



Pharmaceutical Update and RCRA Review

Sacramento Regional County
Sanitation District
(SRCSD)

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Agenda

What's new: legislative and regulatory update

RCRA 101: Which drugs become hazardous waste

Practical steps to get started

Making it happen: practical examples



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

Reported that there are no sewage treatment systems engineered to remove pharmaceuticals

Acknowledged continuous low-level exposure to chemo drugs, hormones, anti-depressants, antibiotics, and seizure meds found in our water could be impacting human health.

September 14, 2008

Continuing inquiry into disposal practices by hospitals, long term care facilities, other healthcare organizations

Majority of medical 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



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

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

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



EPA May Regulate Pharms in Drinking Water

104 chemicals being considered for possible regulation under the Safe Drinking Water Act

Pharmaceuticals considered for the first time

Several estrogens included:

estradiol, estrone, ethinyl estradiol, mestranol

Also erythromycin (antibiotic) & nitroglycerin (cardiac)

Collection and evaluation will take years (2013) but could result in drinking water standards for drugs

http://www.pharmacology.com/pedd/jsp/static/a6_news_alert.jsp



EPA Proposal to Add Pharmaceuticals to Universal Waste Rule

Federal Register publication Dec 2, 2008 – Comments were due March 4, 2009

<http://www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.htm>

Information:

<http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm>

Proposed UWR only applies to drug waste that meets the definition of RCRA hazardous waste

Only intended for healthcare-type generators, not manufacturers

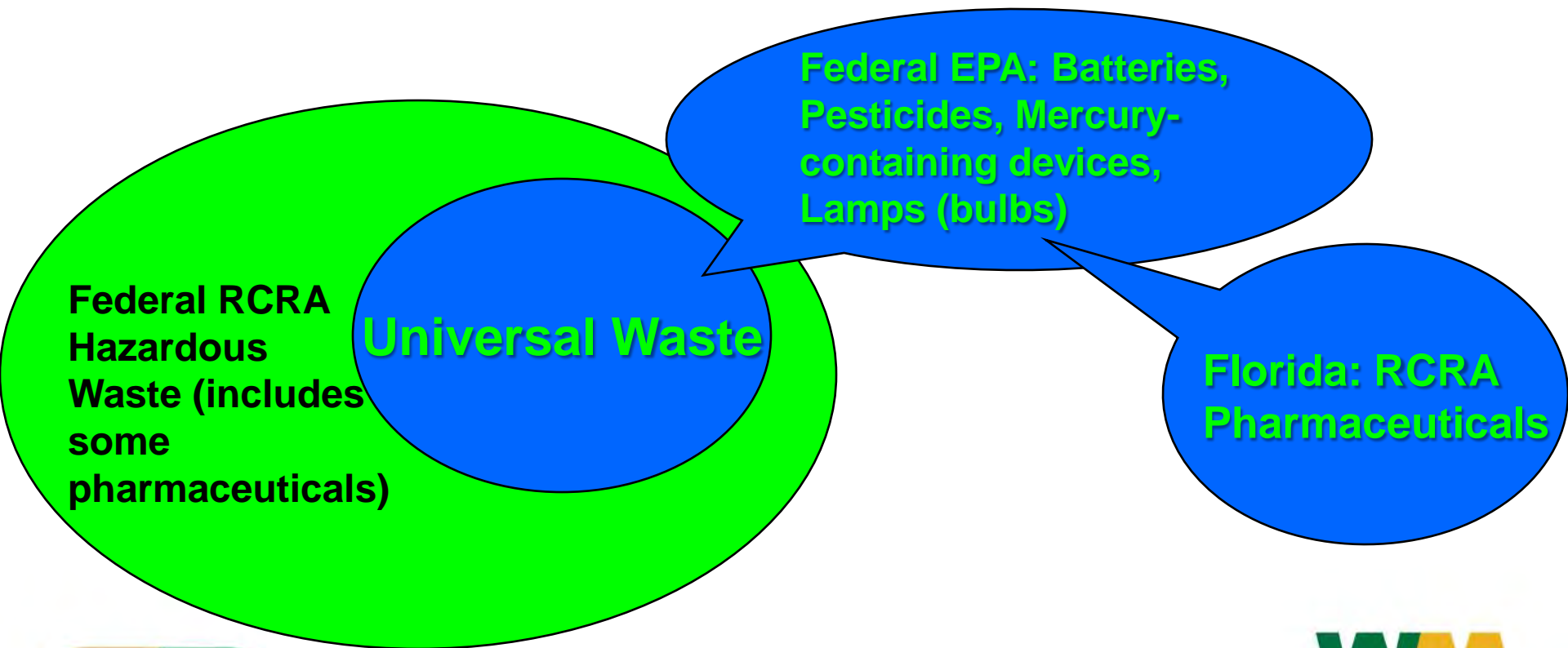
Intent to streamline pharmaceutical waste management and encourage consumer take-back programs

Estimated April, 2011 for federal enactment; states may or may not adopt



RCRA and Universal Waste

“Universal Waste” is a subset of RCRA hazardous waste.



Impact of Universal Waste Regulations

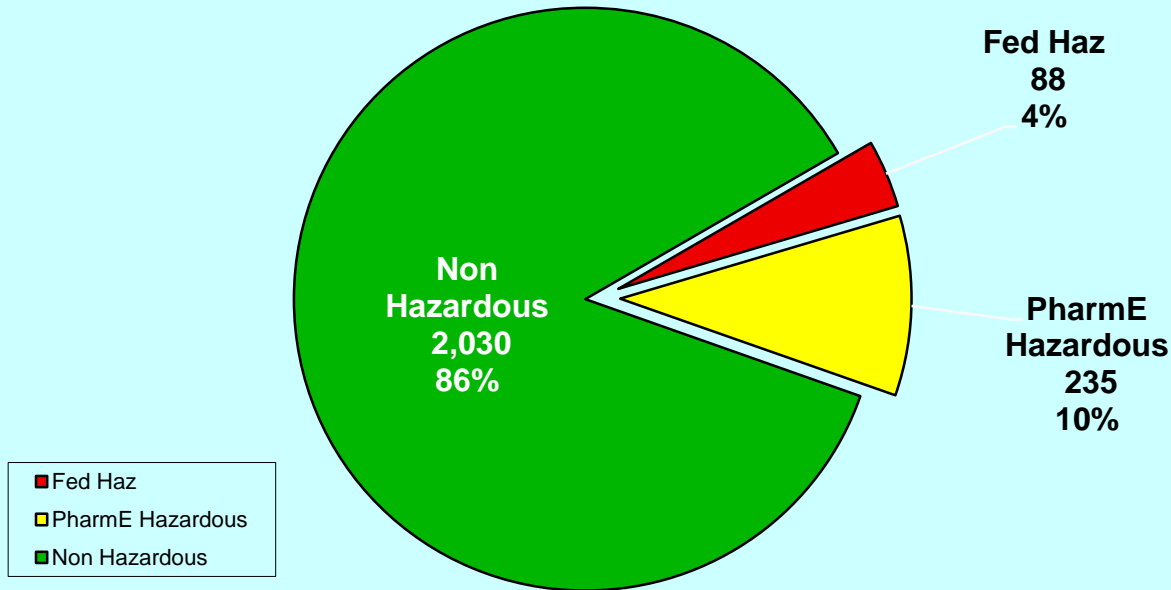
Applies **ONLY** to 4% of drugs in the marketplace that are RCRA hazardous waste... does not address other 96% of drugs.

Brings attention to the industry regarding the proper disposal of pharmaceutical waste.



Percentage of RCRA & PharmE Haz[®] in 149 Hospitals, 2008

PharmE[®] Inventory Analysis
Average for 149 Facilities



General Goals of UWR

To encourage resource conservation

To improve implementation of current RCRA subtitle C hazardous waste regulatory program

To separate UW from the municipal waste stream



Specific Benefits of Adding Pharmaceuticals to UWR

Hazardous pharmaceutical waste would no longer contribute to the generator size

Storage time limits would increase to one year total (currently in California), allowing more time in storage accumulation area



What Makes Drug Waste Unique? Security Issues

Legend Pharmaceuticals (Rx only) are deliberately restricted in their availability to the consumer AND within the supply chain due to their inherently “dangerous” status regarding human use

The street value of non-controlled substances continues to climb due to increased drug costs and shrinking personal resources

Waste pharmaceuticals continue to have value, including empty vials of IV admixtures that can be used for introducing counterfeit drugs back into the supply chain



Burning Question: Should I Wait for the UWR to Develop My System?

NO:

It will take a MINIMUM of 18 months for a new rule to be adopted federally

It will take YEARS for each state to adopt either the federal version or their own version of the UWR

Hazardous waste will still need to be identified and manifested when traveling through states that have not adopted the UWR

Your organization will still need to segregate hazardous waste to avoid premier disposal charges



Enforcement in California

RCRA is enforced by USEPA Region 9 and by the California EPA Dept. of Toxic Substances Control (DTSC)

California State Hazardous Waste is enforced by Dept. of Public Health (DPH) under the Medical Waste Management Act (MWMA)



RCRA: Risk Management & Liability

Civil and criminal liability

Civil: State/USEPA enforcement

Criminal: FBI, Attorney General, Grand Jury

Corporate fines: \$37,500/violation/day

Personal liability: Fines and/or imprisonment

No statute of limitations

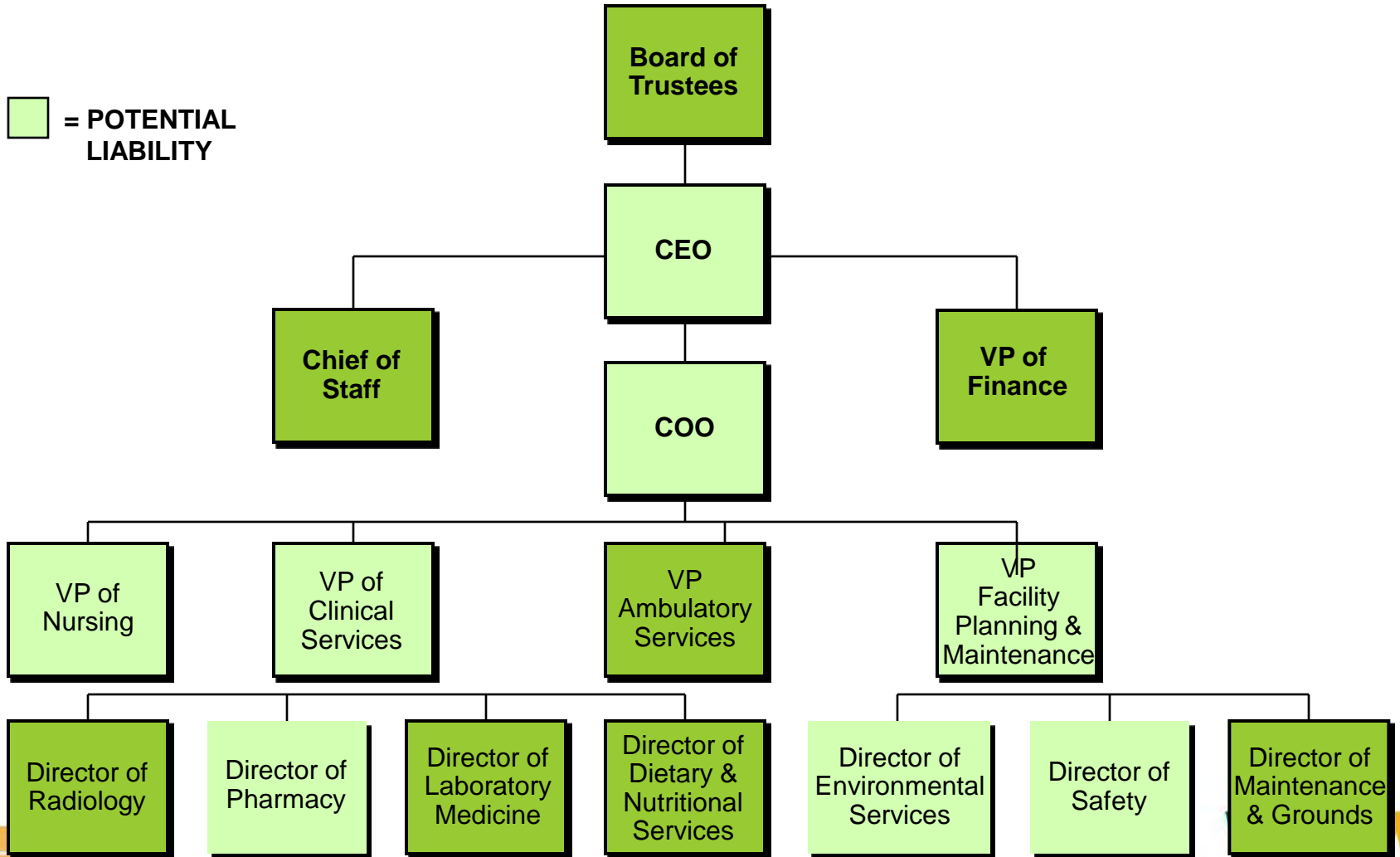
Managers up through CEO liable



<http://www.epa.gov/compliance/resources/policies/criminal/exercise.pdf>



Potential Liability for Rx Hazardous Waste Management



Applying Your Knowledge!

Mix & Match Exercise
The “All-Seeing Eye”
holds the clues!



Which Discarded Drugs Become Hazardous Waste?

P-listed chemicals (acutely hazardous)

Sole active ingredient; unused; empty containers

U-listed chemicals (toxic)

Sole active ingredient; unused

Characteristic of hazardous waste

Ignitability

Toxicity

Corrosivity

Reactivity



Examples of P-Listed Pharmaceutical Waste



Arsenic trioxide (chemo)

P012

Epinephrine base*

P042

Nicotine

P075

Nitroglycerin** (weak)

P081

Phentermine (CIV)

P046

Physostigmine

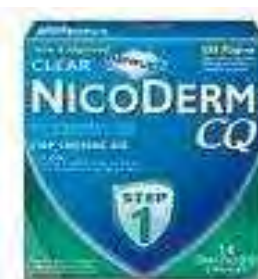
P204

Physostigmine Salicylate

P188

Warfarin >0.3%

P001



*Salts excluded federally as of Oct. 15th, 2007; California has adopted this position.

**Excluded from the P list federally but and in California.



Examples of U-Listed Pharmaceutical Waste



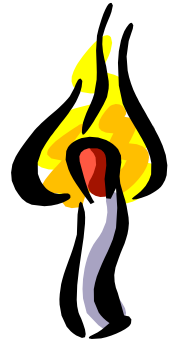
Chloral Hydrate(CIV)	U034	<i>Streptozotocin</i>	U206
<i>Chlorambucil</i>	U035	Lindane	U129
<i>Cyclophosphamide</i>	U058	Saccharin	U202
<i>Daunomycin</i>	U059	Selenium Sulfide	U205
Diethylstilbestrol	U089	<i>Uracil Mustard</i>	U237
<i>Melphalan</i>	U150	Warfarin<0.3%	U248
<i>Mitomycin C</i>	U010		



Examples of U-Listed Pharmaceuticals



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 pH $<$ or $=$ 2 or $>$ 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 – may come out of regulation due to dilution

Examples of potential toxic pharmaceuticals:

Arsenic

Barium

Cadmium

Chromium

Lindane

m-Cresol

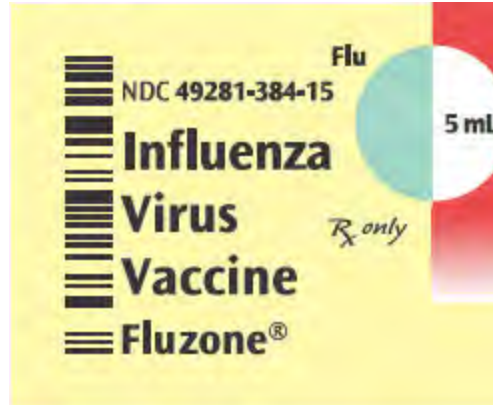
Mercury (thimerosal,
phenylmercuric acetate)

Selenium

Silver



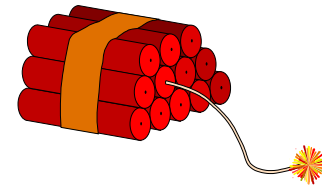
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



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, unless they exhibit another characteristics, such as ignitability.

CalEPA DTSC has adopted the federal exclusion for nitroglycerin.

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

Residue of “P” or “U” listed drugs in a used syringe is exempted and should be discarded as biohazardous waste or trace chemo. California has adopted.



What Is PharmE Hazardous[®] Waste?

Drugs which may cause harm to human health or the environment and need to be managed according to BMPs

- 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



Identified as PharmE Hazardous[®] in Inventory Analysis

BMP recommendation is to segregate at least chemo agents into RCRA toxic hazardous waste containers and to dispose of other agents through incineration



The Medical Waste Management Act and California-Only Hazardous Waste

Causes pharmaceutical waste to be defined as “biohazardous” – out of sync with usual and customary definition as infectious waste

Defines “empty” chemo container

Defines pharmaceuticals as all drugs that are not RCRA and not radioactive

Intent is to regulate CAL-ONLY haz waste

Requires incineration at a regulated medical waste facility or approved alternative



California Hazardous Waste

Primary applicable criteria is an LD50 of 2500 mg/kg or less

Changed from original criteria of LD50 of 5000 mg/kg or less

New criteria is half as stringent

Acute aquatic 96-hour LC50 < 500mg/liter

Carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative, persistence in the environment

No complete list

Practical solution: manage all non-RCRA pharmaceuticals as Cal-Hazardous



How Should California Hazardous Pharmaceutical Waste be Handled, Stored and Disposed?

DPH prohibits sewerage and landfilling of California Hazardous drugs

Segregate into appropriate non-RCRA Pharmaceutical Waste container

Label “Incinerate Only”

Dispose at a regulated medical waste incinerator in accordance with the Medical Waste Management Act



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



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
Cal-hazardous Rx	White/Blue	Cal-hazardous Rx	RMW Incineration



Containment

Traditional Chemo Waste Containers

Empty chemo vials, syringes, IVs, tubing, gowns, gloves, etc.



Hazardous Waste Containers

Bulk chemo in vials, unused IV's, P, U. toxic D



Cal-Hazardous Waste Containers

Cal-Hazardous pharmaceuticals



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 Pyxis, etc. and MAR
(Medication Administration Record) and/or

Stickers Applied Manually



Labeling the Pharmacy Shelves

Avery Standard Shipping labels #5164



Label Alert: PYXIS

Medications dispensed by the PYXIS medication station

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

Pyxis alert:

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

DISPOSE >TRACE IN “BLACK” CONTAINER OR RETURN TO PHARMACY



Courtesy Lahey Clinic Medical Center, Burlington, MA





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

Courtesy Lahey Clinic Medical Center, Burlington, MA

TEST, PATIENT 666666
T01 TEST ORD# 5886072
08/19/08
CORTISPROIN OTIC SUSPENSION
Dose: 1 DROP OT BID
0900 2100
(D-DRUG)



6157003410

TEST, PATIENT 666666
T01 TEST ORD# 5886072
CORTISPROIN OTIC SUSPENSION
Dose: 1 DROP OT BID 09:31

TEST, PATIENT 666666
T01 TEST ORD# 5886120
08/19/08
CHLORAMPHENICOL 0.5% EYE DROPS
Dose: 1 DROP OU QID
0900-1400-1800-2200
(HD-DRUG)



1159010008

Prep by: _____ Checked by: _____

TEST, PATIENT 666666
T01 TEST ORD# 5886120
CHLORAMPHENICOL 0.5% EYE DROPS
Dose: 1 DROP OU QID 09:39

TEST, PATIENT 666666
T01 TEST ORD# 5886080
08/19/08
NITROGLYCERIN 2% OINTMENT
Dose: 1 INCH TD QID
0900-1400-1800-2200
FLOOR STOCK (NOT IN PYXIS) (P-DRUG)



9016902630

TEST, PATIENT 666666
T01 TEST ORD# 5886080
NITROGLYCERIN 2% OINTMENT
Dose: 1 INCH TD QID 09:31

TEST, PATIENT 666666
T01 TEST ORD# 5886074
08/19/08
LINDANE 1% SHAMPOO
Dose: 1 DOSE TP TODAY
(U-DRUG)



0050-069237

TEST, PATIENT 666666
T01 TEST ORD# 5886074
LINDANE 1% SHAMPOO
Dose: 1 DOSE TP TODAY 09:31

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

**SPECIAL DISPOSAL
REQUIRED**

Courtesy North Memorial Health Care



NEW Hazardous Waste Containers

YELLOW “Soft” Hamper Trace/Soft Chemo/Bio

- Gowns, Gloves, Chux and soiled linens, ONLY)



YELLOW HARD CONTAINER Trace / Sharps

- **EMPTY** Syringes or Sharps
- **TRACE** amounts of Chemo / Biotherapy ONLY Empty syringes, IV bags, tubing



P, U, D, HD, BLACK CONTAINER

- **BULK** (Larger than TRACE) amounts of Chemo / Bio
- Chemo-Spill products



Courtesy Lahey Clinic Medical Center, Burlington, MA

Example: “D” Type Hazard Insulin Containing M-Cresol

A used syringe of this type of insulin



An empty insulin vial



A half empty insulin vial



An outdated insulin vial



Courtesy Lahey Clinic Medical Center, Burlington, MA

Hazardous Pharmaceutical Waste Storage Accumulation



HAZARDOUS WASTE

FEDERAL LAW PROHIBITS IMPROPER DISPOSAL.
IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY AUTHORITY OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY.

GENERATOR INFORMATION:

NAME _____

ADDRESS _____ PHONE _____

CITY _____ STATE _____ ZIP _____

SPC / MANIFEST ID NO. / DOCUMENT NO. _____

ACCUMULATION START DATE _____ SPC WASTE NO. _____

HANDLE WITH CARE!



Federal Waste Generation Status

Large Quantity Generator (LQG): generates more than 1000 kg/month of hazardous waste **or** >1 kg/month “P” listed waste.



Small Quantity Generator (SQG): Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month “P” listed waste.

Conditionally Exempt Small Quantity Generator (CESQG) : Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month



Creating a Hazardous Waste Profile

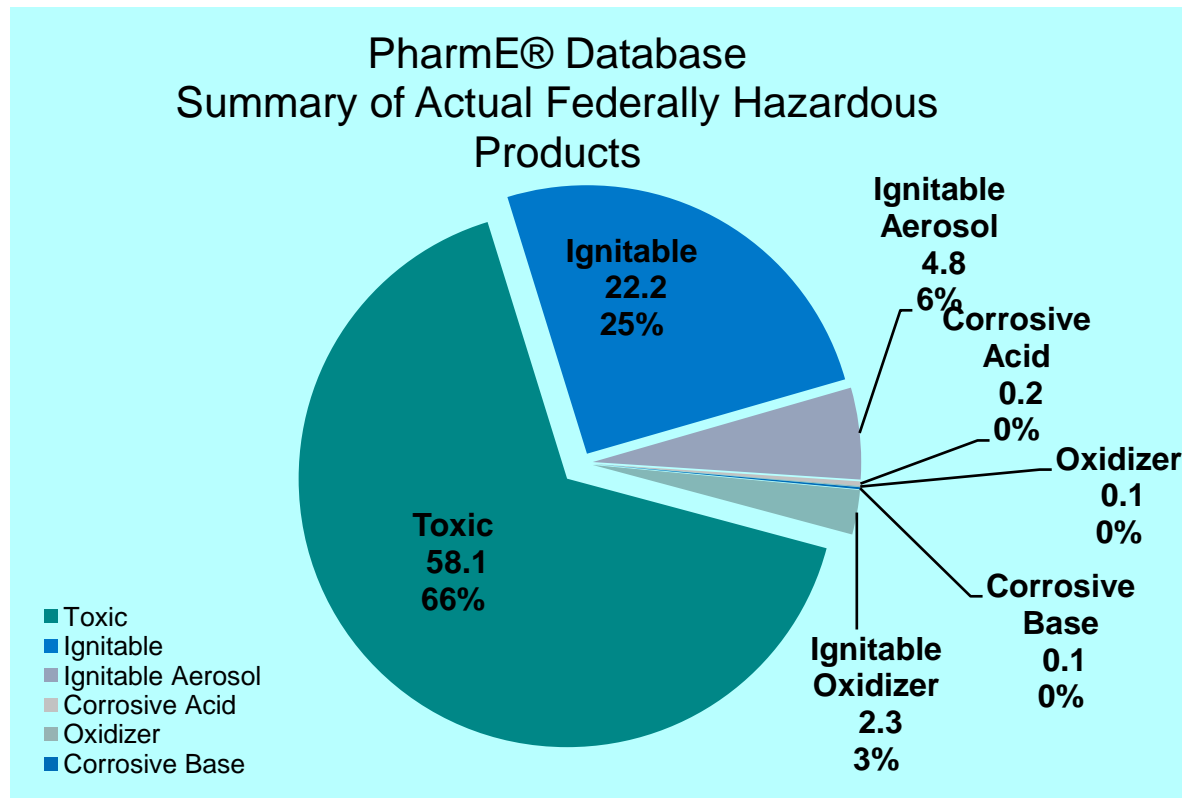
Work with hazardous vendors to create a certified hazardous waste profile of all toxic & ignitable drug waste, including ignitable aerosols

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

Ship any corrosive acids/bases or oxidizers separately



Percentage of Hazard Categories in 149 Hospitals (2008)



97% Toxic or Ignitable

Cal-Hazardous Pharmaceutical Waste

Managed through
medical waste
incineration under the
Medical Waste
Management Act



Courtesy North Memorial Health Care



Examples of Cal-Hazardous Pharmaceutical Waste Collection & Storage



Final Steps

Staff cooperation and participation will be required for successful program implementation

Remaining steps include:

- Pilot your labeling/segregation program in the pharmacy and selected nursing units
- Modify the program as necessary
- Finalize policies and initiate system-wide implementation



Resources

Bay Area Pollution Prevention Group

Cal Blueprint on Pharmaceutical Waste Management

<http://www.bacwa.org/LinkClick.aspx?fileticket=dLjPqQLP5nl%3d&tabid=71&mid=415>

NIOSH Hazardous Drug Alert

<http://www.cdc.gov/niosh/docs/2004-165/#sum>

ASHP Guidance on Handling Hazardous Drugs

<http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyDocumentType/GuidelinesMain.aspx>

OSHA Technical Manual

http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

Practice GreenHealth (formerly Hospitals for a Healthy Environment)

<http://www.practicegreenhealth.org/>

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

Healthcare Education Resource Center (HERC)

Blueprint on Pharmaceutical Waste Management (Revised)

<http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

WMHS PharmEcology Services

www.pharmecology.com

FAQs, state and federal waste regulations, PharmE® Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria



QUESTIONS?

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