions





History of Pharmaceutical Waste Involvement

Pharmacist since 1968

Co-founded Capital Returns, Inc., a nationally known reverse distributor, in 1991

Worked with 40% of hospitals in the country by 1997 when we sold to a private equity firm

Founded PharmEcology Associates, LLC in 2000

Developed On-site Risk Assessment, Waste Wizard, Inventory Analysis, other tools

Have worked with over 400 hospitals

Have given 100s of seminars

Sold to Waste Management Healthcare Solutions , Inc. in April, 2009

Continue as Director, PharmEcology Services



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Agenda

- Drivers for pharmaceutical waste enforcement
- How hazardous waste regulations apply to discarded pharmaceuticals
- How pharmaceutical waste is disposed: current vs. compliant
- Implementation Steps for Healthcare Facilities



What's Driving Industry Concerns and New Regulatory Initiatives?



The Faroes Statement

200 environmental scientists from five continents met at the Faroes Islands in the North Atlantic –May 24, 2007

Warned of fetal exposure to toxic substances resulting in “fetal programming” to the 2nd and 3rd generation

Lifelong effects: obesity, diabetes, cancers, ADHD, Parkinson’s, Alzheimer’s, reduced immune system

“The dose makes the poison” replaced by “The timing makes the poison”

New approach to testing of chemicals strongly advocated; 80% of major chemicals never tested for damage to early development

www.precaution.org/lib/rpr-html.htm



WASTE MANAGEMENT

Think Green!



Species at Risk



Effects of Chronic Exposure to Prozac

- Developmental delays, forelimb formation, tail resorption
- Increased time to metamorphosis
- Increased mortality



Control



38 ppb Prozac

Black, MC; Rogers, ED;
Henry, RB. Endocrine Effects
Of Selective Serotonin Reuptake
Inhibitors (SSRIs) on Aquatic
Organisms



Drugs in Drinking Water & Healthcare Pharmaceutical Waste

March 9, 2008

5-month inquiry discovered that drugs were detected in the drinking water supplies of 24 major metropolitan areas

September 14, 2008

Majority of 5,700 hospitals and 45,000 long-term care facilities flush unwanted drugs down the drain and do not document amounts according to EPA survey

Extrapolation of data from 14 representative facilities in Minnesota yielded an estimated total volume of 250 million pounds of drug waste annually, including packaging



Drugs in Drinking Water & Pharmaceutical Manufacturing Waste

April 19, 2009

U.S. manufacturers, including major drugmakers, have legally released at least 271 million pounds of pharmaceuticals into waterways that often provide drinking water



Pending Legislation

Drug Free Water Act of 2009

Introduced into the House on January 7, 2009: HR 276

Requires EPA to convene a Task Force regarding proper disposal of unused pharmaceuticals



Pending Legislation

Safe Drug Disposal Act of 2009

Introduced into the House on February 25, 2009:
HR 1191

Introduced into the Senate on June 24, 2009: S
1336

To amend the Controlled Substances Act to provide for the disposal of controlled substances by ultimate users and care takers through State take-back disposal programs

To amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing



Pending Legislation

Secure & Responsible Drug Disposal Act of 2009

Introduced into the House on March 5, 2009: HR 1359

Introduced into the Senate on June 18, 2009: S. 1292

To amend the Controlled Substances Act to enable
consumer take-back programs



State of Illinois Bans Drain Disposal of Drugs

Pharmaceutical Disposal Act, Aug. 10, 2009

Prohibits the disposal of solid dosage forms into wastewater systems by any healthcare provider, including hospitals, long term care, hospice, and home health organization

IVs are excluded; no mention of oral liquids

Provides for an exclusion for Schedule II drugs for long term care facilities

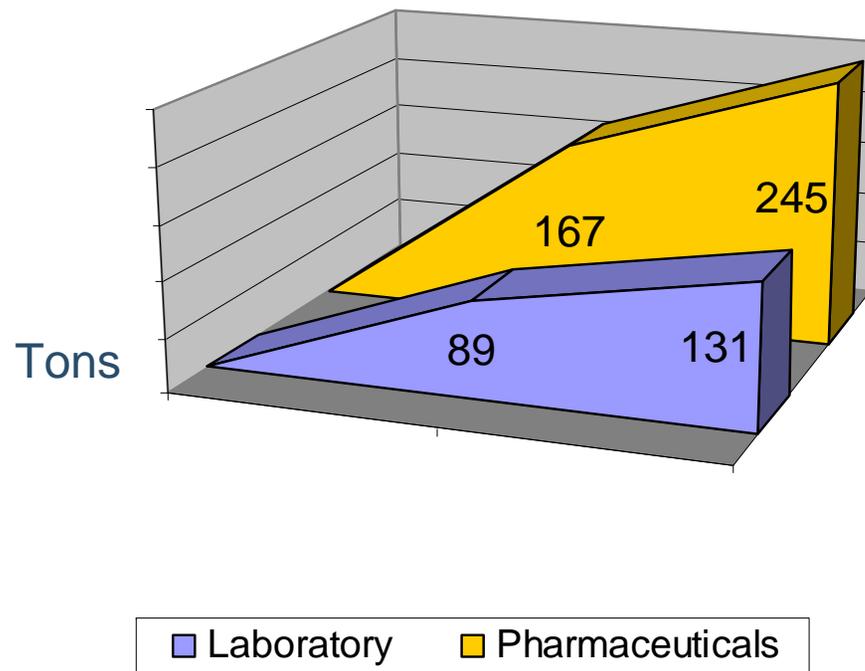
Takes effect January 1, 2010

www.pharmacology.com/pedd/jsp/static/a6_news_20090826.jsp



Preliminary Results of MPCA* Initiative

Annual Increase in Hazardous Waste



*Minnesota Pollution Control Agency



Where is Pharmaceutical Waste Generated?

Pharmacy/Satellites

Patient Care Units

Emergency Room/Operating Room

Intensive Care Unit (ICU)

Oncology/Hematology and other outpatient clinics

Long Term Care Facilities

Home Health Care Services



What Departments Get Involved in Generating and Managing Pharmaceutical Waste?

Pharmacy

Nursing

Infection Control

Environmental Services

Safety

Facility Management

Risk Management

Purchasing



Where are Waste Drugs Going Today?

Sewer System

Unused, partial intravenous drips, including antibiotics

Compounding residues

Liquids

Red Infectious Waste Sharps Containers, Bags

Yellow or White Chemotherapy Sharps
Containers, Bags

Hazardous Waste Containers ????



Common Red Sharps Containment



Common Current Disposal: Autoclave/Microwave or Medical Waste Incinerator



Common Current Disposal: Sewering

EPA Office of Water
& Office of Resource
Conservation & Recovery
discourage drain disposal



Common Pharmaceutical Waste Stream Management

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) + Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, etc. + Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow	Bulk & Trace Chemo, needles, tubing	RMW Incineration
Sewer		Unused IVs, tablets, etc.	Wastewater Treatment Plant
Municipal Trash		Unused ointments, etc.	Landfill



Which Discarded Drugs Become RCRA* Hazardous Waste?

P-listed chemicals

Sole active ingredient; unused, and empty containers

U-listed chemicals

Sole active ingredient; unused

Characteristic of hazardous waste

Ignitability

Toxicity

Corrosivity

Reactivity

* Resource Conservation & Recovery Act



Examples of P-Listed Pharmaceutical Waste

<i>Arsenic trioxide</i>	P012
Epinephrine base*	P042
Nicotine	P075
Nitroglycerin** (weak)	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

*Salts excluded federally as of Oct. 15th, 2007; Many states have adopted this position.

** Excluded from the P list federally and in many states.



Examples of P-Listed Pharmaceutical Waste



Trisenox
(arsenic trioxide)
injection



NDC 0056-0176-70
2 1/2 mg
COUMADIN
(Warfarin Sodium Tablets)
Crystalline
HIGHLY POTENT ANTICOAGULANT
WARNING: Serious bleeding may occur
if overused. Do not use or discontinue
before reading directions and warnings
accompanying product information.
USUAL ADULT DOSEAGE: See
accompanying product information.
PROTECT FROM LIGHT.
100 TABLETS



**CLEAR
NICODERM
CQ**
NICOTINE TRANSDERMAL SYSTEM
14 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID
Directions: DO NOT OPEN POUCH UNTIL READY TO USE.
Apply one new patch every 24 hours on skin that is dry, clean
and hairless. Refer to User's Guide for detailed instructions.
Keep out of reach of children and pets. Used patches have
enough nicotine to poison children and pets. If swallowed, get
medical help or contact a Poison Control Center right away.
Dispose of the used patches by tucking sticky ends together and
inserting in disposal tray in this box.
Do not use if pouch is open or torn.
Store at 20 - 25°C (68 - 77°F)
Manufactured by Alza Corporation
Mountain View, CA 94043
50053806
50053806



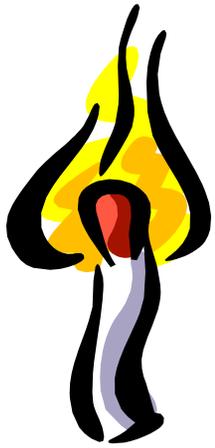
Examples of U-listed Pharmaceutical Waste

Chloral Hydrate(CIV)	U034	<i>Streptozotocin</i>	U206
<i>Chlorambucil</i>	U035	Lindane	U129
<i>Cyclophosphamide</i>	U058	Saccharin	U202
<i>Daunomycin</i>	U059	Selenium Sulfide	U205
<i>Diethylstilbestrol</i>	U089	<i>Uracil Mustard</i>	U237
<i>Melphalan</i>	U150	Warfarin<0.3%	U248
<i>Mitomycin C</i>	U010		



Examples of U-Listed Pharmaceutical Waste





Characteristic of Ignitability

Aqueous Solution containing 24% alcohol or more by volume & flash point <math><140^{\circ}\text{F}</math>

Non-aqueous solutions with flash points <math><140^{\circ}\text{F}</math>

Oxidizers

Flammable aerosols

Hazardous Waste Number: D001

Rubbing Alcohol

Topical Preparations

Injections





Characteristic of Corrosivity

An aqueous solution having a $\text{pH} < \text{or} = 2$ or $> \text{or} =$
to 12.5

Examples: Primarily compounding chemicals

Glacial Acetic Acid

Sodium Hydroxide

Hazardous waste number: D002





Characteristic of Toxicity

40 chemicals which must be below specific leaching concentrations

Must pass the Toxicity Characteristic Leaching Procedure (TCLP)

Must evaluate IVs, such as TPN (total parenteral nutrition) – may come out of regulation due to dilution

Examples of potential toxic ingredients of pharmaceuticals:

Arsenic

m-Cresol

Barium

Mercury (thimerosal,

Cadmium

phenylmercuric acetate)

Chromium

Selenium

Lindane

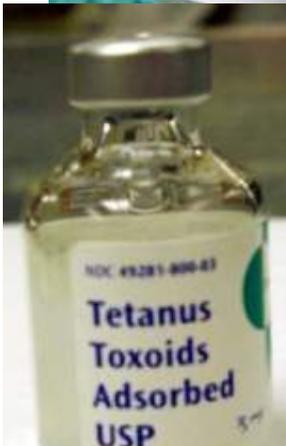
Silver



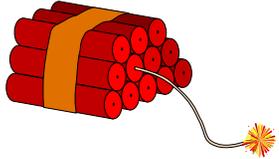
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



Heavy Metals: Selenium, Chromium and Silver



Preservatives: thimerosal & m-cresol



Characteristic of Reactivity

Meet eight separate criteria identifying certain explosive and water reactive wastes

Nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001, unless they exhibit another characteristics, such as ignitability.

Most states have adopted the federal exclusion for nitroglycerin. Waste must still be evaluated for ignitability.

Hazardous Waste Number for reactives: D003



Three Types of Chemotherapy Waste

Trace Chemotherapy Waste (yellow)

Medical waste hauler protocols for “Chemo Waste”
Empty vials, syringes, IV’s, gowns, gloves, ziplock
bags

Treated as infectious medical waste through
regulated medical waste incineration

“Bulk” Chemotherapy Waste (black)

If not empty, should be placed into RCRA
Hazardous Waste container

Spill Clean-up (black)

Manage as RCRA Hazardous Waste



Definition of “Empty”

“P” List

Containers of “P” listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste.

“U” List and D codes

Containers of “U” listed chemicals or D codes are empty only when

All contents removed that can be removed through normal means

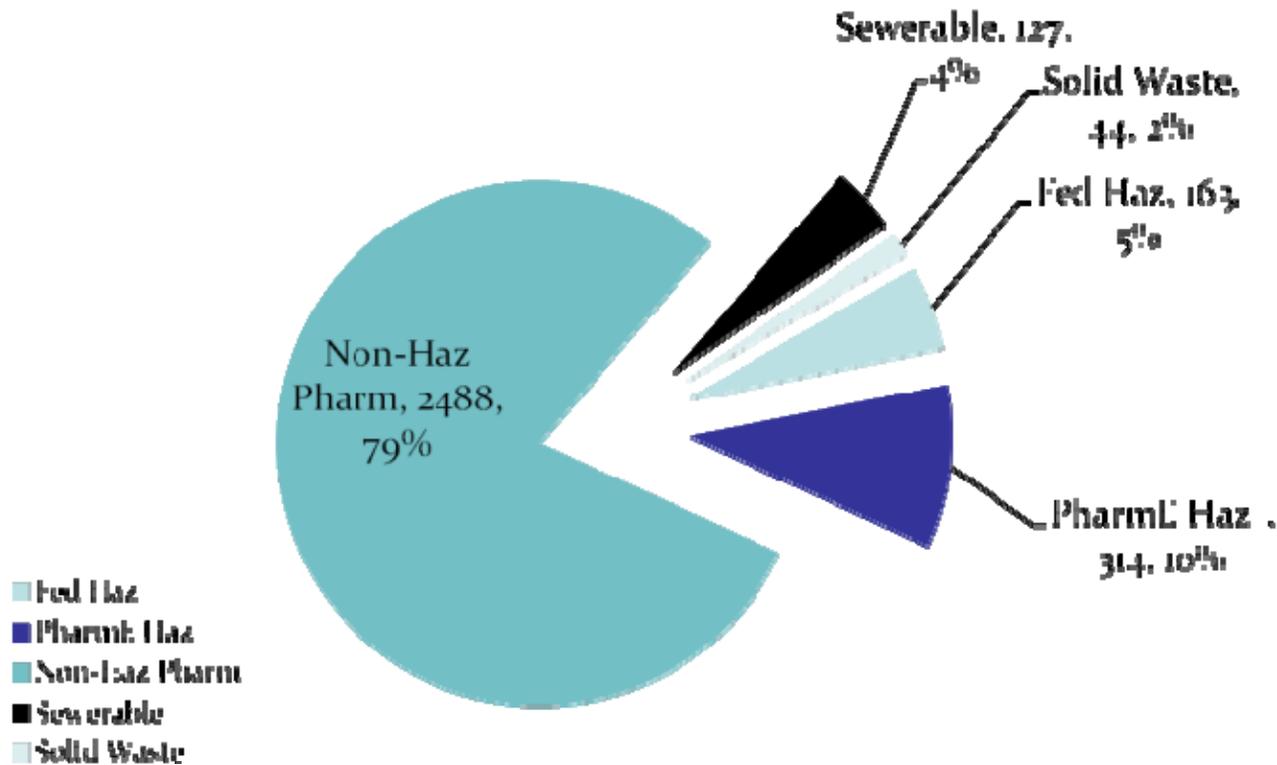
And no more than 3% by weight remains

Example: “Empty” Cytosin vial would be “trace” chemotherapy

Epinephrine syringe exclusion expanded to other P and U-listed drugs federally by USEPA. Many states have accepted this exclusion.



Sample Summary of Pharm E[®] Inventory Analysis Results



PharmE Hazardous® Category: Captures an Additional 10%

Drugs which may cause harm to human health or the environment – sample criteria

NIOSH Hazardous Drug Alert Appendix A

The US Department of Health and Human Services
National Toxicology Program's Report on
Carcinogens (11th Edition)

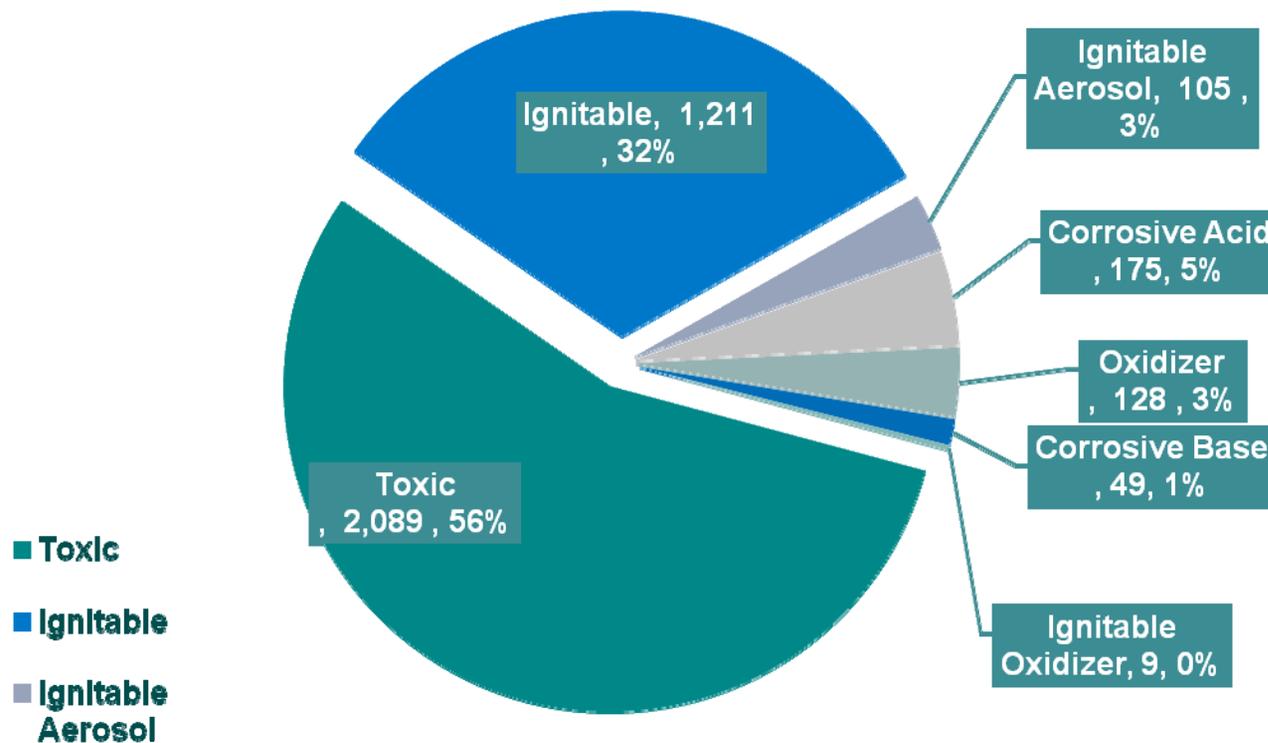
Drugs with LD50s at or below 50mg/kg

Endocrine disruptors

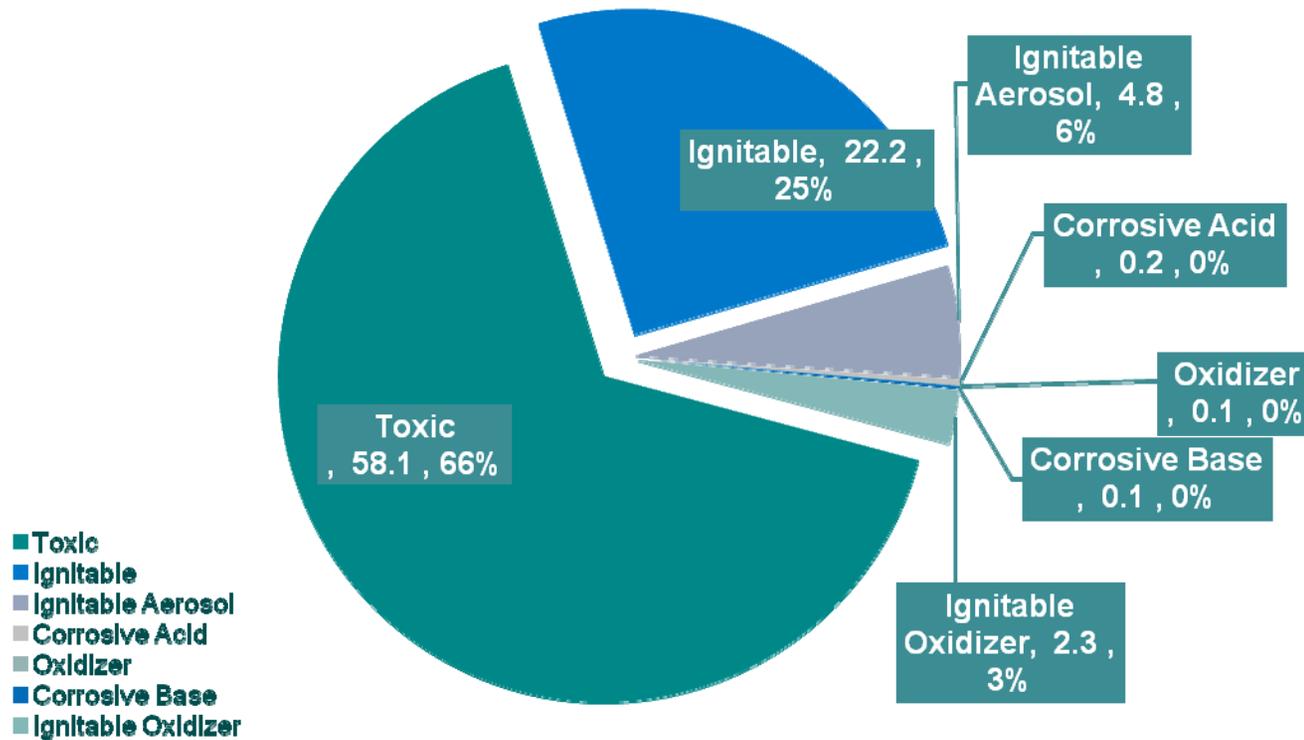
BMP recommendation is to segregate into RCRA toxic hazardous waste containers



Percentage of Hazard Categories in PharmE® Database



Percentage of Hazard Categories in 149 Hospitals (2008)



Compliant Pharmaceutical Waste Disposal Practices (New Management Systems)





Trace Chemotherapy Waste Containers

RCRA Hazardous Waste Containers



Non-hazardous Pharmaceutical Waste Containers



Management Recommendations For Pharmaceutical Waste

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) No Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, No Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow	Biohazardous & Trace Chemo	RMW Incineration
RCRA Toxic/ Ignitable Hazardous Rx	Black	RCRA & BMP Hazardous Rx	RCRA TSDF
Non-hazardous Rx	White/Blue	Non-hazardous Rx	RMW Incineration



Considering the Optimal Management Options

Need to label items that need segregation in a manner that makes it easy for pharmacy and nursing personnel

Shelf stickers in pharmacy

Data Applied to Dispensing Software and/or

Message inserted into automated dispensing cabinets (Pyxis, etc.) and MAR (Medication Administration Record) and/or

Stickers Applied Manually



Approaches to Pharmaceutical Waste Management

Model 1: Automatic Sorting Device

Model 2: Data Applied to Dispensing Software

Model 3: Stickers Applied Manually

Model 4: Centralizing Segregation

Model 5: Managing All Drug Waste As Hazardous



Performing a Drug Inventory Review

Perform initial inventory review

- Obtain drug specific data from purchasing records

- Identify ingredients

- Determine RCRA hazardous waste code

- Make Best Management Practice determinations

Document decision making process

Keep the review current



Labeling the Pharmacy Shelves

Avery Standard Shipping labels #5164



Label Alert: PYXIS

Courtesy Lahey Clinic Medical Center, Burlington, MA

Medications dispensed by the
PYXIS medication station

P, U, D, or HD a pop-up alert to
properly dispose of the
medication

For example:

Pyxis alert:

***THIS DRUG IS A FEDERAL HAZARDOUS
WASTE TYPE (specifies P, U, D)***

***DISPOSE > TRACE IN "BLACK" CONTAINER
OR RETURN TO PHARMACY***





IV / Medication Label Alert: P, U, D, HD

Courtesy Lahey Clinic Medical Center, Burlington, MA

TEST. PATIENT
T01 TEST
08/19/08
CORTISPROIN OTIC SUSPENSION
Dose: 1 DROP OT BID
0900-2100
(D-DRUG)

666666
ORD# 5886072

6157983410

TEST. PATIENT
T01 TEST
08/19/08
CORTISPROIN OTIC SUSPENSION
Dose: 1 DROP OT BID 09:31

666666
ORD# 5886072

TEST. PATIENT
T01 TEST
08/19/08
CHLORAMPHENICOL 0.5% EYE DROPS
Dose: 1 DROP OU QID
0900-1400-1800-2200
(HD-DRUG)

666666
ORD# 5886120

1190010908

(7.5 ML)
Prep by: _____ Checked by: _____

TEST. PATIENT
T01 TEST
08/19/08
CHLORAMPHENICOL 0.5% EYE DROPS
Dose: 1 DROP OU QID 09:39

666666
ORD# 5886120

TEST. PATIENT
T01 TEST
08/19/08
NITROGLYCERIN 2% OINTMENT
Dose: 1 INCH TD
0900-1400-1800-2200
FLOOR STOCK (NOT IN PYXIS) (P-DRUG)

666666
ORD# 5886080

90163032630

TEST. PATIENT
T01 TEST
08/19/08
NITROGLYCERIN 2% OINTMENT
Dose: 1 INCH TD QID 09:31

666666
ORD# 5886080

TEST. PATIENT
T01 TEST
08/19/08
LINDANE 1% SHAMPOO
Dose: 1 DOSE TP TODAY
(U-DRUG)

666666
ORD# 5886074

0930-065283

TEST. PATIENT
T01 TEST
08/19/08
LINDANE 1% SHAMPOO
Dose: 1 DOSE TP TODAY 09:31

666666
ORD# 5886074

Labeling & Containers

Items identified by PharmE Inventory Analysis

Marked with black labels
“Special Disposal Required”
Coded in Pyxis dispensing machine also

Black hazardous waste containers purchased from Covidien

Courtesy North Memorial Health Care



**SPECIAL
DISPOSAL REQUIRED**



Selecting the Right Waste Vendor(s)

For RCRA hazardous waste, vendor must be permitted by EPA as a treatment, storage and disposal facility (TSDF)

Insure your current vendor can handle all new waste codes

Ask for a waste profile to be generated to enable manifesting without documenting each item in each container

Determine if you will have special needs, such as hazardous controlled substances or mixed hazardous/regulated medical waste streams



Creating a Hazardous Waste Profile

Work with hazardous vendors to create a certified hazardous waste profile of all toxic & ignitable drug waste, including ignitable aerosols

Ship commingled as Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II, UN3248

Ship any corrosive acids/bases or oxidizers separately



Examples of Hazardous Pharm Waste Satellite Accumulation



Hazardous Pharmaceutical Waste Storage Accumulation



Weekly Volumes of 55 gal drums: 16 Non-haz; 4-5 Haz (600 beds)



Photos courtesy of Abbott Northwestern Hospital

Non-Hazardous Pharmaceutical Waste

Managed through non-hazardous incineration as a Best Management Practice



Courtesy North Memorial Health Care



Examples of Non-Hazardous Pharm Waste Collection & Storage



Maintaining the Inventory

PharmE® Waste Wizard

Web-based annual subscription service.

Waste classifications, including container recommendations & **Material Safety Data Sheets**

The screenshot shows the PharmEcology website homepage. At the top, the logo "pharm@ecology" is displayed as "A Waste Management Company". Navigation links include "CONTACT US", "SITE MAP", "ABOUT PHARM@ECOLOGY", "FAQ", "RESOURCES", "NEWS", and "SERVICES". A central banner features a scientist and the text: "Establishing compliant and cost-effective procedures to manage pharmaceutical waste." To the left is a login form for "PharmEcology Waste Wizard Subscribers" with fields for email, password, and a "Remember me" checkbox, along with "LOGIN", "Take Our Tour", and "Are You In Compliance?" buttons. To the right are service highlights: "PharmEcology Inventory Analysis", "PharmEcology Waste Wizard", "PharmEcology On-Site Risk Assessment", "PharmEcology Implementation Support and Certification", and "PharmEcology Policies and Procedures". A "News Alert" section lists three items: "Waste Management Subsidiary Acquires PharmEcology Associates", "Questions and Answers for PharmEcology Customers", and "NIOSH Proposes Changes to the List of Hazardous Drugs". The footer contains contact information for 12228 West North Avenue, Suite 2, Wauwatosa, Wisconsin 53226, and copyright notices for 2001-2009.



Summary

Healthcare facilities are looking for guidance in managing pharmaceutical waste

Healthcare leaders are frustrated by lack of a level enforcement playing field

Management of pharmaceutical waste is an integral part of the “greening” of healthcare and society in general



Resources

NIOSH Hazardous Drug Alert

www.cdc.gov/niosh/docs/2004-165/#sum

ASHP Guidance on Handling Hazardous Drugs

www.ashp.org/s_ashp/bin.asp?CID=6&DID=5420&DOC=FILE.PDF

OSHA Technical Manual

www.osha-slc.gov/dts/osta/otm/otm_vi/otm_vi_2.html

Practice GreenHealth (fka Hospitals for a Healthy Environment)

www.practicegreenhealth.org

Pharmaceutical waste webpage: www.h2e-online.org/hazmat/pharma.html

Healthcare Education Resource Center (HERC)

Blueprint on Pharmaceutical Waste Management (Revised)

www.hercenter.org/hazmat/tenstepblueprint.pdf

WM Healthcare Solutions, PharmEcology Services

www.pharmecology.com

FAQs, state and federal waste regulations, subscription search engine

PharmE™ Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria



QUESTIONS?

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