

Pharmaceutical-Related Legislation Passed or Proposed



Charlotte Smith, R. Ph., M.S.
Director, PharmEcology Services
WM Healthcare Solutions, Inc.

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Legislation, Regulation, Enforcement, and Guidance Documents

All play different roles in changing behavior

RCRA (Resource Conservation & Recovery Act):

Legislation established the legal basis for the definition and management of solid waste and hazardous waste

Regulation defined the specific categories of hazardous waste and management requirements

Enforcement ensures that the regulations are followed by the regulated community



Legislation: Enabling vs Enforcement

Legislation can enable best practices to occur

Amendment to the CSA

Minnesota legislation enabling additional parties to have possession of prescription drugs for the purpose of disposal

Legislation can also break new ground

Illinois law prohibiting drain disposal of solid dosage forms of drugs

Enforcement can provide a strong argument for compliance



Rx Waste: Businesses vs Consumers

Businesses (hospital, clinics, surgery center, etc.):

- Already regulated under RCRA

- Enforcement highly variable depending on EPA region and state

- Early Leaders: MN, FL, EPA Regions 1 and 2

Consumers:

- Not regulated

- EPA and TCEQ exempt consumer-generated Rx hazardous waste from regulation

- Lack of DEA regulation forms a barrier

Long term care facilities, other residential treatment centers: business or household?



Legislation/Regulation/Guidance/ Enforcement Affecting Healthcare Businesses

Water Quality Investment Act

Water Protection & Reinvestment Act

Potential regulation of pharms in drinking water

2010 Effluent Guidelines

Addition of hazardous pharmaceutical waste to the
Universal Waste Rule

Increased state and EPA enforcement of RCRA



Current Water Protection Legislative Initiatives

Water Quality Investment Act of 2009 (Oberstar) HR 1262

Task Force on proper disposal of Unused Pharmaceuticals

“(B) provide for limiting the disposal of unused pharmaceuticals through treatment works in accordance with the Federal Water Pollution Control Act”

<http://thomas.loc.gov/cgi-bin/query/F?c111:4:./temp/~c111DxK77b:e63062:>

Water Protection and Reinvestment Act of 2009 (Blumenauer) HR 3202

(1) an excise tax on the sale of containers of water-based beverages, water disposal products, and pharmaceutical products

(3) take back and dispose of prescription and over-the-counter drugs in an environmentally sound manner

<http://www.govtrack.us/congress/bill.xpd?bill=h111-3202&tab=summary>



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 Solicited Comments: Preliminary 2010 Effluent Guidelines Program Plan

Presented summary of current efforts since 2008 to solicit information regarding drug disposal, primarily within the healthcare sector

Offered opportunity to provide a variety of input comments on page 68614, section B.

Comment period closed February 26, 2010

Access at

<http://edocket.access.gpo.gov/2009/pdf/E9-30625.pdf>



EPA's Office of Water Moving Forward Without Survey

“EPA estimates that it has gathered sufficient data from its site visits and outreach to *begin the development of best practices for unused pharmaceutical management at health care facilities.* During the next year EPA will continue to work with a variety of stakeholders in the development of these best practices and the means for their dissemination and adoption. EPA expects to have a draft of the development of these best practices for the final 2010 Plan.”

EPA Region 1, Janet Bowen, Hospital Email, Sept. 3, 2009



State of Illinois Bans Drain Disposal of Drugs

Safe 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

Took effect January 1, 2010

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



NY Fines Send Shock Waves

New York Office of Attorney General cites 2 hospitals, 3 nursing homes for inappropriate disposal of drugs. Including flushing and hazardous waste violations

More inspections on the horizon

Precedent-setting action draws national attention to pharmaceutical waste management practices

http://www.ag.ny.gov/media_center/2010/jan/jan12a_10.html



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

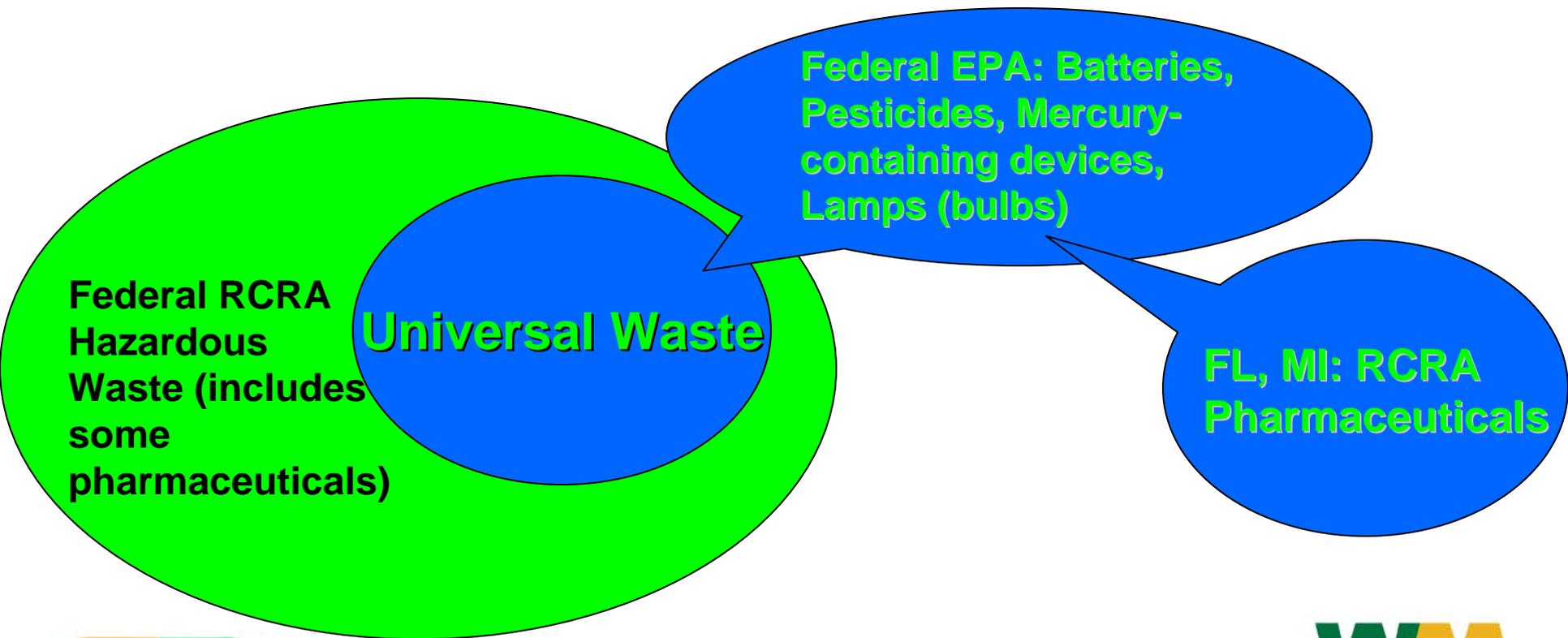
Intent to streamline pharmaceutical waste management and encourage consumer take-back programs

Estimated Summer, 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.



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, allowing more time in storage accumulation area



Economic Impact

Suggested practice of managing all Rx waste as universal waste

Fee differential as large as 5x to 10x between medical incineration and RCRA hazardous waste incinerator

RMW: \$.19/lb - \$.50/lb

RCRA: \$.95/lb - \$4.95/lb



Legislation/Regulation/Guidance/ Enforcement Affecting Consumer Take-back Efforts

FDA Guidance:

Options include rendering non-recoverable and disposing in kitty litter

Controversial “flush list” for highly toxic controlled substances

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>



Pending Legislation to Amend the Controlled Substances Act

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 direct DEA to issue federal rules governing consumer take-back programs



Minnesota Bill Passed to Broaden Legal Possession of Non- DEA Rx Drugs for Disposal

HF 1217 – passed House and Senate April 2010

1 A bill for an act

1.2relating to health; expanding categories of persons allowed to possess legend and

1.3nonprescription drugs to include those disposing of them

Enables counties and their designees to be in possession of legend and OTC drugs for the purpose of disposal

Must still comply with DEA regulations



State of New York

Don't Flush Your Drugs Campaign

August 8, 2008: <http://www.dec.ny.gov/chemical/>

October 20 -24, 2009: Numerous pharm waste collection events around the state



An Act to amend the environmental conservation law, in relation to the management and disposal of drugs

Became law September 25th, 2008

Requires public information, displayed in every pharmacy



Summary: Healthcare Facilities

Regulations already exist requiring proper identification, segregation and disposal of RCRA hazardous pharmaceutical waste

Enforcement has not been consistent at the state or EPA regional level

Decision needed regarding long term care and other residential treatment facilities (business or household)

Guidance in process on disposal of non-RCRA drug waste



Summary: Consumer Take-back Scenarios

- Continue to be hampered by DEA regulations
 - Need amendment of Controlled Substances Act
 - Some confusion in recent press releases regarding ability to include controlled substances
- Need to work with State Board of Pharmacy, others, to insure that state enables possession of “legend” drugs (Rx only) by relatives, waste vendors, and other involved parties.
- Need consistent funding – Product Stewardship Legislation?



Proposed Product Stewardship Bills

Florida: HR 1357, SB 2650 (previous session)

Maine: HP0557, LD 821 – passed House, died in Senate 3/26/10

Maryland: HB 648 – unfavorable report, 3/22/10

Minnesota: HF 1217, SF 1568 – heavily modified

Oregon: SB 598 (previous session)

Washington State: SHB 1165, SB 5279 re-introduced 3/15/10

None have passed to date – only a matter of time



What's Needed: Product Stewardship Model Language

States are clearly adopting language from each other
Washington State, Maine, Minnesota very influential

Suggested Action Item:

- Draft model language that retains much of the acceptable common elements

- Involve industry in dialog

- Move the discussion to federal legislation with some state flexibility

Use federal act to move hazardous pharmaceuticals into Universal Waste Rule (UWR) in tandem with EPA



Questions?

Contact information:

Charlotte A. Smith, R. Ph., M.S., HEM
Director, PharmEcology Services

1021 Main Street

1 City Center, Suite 1000

Houston, TX 77002

713-725-6363 (cell)

csmith@pharmecology.com

csmith32@wm.com



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Alternative Methods of Disposal or Management of Unused Pharmaceuticals – Healthcare Industry



TCEQ

April 22, 2010

Charlotte A. Smith, R. Ph., M.S.

414-292-3959

csmith@pharmecology.com



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Differentiating Between Products and Waste

Expired products often eligible for credit through reverse distribution

Virtually 100% of hospitals and most retail pharmacies use reverse distributors for outdated drugs

Samples and items purchased on a “no return” basis not eligible (most flu vax)

Not available to clinics, surgery centers, long term care facilities, dental offices, veterinary practices

Do not use the same wholesale drug network, volumes too low to



Expired Drugs Eligible for Reverse Distribution

Expired drugs in manufacturers' original packages
May be eligible for credit, managed as "products,"
not waste

Sent through a reverse distributor

Licensed by state board of pharmacy

DEA registrant

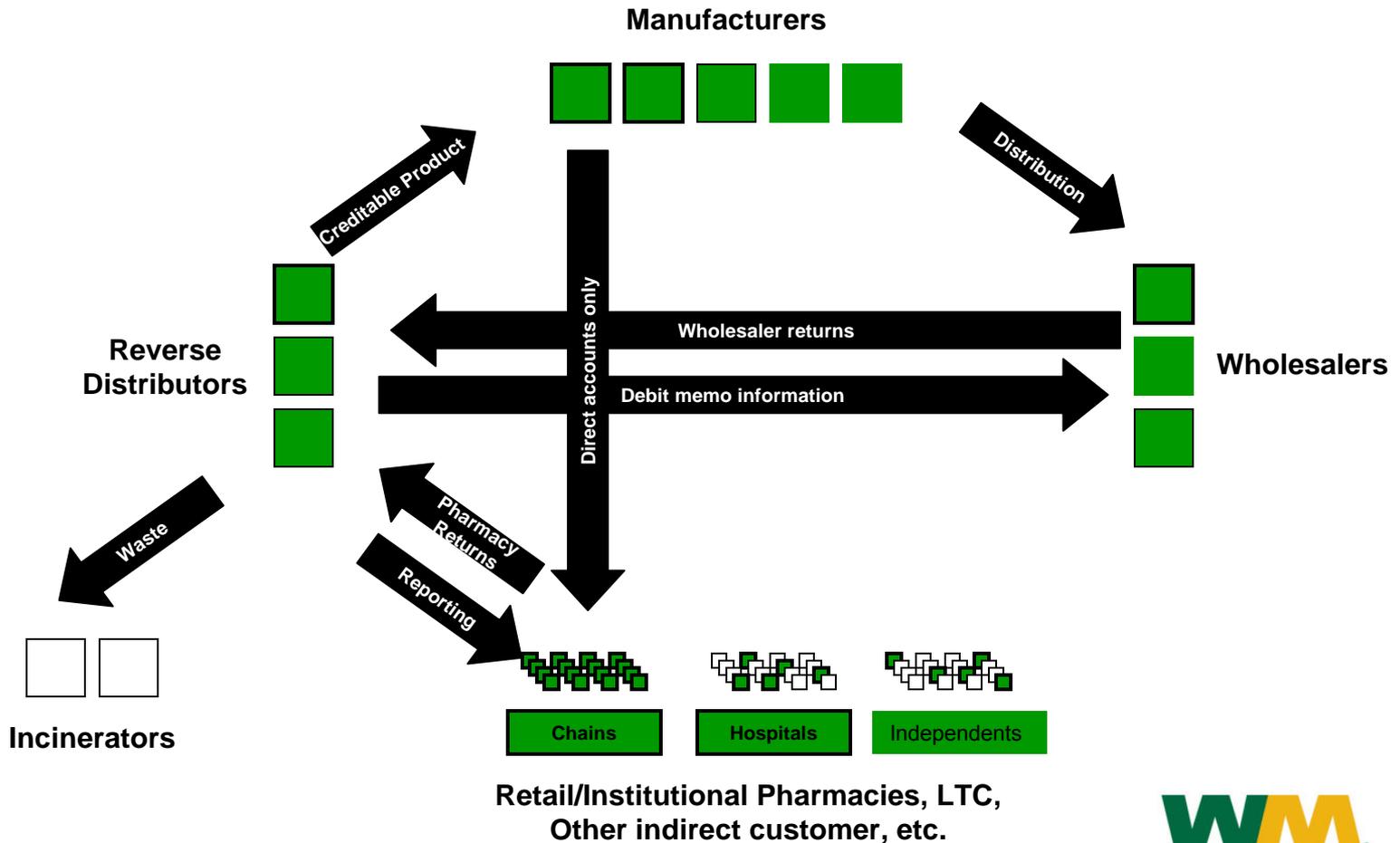
Large quantity hazardous waste generator (not
TSDF)

Complete inventory returned to pharmacy



Process Overview

Rx Industry Distribution and Reverse Distribution Model



When is an Outdated Drug a Waste?

At the time and place the decision is made to
discard it

Two EPA guidance letters to the industry:

Merck & Co., 1981

BFI Pharmaceutical, 1991

Enables shipping of potentially creditable
outdates to a reverse distributor as product

PROHIBITS the shipping of waste-like items,
such as unused IVs, partial vials, expired
repacks, samples

Hospital is liable for using due diligence in
selecting a vendor





Non-returnable
Waste

Returnable Expired
Product



Where is Pharmaceutical Waste Generated in a Hospital?

Pharmacy/Satellites

Patient Care Units

ER/OR

ICU/CCU/NICU

Oncology/Hematology, Ambulatory OR, and other outpatient clinics

Radiology

Satellite Medical Clinics

Long Term Care Facilities



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

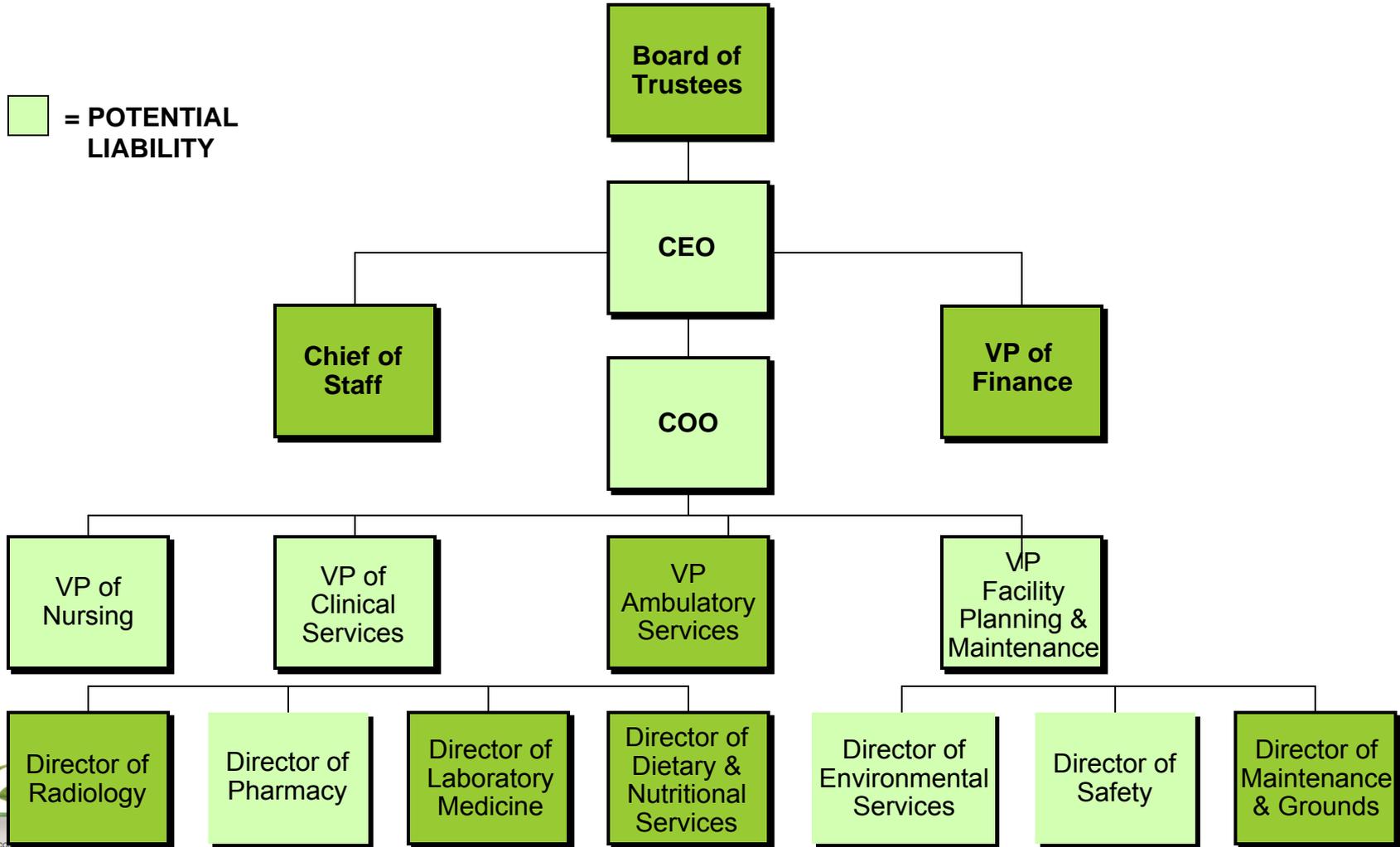
No statute of limitations

Managers up through CEO liable

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



Potential Liability for Rx Hazardous Waste Management



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



Listed Hazardous Pharmaceutical Waste

P-listed Chemicals

Sole active ingredient

Examples:

Arsenic trioxide

P012

Nicotine

P075

Warfarin

(conc. greater 0.3%)

P001

U-listed Chemicals

Sole active ingredient

Examples:

Chloral Hydrate (CIV)

U034

Cyclophosphamide

U058

Lindane

U129



Characteristic Hazardous Waste

Ignitability: $\geq 24\%$ alcohol, oxidizers, flammable propellants

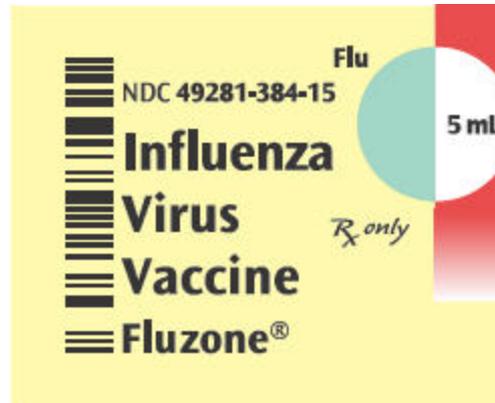
Corrosivity: $\text{pH} \geq 12.5$ or ≤ 2

Toxicity: Heavy metals and other chemicals specifically listed with individual leaching concentrations prohibited
Mercury, barium, selenium, chromium, etc.

Reactivity: Nitroglycerin in finished dosage forms excluded federally and in Texas



Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



Heavy metals: selenium, chromium and silver

Preservatives: thimerosal & m-cresol

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

Stickers Applied Manually



How Should RCRA Hazardous Waste be Handled?

Need a new waste stream in Pharmacy, Patient Care Areas, Oncology Clinics

RCRA Hazardous Waste: Toxic

P, U, toxic Ds, (all Chemotherapy Residues, Chemo Spills)

RCRA Hazardous Waste: Ignitable (D001)

Hazardous waste vendor develops a waste profile that includes all possible waste codes



How Should RCRA Hazardous Waste Be Disposed?

Either contract with a hazardous waste broker or develop internal expertise for:

- Waste profiling

- Manifest preparation

- Land ban preparation

Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)



Labeling the Pharmacy Shelves

Avery Standard Shipping labels



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

ORD# 5886072
666666

6157003410

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

ORD# 5886120
666666

1190010008

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

ORD# 5886080
666666

00163032630

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

ORD# 5886074
666666

0090-069283



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 contracted vendor

**SPECIAL DISPOSAL
REQUIRED**



Courtesy North Memorial Health 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 & $< \text{or} = 1$ kg/month “P” listed waste.

Conditionally Exempt Small Quantity Generator (CESQG) : Generates $< \text{or} = 100$ kg haz waste/month, $< \text{or} = 1$ kg 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

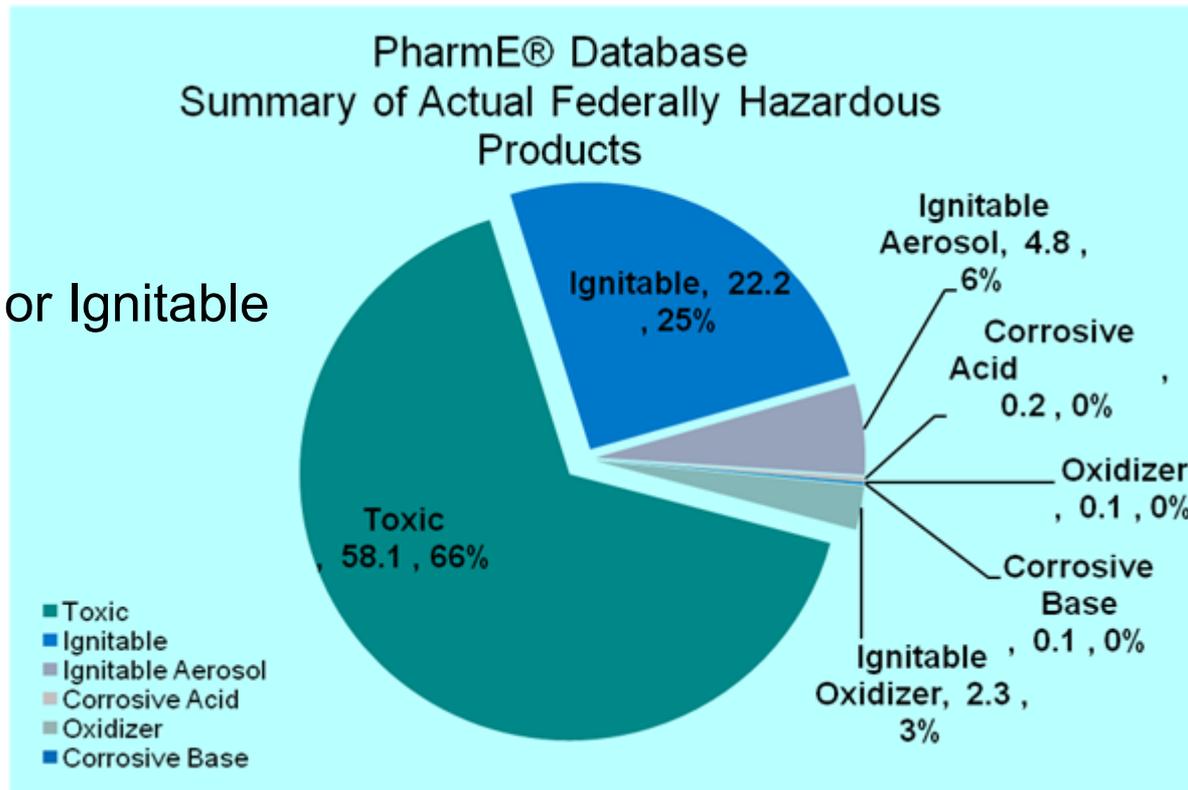
Ship commingled as UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II

Ship any corrosive acids/bases or oxidizers separately



Percentage of Hazard Categories in 149 Hospitals (2008)

97% Toxic or Ignitable



Hazardous Pharmaceutical Waste Storage Accumulation



Examples of Non-Hazardous Pharmaceutical Waste Collection & Storage



Resources

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?

Charlotte A. Smith, R. Ph., M.S.
Director, PharmEcology Services
WM Healthcare Solutions

www.pharmecology.com

414-292-3959

csmith@pharmecology.com



Alternative Methods for Managing Unused Pharmaceuticals – Consumers



Jeff Gloyd, MPH
Manager, Community Programs
WM Healthcare Solutions, Inc.

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Alternative Options for Consumers

Common Goals:

To get unused drugs out of the house

Avoid accidental poisonings

Avoid unintended use

To provide alternative options to flushing

An education/awareness tool

Currently very difficult to know if it would impact environment at all.

Consumer behavior and desire



Success

Accessible

Cost effective

Simple to operate

Legal



Alternative Options for Consumers

- 1) One-time/Irregular Community Collection Events
- 2) Permanent Collection Facilities
 - Kiosk/drop box
 - Household Hazardous Waste (HHW) event
- 3) Mail-back Programs
- 4) Trash (municipal waste)
- 5) Other (need for regulatory direction/action)



Other –Regulatory Action and Direction Needed

Pharmacists – some taking back drugs

HHW program – dissolve in acid, controlled included

– take back all drugs in 5-gal pail, landfill

Kiosks – outside



Irregular Community Collection Events

Drive-through or drive-up day time operation

To accept controls: requires law enforcement

Immediate segregation into controlled/possibly controlled substances and other drugs.

Law enforcement must secure controlled substances and witness/document disposal.

Various levels of sorting and inventorying collected items.



Irregular Community Collection Events

Regulatory Requirements:

Contact Waste Permits Division of TCEQ.

Requirements may differ depending on if event accepts HHW or only drugs.

Most examples of this event co-mingle all non-controlled pharmaceuticals.

Disposal choice:

- Permitted hazardous waste incineration if part of HHW event.
- Other options if an independent collection.



Irregular Community Collection Events

Pros:

- Alternative to flushing
- Reduced opportunity for poisoning or diversion (in some cases)
- Education and awareness
- Develop community partnerships (law enforcement, other)

Cons:

- No effect on excretion of meds (environmental impact questionable)
- Need law enforcement involvement for controlled substances
- Sorting may be necessary in most areas (controlled vs. non)
- Can be costly
- Need for transportation and disposal



Irregular Community Collection Events

Discussion point:

Can this work for Texas?



Permanent Collection Facilities - Drop Boxes/Kiosks

Examples of locations:

Pharmacies

Long-Term Care Facilities

Police stations/sheriff's offices

Most can't accept controlled substances (except law enforcement office)

Co-mingling of hazardous and non-hazardous pharmaceuticals likely to occur.

Regulatory Requirements: Contact TCEQ Waste Permits Division for direction.



Permanent Collection Facilities - Drop Boxes/Kiosks

E.g. Retail Pharmacies, King County, WA:

Mechanism for refusing controlled substances

Consumers place drugs in tray

Pharmacy staff immediately inspect with customer present

Pharmacy staff refuse controlled substances (consumer keeps material not accepted)



Permanent Collection Facilities - Drop Boxes/Kiosks

Pros:

- Alternative to flushing
- Reduced opportunity for poisoning or diversion (in some cases)
- Education and awareness
- Accessible
- Brings customers into store

Cons:

- Can't accept controlled substances (law enforcement not onsite).
- Training staff to segregate accepted from not-accepted substances and available time.
- Cost of boxes and disposal services.
- May require TCEQ authorizations.
- Doesn't address excretion component.



Permanent Collection Facilities - Drop Boxes/Kiosks

Discussion point:

Can this work for Texas?



Permanent Collection Facilities - via HHW event/station

Pros:

- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Can choose to accept or refuse certain drug/waste types if staff trained to identify those while customer waits.
- Provides alternative to flushing.
- Disposal facility and transport/disposal arrangements already established.

Cons:

- Can't accept controlled substances (law enforcement not onsite).
- If co-mingle waste, must all be transported/disposed of as hazardous.
- Training staff to segregate accepted from not-accepted substances.
- Cost
- May require TCEQ authorizations.
- Doesn't address excretion component.



Permanent Collection Facilities - via HHW event/station

Discussion point:

Can this work for Texas?



Mail-Back

For example, pre-paid mailing envelopes offered in pharmacies, clinics, nursing homes etc.

Consumers place unused drugs in envelope & post them back to pre-determined location.

Mail received at collection location & destroyed.

Example: Maine

Goes through USPS – considered secure.

US DoJ DEA approved to accept controlled substances.

Example: Illinois

Goes to incinerator in Texas; no controlled substances allowed.



Mail-Back

Pros:

- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Provides alternative to flushing.
- May be good option for people with limited access (e.g. place envelopes in nursing homes, or with in-home care providers).

Cons:

- May not be able to accept controlled substances.
- Cost
- May require TCEQ authorizations.
- Doesn't address excretion component.



Mail-Back

Discussion point:

Can this work for Texas?



Household/Municipal Trash

Federal guidelines provide step-by-step instructions about how to dispose of unused drugs in household trash.

Examples are mostly consistent:

White House Office of National Drug Control Policy

Food & Drug Administration

SMARxT Disposal partnership

<http://www.smarxtdisposal.net/>



Household/Municipal Trash

Should include significant education component

Examples:

Potential posters or brochures in pharmacies, clinics, nursing homes, police stations.

Labeling

Webpage & consistent messages across State/local agencies.

In home disposal kits.



Household Trash Combined with Education

Pros:

- Gets unused drugs out of house (may avoid potential for accidental poisoning and/or diversion).
- Provides alternative to flushing.
- Consistent with Federal disposal guidelines.
- No additional cost for consumer (except household waste collection/disposal fees)
- No authorizations or rule changes required.

Cons:

- Cost of advertising, webpage development, coordinating State staff member.
- Need support from all relevant state agencies, local government, law enforcement (all stakeholders).
- Recommendations based on current knowledge (will need to be flexible in future if knowledge base changes).
- Doesn't address excretion component.



Household Trash Combined with Education

Discussion point:

Can this work for Texas?



Summary/Discussion

Any other options for Consumers, Utilities, Government Bodies?

When assessing alternatives we should consider:

What is the effect, if any, on public health?

What is the effect, if any, on the environment?

Feasibility and long-term sustainability

What should be the measures of success?



Questions?

Contact information:

Jeff Gloyd, MPH
Manager, Community Programs
1021 Main Street
Suite 1070
Houston, TX 77002
713-202-3469 (cell)
jgloyd@wm.com

