WMSS PharmEcology

Managing Pharmaceutical Waste: What Healthcare Laundry Facilities Need to Know

Charlotte A. Smith, R. Ph., M.S.
csmith@pharmecology.com
713-725-6363

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HLAC Webinar

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WASTE MANAGEMENT

HEALTHCARE LAUNDRY ACCREDITATION COUNCIL HLAC

AMERICAN REUSABLE TEXTILE ASSOCIATION

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

Senior Regulatory Advisor
PharmEcology Services
WM Sustainability Services

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What You Will Learn Today

How handle waste received in the laundry

- Types of waste found in laundry
- Employee safety concerns
- Federal/State/Local waste regulations
- Critical waste policy decisions for your laundry
- What should be in your customer contracts?

Brattleboro Reformer

Cheshire Medica for hazmat violati

$200K

Posted Wednesday, November 4, 2015 8:51 am

By Reformer Staff

KEENE, N.H. >> Cheshire Medical Center agreed to a $200,000 penalty for the improper disposal pharmaceutical waste.

According to a press release from N.H. Attorney General Joseph A. Foster and Commissioner Thomas S. Burack of the New Hampshire Department of Environmental Services a Merrimack County Superior Court judge approved a consent

Environmental officials issue penalties to 2 hospitals

Associated Press • Published: September 29, 2015 1:20 AM CDT • *Updated: September 29, 2015 1:20 AM CDT*

0 shares

DOVER, Del. (AP) — State environmental officials have issued penalties to two Delaware hospitals for hazardous wa

Officials say Bayhealth Kent Gener
Hospital in Wilmington for haza
appeal the penalty orders.

Kent General has been ordered t
and just over $11,000 in cost recov
identified 22 violations regarding hand

St. Francis has been ordered to pay a penalty of just over $13,000 and nearly $2,000 in cost recovery after inspector found 10 violations

$73,509

If the Facility Generates It, You May Receive It!

- Sharps: syringes with needles, lancets, scalpels, etc.
  - Employee risk from potentially infectious material
- Drugs: vials, ampules, syringes, patches, IV bags, inhalers, etc.
  - Is the drug an OSHA employee hazard?
  - Is the drug a chemotherapy agent?
  - Is the drug a hazardous waste?
  - Is the drug a controlled substance?
- What are your management options?
- What should be in your agreement with your client?

Regulatory Agencies that Oversee Pharmaceutical Waste Management in Healthcare

Environmental Protection Agency (EPA)

Resource Conservation & Recovery Act (RCRA)

State Environmental Protection Agencies

Department of Transportation (DOT)

Drug Enforcement Administration (DEA)

Occupational Safety and Health Administration (OSHA)

Local Publicly Owned Treatment Works (POTW)

Pharmaceutical Waste Basics

What Does *Hazardous* Mean?

Biohazardous: Potentially infectious; e.g. used needles, contaminated linens

OSHA Hazardous: Potentially hazardous to employees if exposed: e.g. chemotherapy

EPA Hazardous: Defined as hazardous to the environment under the Resource Conservation & Recovery Act (RCRA); e.g. some chemotherapy drugs

DOT Hazardous: Poses a hazard in shipping; e.g. flammable items

What Is the Difference Between Regulated Medical Waste and Hazardous Chemical Waste?

Regulated Medical Waste aka Red Bag, Red Sharps:

- Known infection risk, other potentially infectious material (OPIM)
- Rules, regulations, and enforcement at the state level
- Pathology waste, needles, linens, used devices
- All linens received from a healthcare facility should be considered OPIM from an employee protection perspective but SHOULD NOT be discarded in the red bag

Hazardous Chemical Waste:

- Chemicals, including pharmaceuticals, that are defined as hazardous waste from an environmental perspective
- Regulated federally by the Environmental Protection Agency (EPA) and all state agencies except Iowa and Alaska

RMW vs Hazardous Waste Vendors

Regulated Medical Waste Vendors:

- May autoclave or microwave all RMW except pathological waste and trace chemotherapy waste
- May incinerate all RMW including pathological and trace chemotherapy waste
- MAY be permitted to treat non-hazardous pharmaceutical waste at incinerators; not at autoclaves or microwaves
- Permitted by the states; incinerator also permitted by federal government under the Clean Air Act and must meet federal MACT standards (Maximum Allowable Control Technology) for emissions control

Hazardous Waste Vendors:

- Must be permitted at the federal level for hazardous waste receipt and destruction at high temperature
- May also be permitted at the state level for incidental RMW
- Can receive both hazardous and non-hazardous pharmaceutical waste

Commonly Used Pharmaceutical Waste Streams

Hazardous Pharmaceutical Waste

Non-Hazardous Pharmaceutical Waste

Trace Chemotherapy Waste

Regulated Medical Waste

EPA's Resource Conservation & Recovery Act (RCRA)

Definition of hazardous waste applies to approximately 5% of drugs

Increased enforcement by EPA and state agencies

Immediate compliance risk including significant fines for non-compliance - $40,779 per violation per day plus up to $93,750 additional for economic benefit of non-compliance

Proposed Management Standards for Hazardous Waste Pharmaceuticals to be finalized in 2018

Your clients **should** have a robust pharmaceutical waste management program!

Your contracts should prohibit the shipment of pharmaceutical waste and should provide specific language for non-conforming waste management


THE VIAGRA IN THE WATER MAKES ME WANT TO SWIM UPSTREAM, BUT THE PROZAC IS MAKING ME TOO TIRED...
Rx
WASTE

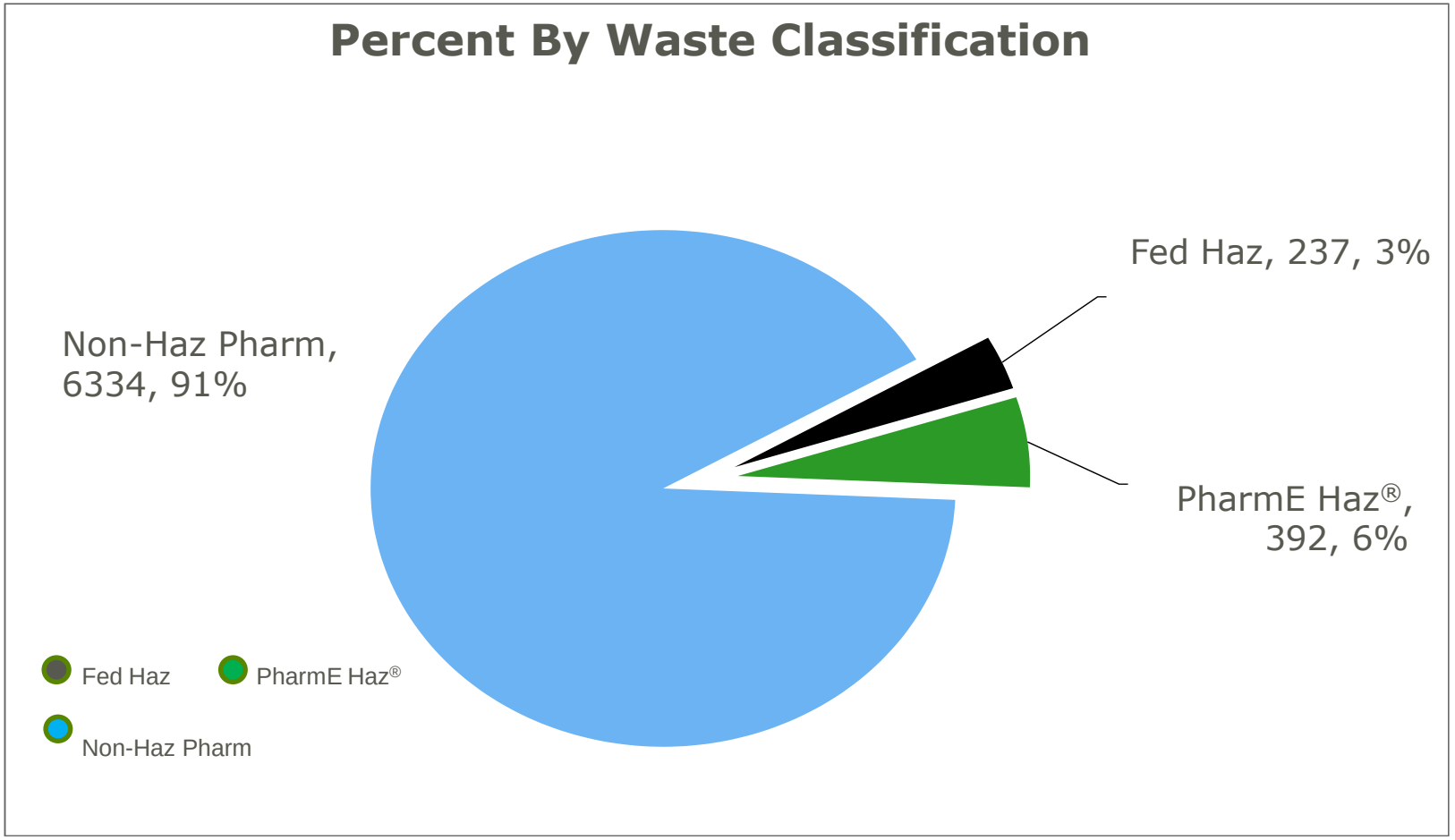
State-Specific Regulations

The following states have regulations that exceed the federal definitions of hazardous waste and are applicable to waste pharmaceuticals:

California	Michigan
Colorado	Minnesota
Connecticut	Oregon
Hawaii	Rhode Island
Maine	Washington State

NOTE: These designations do not address those states, counties, or municipalities that overtly prohibit sewering of non-hazardous pharmaceutical waste. As a best practice, PharmEcology recommends sewering ONLY hydration fluids containing sugars and electrolytes.

Typical Summary By Waste Classification



Three Types of Chemotherapy Waste

Trace Chemotherapy Waste (yellow container)

- 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 container)

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

Spill Clean-up (black container)

- Manage as RCRA Hazardous Waste

Managing Trace and Bulk Chemotherapy Waste

Bulk Chemotherapy, Spill Clean-up (Hazardous Waste)

Spill clean-up materials
Overtly contaminated linens, disposable gowns, gloves

Federally Permitted Hazardous Waste Incinerator

Trace Chemotherapy Waste (Regulated Medical Waste)

Needles/Syringes, empty IV bags, vials, ampules

Trace contaminated disposable gowns, gloves

Medical Waste Incinerator

Summary of Pharmaceutical and Related Waste Streams Potentially Received by Laundries

Chemo Linens Contaminated

Pre-wash cycle

Normal wash cycle

Compatible Hazardous Waste

- RCRA
- Bulk chemo
- Haz/Chemo spill clean-up
- **NO NEEDLES**

- Pressurized aerosols

Controlled Substance Wastage

Contents of Sequestration Device (Rx Destroyer, Etc.)

Non-Hazardous Pharm Waste

All non-RCRA

Trace Chemo (Sharps)

- Empty chemo vials, IVs ampules, syringes and needles
- PPE
- Tubing
- Wipes
- Packaging

- **NO BULK CHEMO**

Red Sharps

- Empty syringes with needles
- Empty non-chemo drug vials, ampules

- **NO DRUGs**

Municipal Solid Waste

- Most packaging
- Most empty plastic, IVs
- Paper
- Plastic

- **NO DRUGS**

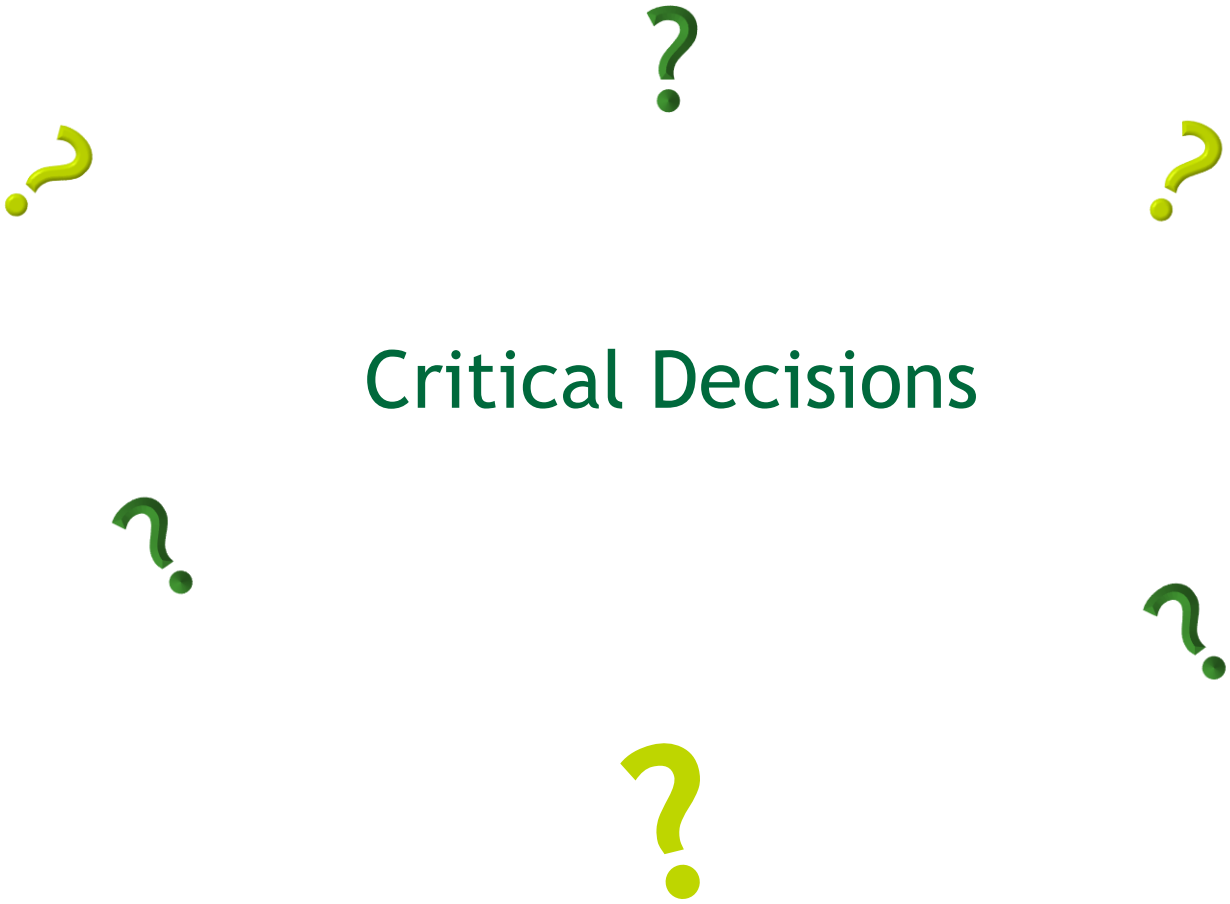
Sewer System

- IVs
  - Dextrose
  - Saline
  - Sterile Water
  - LR
  - K, Ca, Mg salts

- **NO OTHER DRUGS**

Sewerable Seven: These IV Solutions Can be Sewered

- Dextrose
- Saline
- Sterile Water
- Lactated Ringer's
- K^{+} (potassium) salts
- Ca^{++} (calcium) salts
- Mg^{++} (magnesium) salts



Critical Decisions

Critical Decisions

Can the laundry send the drug waste back to the facility?

No legal pathway for return to the facility.

Will the laundry take “ownership” of the drug waste?

Will the laundry segregate hazardous pharmaceutical waste from non-hazardous pharmaceutical waste?

Implications of Taking Ownership of the Waste

Laundry becomes the generator of the waste

Either make a waste determination whether or not the waste is a hazardous waste

OR

Manage, manifest, and ship any pharmaceutical waste as a hazardous waste

Charge the healthcare facility for all related costs

Additional regulations apply and must be understood but are not terribly onerous at the level of generation involved

Implication of Not Taking Ownership of the Waste

The laundry would notify the hospital of the receipt of the pharmaceutical waste

Ideally the laundry would still check to determine if the drug is a hazardous waste.

If yes, the drug would be stored in a small hazardous waste container. It would be shipped asap from the laundry by a hazardous waste transporter but under a manifest ***listing the healthcare facility as the generator***.

The transporter would have to fully understand the difference between the generator and the shipping location and would prepare the waste profile, manifest, and land disposal restriction form.

The cost of such a small pick up would be very high on a per pound basis.

Implication of Not Taking Ownership of the Waste

Non-hazardous waste could be accumulated together and a fee charged to the healthcare facility prorated for their contribution to the total cost of managing the non-hazardous pharmaceutical waste.

IF the laundry does not make a waste determination, all pharmaceutical waste must be assumed to be hazardous and shipped individually as hazardous waste listing the healthcare facility as the generator.

This is a very expensive option for your clients but could lead to tighter controls at their facility.

RMW

Trace Chemo

Managing Specific Waste Streams

Hazardous Rx

Sharps

How to Identify and Manage Trace Chemotherapy Waste

- Any non-drug item inadvertently found in the laundry bags labeled as “chemotherapy” must be placed into the yellow trace chemotherapy container
- Any drug item found in the “chemotherapy” laundry bags should be placed immediately into a ziplock bag, documented, and placed into the black hazardous waste container
- All disposable personal protective equipment worn while handling “chemotherapy” laundry bags must be discarded into the yellow trace chemotherapy container
- Consider providing both a plastic yellow hamper bag for PPE and soft items and a hard plastic yellow sharps container for empty drug vials, ampules, or needles/syringes found in the “chemotherapy” linens

How to Identify and Manage Hazardous Pharmaceutical Waste

- Ideally, the laundry should have access to some type of database that can provide information on a particular drug in terms of its hazardous or non-hazardous waste status based on EPA and state regulations
- Assuming this is the case, any drugs discovered in the linens should be segregated, transferred to a manager, a photo taken to document, and then the manager should look up the drug and determine its hazardous waste status
- Some databases also offer information on whether the drug is a NIOSH hazardous material from an OSHA perspective
- The assumption should always be made that employees need to be protected through appropriate training and PPE

How to Identify and Manage Hazardous Pharmaceutical Waste

- Drugs that designate as a hazardous waste should be stored in a black container designed for that purpose (available from Covidien, BD, and other sources).
- The date a drug is first placed into the container must be noted and a log should be kept of the generic name of the drug (as opposed to the brand name). The container should be stored in a secured area.
- Depending on the state, additional information may also be needed.
- Assuming the laundry is a CESQG (conditionally exempt small quantity generator) of hazardous waste, the waste can be shipped when the container is full, regardless of storage time.
- A permitted hazardous waste vendor should be contracted to complete the waste profile, shipping label, land disposal restriction form, and shipping manifest.

How to Manage Non-hazardous Pharmaceutical Waste

- Once a waste categorization has been confirmed through an appropriate database, all non-hazardous pharmaceutical waste can be accumulated in an appropriate non-hazardous pharmaceutical waste container (usually blue or white).
- The area in which the pharmaceutical waste is stored should be secured with limited access.
- There is no storage accumulation time limit.
- The non-hazardous pharmaceutical waste should be managed by either a regulated medical waste company with a permit to manage non-hazardous pharmaceutical waste or by a hazardous waste transporter.
- The non-hazardous pharmaceutical waste should be incinerated at either a permitted regulated medical waste or waste-to-energy facility. It can be incinerated at a hazardous waste facility but usually at a higher cost.

Storage Accumulation Area

Secured area for storage of filled and sealed hazardous waste containers

No time limit for conditionally exempt small quantity generators

Should be labeled as Hazardous Waste and include the date entered into the storage accumulation area (check state regulations for any CESQG time limits)

Choosing a Hazardous Waste Vendor

Hazardous waste vendors/brokers available throughout the country

Only SIX hazardous waste incinerators

Choose a vendor with extensive experience managing hazardous pharmaceutical waste from healthcare facilities

Ask for references and check them!

Vendor should provide a comprehensive hazardous waste profile based on their knowledge of typical hazardous pharmaceutical waste from healthcare facilities

OR they may “lab pack” the pharmaceutical waste at the time of pick up

Vendor should generate the shipping label and manifest

Hazardous waste vendors MAY be able to accept biohazardous waste; RMW vendors CANNOT accept hazardous waste as such but may “sub” it out to a hazardous waste vendor

REQUIRE the vendor to supply their EPA ID number, final destination of the waste

The waste is tracked “cradle-to-grave” on a six-part manifest

How Do You Manage Controlled Substances?

CII, CIII, CIV, CV

- Controlled substances are those drugs which the Drug Enforcement Administration considers to be drugs of abuse and are assigned schedules I through V.
- Schedule I drugs have no recognized medical use and will not be used in your clients' facilities, with the possible exception of medical marijuana.
- Schedules II through V are in order of descending abuse potential and should be tightly managed by the healthcare facility's pharmacy department.
- Vials and ampules from the manufacturer will have the distinctive upper case C with the appropriate Roman numeral, such as CII, on the label. The name of the drug can also be checked against a database to determine its status

How Should Controlled Substances be Managed?

- The DEA's Drug Disposal Rule of 2014 considers drugs that have been charged out to the patient out of the pharmacy's inventory and also out of the DEA's closed loop system.
- These drugs are terms "wastage" and the primary responsibility you have is to prevent diversion.
- Consider purchasing one of the sequestering devices, such as Rx Destroyer, to manage the few controlled substances you might receive. Record the name, strength, and quantity of the drug and double witness the sequestration.
- The majority of controlled substances are non-hazardous pharmaceutical waste and the device can be disposed in the non-hazardous pharmaceutical waste container when discarded.

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Managing Other Potentially Infectious Medical Waste (OPIM)

- All incoming linens should be considered to be OPIM
- Imbedded sharps and other miscellaneous objects pose a special risk of employee exposure
- Provide and DOCUMENT required Blood Borne Pathogen training to all employees
- Provide appropriate personal protective equipment to potentially exposed employees
- Include specific procedures for sharps, scalpels, devices, etc.

Hazards of Not Requiring Haz Mat Training and Personal Protective Equipment

- Responsibility under the OSHA General Duty Clause, Hazard Communication Standard
  - Right to know,
  - Right to understand
- Employee exposure to infectious material, including needlesticks
- Employee exposure to hazardous drugs
  - Chemotherapy, hormonal agents
- Provide and require appropriate personal protective equipment for all employees potentially handling either OPIM or hazardous drugs

Managing Potentially Infectious Medical Waste (PIM)

- Assume all linens are OPIM and wear appropriate PPE
- Pre-wash all linens labeled as “chemotherapy” then re-wash with regular laundry
- Manage non-chemotherapy sharps of all kinds in a **red sharps container** labeled as biohazardous
- Manage TRACE chemotherapy waste in a **yellow sharps container** labeled as “trace chemotherapy” and biohazardous
- Contract with an appropriate regulated medical waste transporter for treatment to a permitted autoclave, microwave, or RMW incinerator for red sharps containers; **RMW incineration only** for yellow trace chemotherapy containers
- Manage manifests based on state regulated medical waste regulations

Summary

- Pharmaceutical waste is recognized as a waste stream that is complex and needs specific management expertise.
- Multiple regulatory agencies are involved in pharmaceutical waste management, including EPA, DEA, OSHA, NIOSH, DOT, and state environmental protection agencies.
- You and your healthcare facility clients have liabilities and responsibilities that can only be managed well with increased awareness and understanding of the regulations.
- Your employees need to be protected from exposure to both potentially infectious materials and hazardous chemicals.
- Consider this information a starting point on a journey to a safer and more compliant operation!
- References and Appendix

WASTE MANAGEMENT

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Questions?

Charlotte A. Smith, R. Ph., M.S.
Senior Regulatory Advisor
WMSS PharmEcology Services
csmith@pharmecology.com
713-725-6363

References

NIOSH Hazardous Drug List 2016

- http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf

OSHA Hazardous Drug Information

- https://www.osha.gov/SLTC/hazardousdrugs/

DEA Drug Disposal Rule and Industry Clarification Letter:

- http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf
- http://www.aha.org/advocacy-issues/letter/2014/141006-let-disposal.pdf
- http://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf

Proposed EPA Hazardous Waste Pharmaceutical Rule

- https://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals

Final Rule: EPA Hazardous Waste Generator Improvements

- https://www.epa.gov/hwgenerators/final-rule-hazardous-waste-generator-improvements

WMSS PharmEcology Services

- www.pharmecology.com
- FAQs, state and federal waste regulations, subscription search engine

Appendix


WASTE MANAGEMENT


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ARTA
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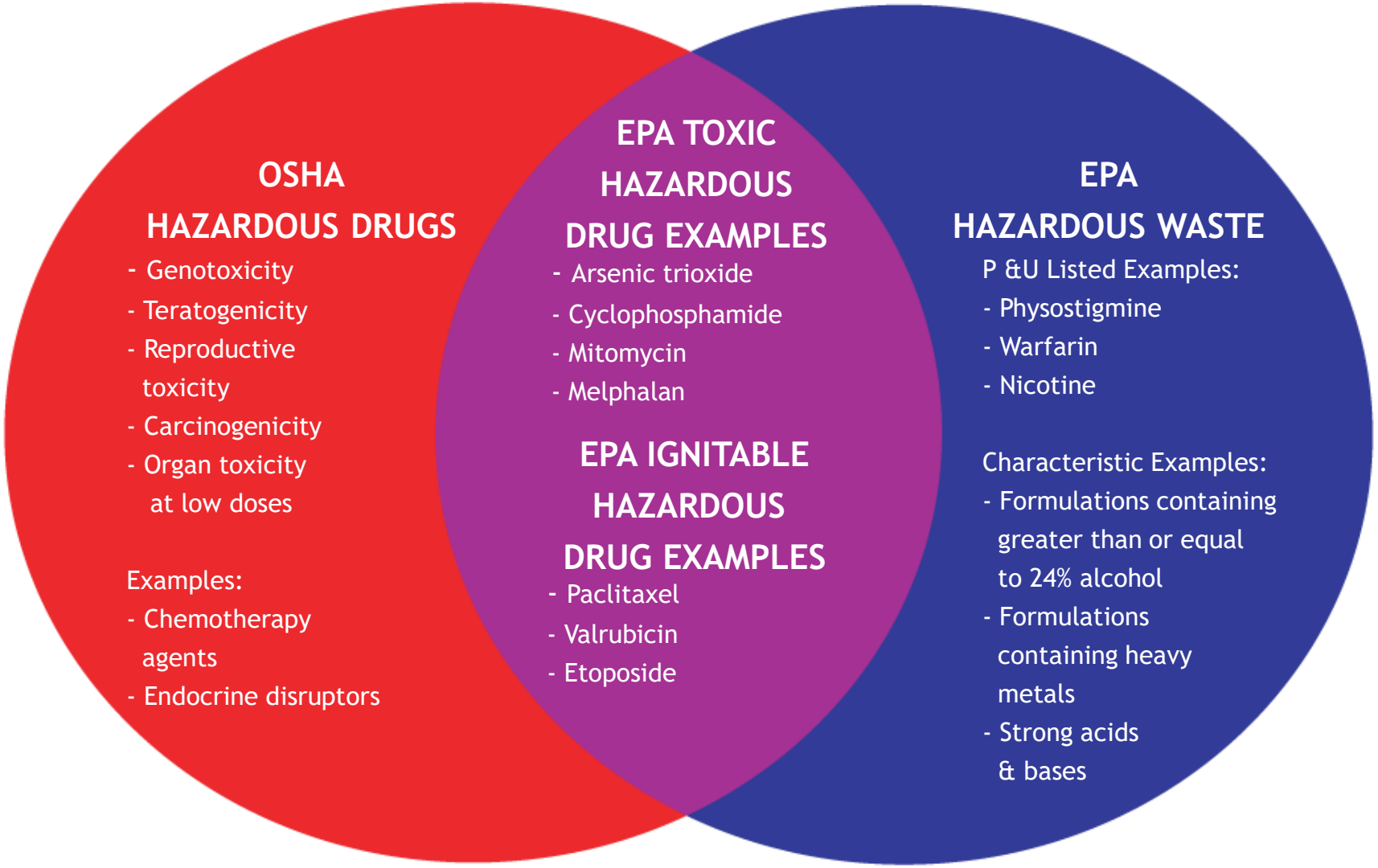
Hazardous Drugs vs. Hazardous Waste
Where OSHA & EPA Meet



Which Discarded Drugs Become Hazardous Waste Under RCRA?

P-listed chemicals (acutely hazardous)

- **Sole active ingredient; unused; empty containers**

U-listed chemicals (toxic)

- **Sole active ingredient; unused**

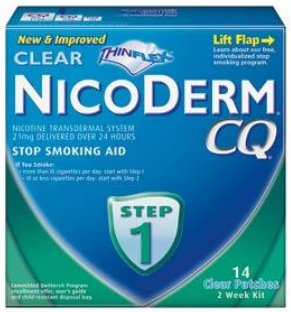
Pharmaceuticals with *characteristics* of hazardous waste: Carry D codes

- Ignitability
- Toxicity
- Corrosivity
- Reactivity

Examples of P- and U-listed Drugs

P-listed Drugs

Arsenic trioxide	P012
Nicotine	P075
Physostigmine Salicylate	P188
Warfarin >0.3%	P001



U-listed Drugs (partial list)

Chloral hydrate (CIV)	U034
Chlorambucil	U035
Cyclophosphamide	U058
Daunomycin	U059
Melphalan	U150
Mitomycin C	U010
Streptozotocin	U206
Lindane	U129
Selenium Sulfide	U205

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. (**Physostigmine ampules**)

Definition of “Empty” (cont’d)

“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” Mitomycin vial would be “trace” chemotherapy**

Residue of “P” or ”U” listed drugs in a used syringe is exempted federally and should be discarded as biohazardous waste or trace chemo, depending on the drug. (Check with state)

Characteristics of Hazardous Waste

Ignitability: Aqueous solution containing 24% alcohol or more by volume and flash point < 140° F, D001

- E.g. alcohol hand sanitizer, ethyl chloride spray, flammable and pressurized aerosols (Hurricane spray, etc.)

Toxicity: Lists of certain drugs and heavy metals in above specific concentrations

- Flu Vaccine, Multi-dose: thimerosal preservative (mercury)
- Human Insulin: m-cresol preservative
- Nutritionals containing chromium and/or selenium depending on concentration e.g. Centrum Silver®
- Heavy metals: selenium, chromium, and silver e.g. Selsun Shampoo, SSD Cream

Corrosivity: An aqueous solution having a pH ≤ 2 or ≥ 12.5, D002

Reactivity: No drug products

Examples of Characteristic Hazardous Wastes (D-coded)

Toxicity

Multi-dose Flu Vaccines (thimerosal preservative)

Human insulin(m-cresol preservative)

Silver Sulfadiazine cream(silver)

Multivitamin/mineral preparations (chromium, selenium)

Ignitability

Paclitaxel prior to dilution

Antibiotic topical preparations

eg. Clindamycin Topical Solution

Many alcohol-based gels

Pressurized aerosol inhalers

Dual Hazardous Waste

An unused needle/syringe that holds a hazardous waste

- Example: Physostigmine, Mitomycin, Insulin

Waste is both biohazardous and EPA RCRA hazardous

Must dispose in a container designed and labeled for both (add biohazard label)

Final Disposition of Pharmaceutical Waste Streams

Compatible Hazardous Waste*	Aerosols	Trace Chemo (Sharps)	Trace Chemo (Soft)	Non - Hazardous Drugs	Red Sharps	Municipal Solid Waste	Sewer System






- IVs
  - Dextrose
  - Saline
  - Sterile Water
  - Lactated Ringer's
  - K salts
  - Ca salts
  - Mg salts
- No other drugs

Federally Permitted Hazardous Waste Incinerator	Medical Waste Incinerator	Municipal Incinerator Permitted for Special Waste (inc. drugs)	Autoclave/ Microwave	Publicly Owned Treatment Works (POTW)
Ash	Ash	Ash	Shredded (Most states)	
Lined Hazardous Waste Landfill	Lined Non-Hazardous Waste Landfill			Water Supply

Hazardous Waste Generation Status

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

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

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

Laundries should be able to remain CESQG – no notification and reporting requirements

Documenting Generator Status

Large quantity generator: no need to record P waste separately.

Small or conditionally exempt small quantity generator: need to segregate all P-listed, including empty containers and document weights, per calendar month OR record the weights as they occur

Cannot exceed 1 kg or 2.2 lbs/month for any given month and cannot accumulate more than 1 kg P-listed waste

Generator Summary Chart:
http://www.epa.gov/osw/hazard/generation/summary.htm

Creating a Hazardous Waste Profile

The vendor will create a certified hazardous waste profile of all toxic & ignitable drug waste

A typical shipping description for commingled toxics and flammables is:

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

Ship any aerosols separately

How to Prevent Receipt of Radioactive Materials

- All of your clients should have Geiger counters installed in their facilities to assure that no “hot” linens leave the facility
- This requirement and responsibility should be written into your agreements

DOT Hazardous Waste Label

- If smaller black containers are being over-packed, the appropriate hazard class labels must be affixed to the final container along with the DOT hazardous waste label
  - For example, Flammable Liquid, Toxic, etc.

- The DOT hazardous waste label is provided and completed by the hazardous vendor at the time of pick up based on the waste profiles
- The generator is ultimately responsible for the appropriate shipping preparations and labeling

EPA's Proposed Rulemaking: Management Standards for Hazardous Waste Pharmaceuticals

Prepublication edition released August 30th, 2015

Official publication in the Federal Register published September 25th, 2015

Initial comment period was extended to December 24th, 2015

Largest change in the proposed management of hazardous waste pharmaceuticals since RCRA regulations were finalized in 1980

What Problems is EPA Addressing?

Healthcare facilities not managing hazardous waste pharmaceuticals in compliance with current regulations

Healthcare facilities sending hazardous waste pharmaceuticals to reverse distributors that is obviously not potentially creditable

Healthcare facilities drain disposing hazardous pharmaceutical waste

EPA sought comment on how to evaluate additional pharmaceuticals for inclusion into the regulations but that will be a separate rulemaking in the future

EPA's Creative Solution

40 CFR part 266 subpart P Management Standards for Hazardous Waste Pharmaceuticals

EPA is proposing "sector-specific" standards for the management of hazardous waste pharmaceuticals for:

1. Healthcare facilities/pharmacies, and
2. Pharmaceutical reverse distributors

Only those already considered to be a hazardous waste

The proposed rule will change how current hazardous waste pharmaceuticals are managed

EPA would prefer that facilities manage all pharmaceutical waste as hazardous waste but has not done a cost analysis which would demonstrate costs would be significantly higher, especially given some of the new proposed requirements

Which Pharmaceuticals Will Be Covered?

Only those already considered to be a hazardous waste

The proposed rule will change how current hazardous waste pharmaceuticals are managed

EPA would prefer that facilities manage all pharmaceutical waste as hazardous waste but has not done a cost analysis which would demonstrate costs would be significantly higher, especially given some of the new proposed requirements

State Implications

Proposed rule is more stringent than existing federal standards

States with authorized RCRA programs will be required to modify their programs to adopt the amendments

When a state adopts the new Subpart P, if elements of the state program are more stringent, the state will have the option of retaining those more stringent elements

States also have the option of adding elements to their programs that are more stringent or broader in scope than the new subpart

No state will be able to add HWPs to their universal waste programs - Florida and Michigan must rescind their universal waste programs

When Will The New Federal Regulations Take Effect?

Comment period ended Dec. 24, 2015

EPA will consider comments and publish final rule in the Federal Register, probably 2018

Rule will take effect six months after date of final publication*

States will begin adoption of the new regulation except for Iowa and Alaska, which are managed federally and will take effect six months after date of publication

*Except for ban on sewering of hazardous waste pharmaceuticals which will take effect nationally on the date of publication

New FINAL Generator Improvements Rule Published 11/28/16

- Replaces the phrase “conditionally exempt small quantity generator” (CESQG) with the phrase “very small quantity generator” (VSQG)
- Re-organization of the regulations so that all generator-related items into 40 CFR part 262 to eliminate current multiple cross-references
- Requirement to indicate the hazards of the hazardous waste, e.g. “flammable,” “toxic,” etc.
- Allows very small quantity generators (VSQGs) (currently conditionally exempt small quantity generators) to send hazardous waste to a large quantity generator (LQG) under the control of the same person for the purpose of consolidation
- Operative federally May 30, 2017; each state except Iowa and Alaska must adopt also

DEA Drug Disposal Rule

DEA Drug Disposal Rule took effect October 9th, 2014

Initial confusion regarding management of controlled substance waste in hospitals

IF controlled substance is part of inventory, must use reverse distributor to discard

IF controlled substance charged out to patient and not entirely consumed, considered “wastage” and up to facility to manage in a manner that prevents diversion

DEA Clarification Letter: October 17, 2014

"Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to **adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted.** For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage."

http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

DEA Clarification Letter: October 17, 2014

"…once a controlled substance has been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to a patient at the registrant's registered location, the substance is no longer in the practitioner's inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial **is not required to be destroyed in accordance with new Part 1317."**

Such wastage cannot be disposed in a receptacle for ultimate user collection

Controlled substances from the pharmacy's inventory cannot be disposed in a receptacle for ultimate user collection.

All destruction must be in accordance with Federal, State, tribal, and local laws and regulations