IMPLEMENTING A PHARMACEUTICAL WASTE PROCESS

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DISCLOSURES

Authors of this presentation have no disclosures concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation

OBJECTIVES

Review history of pharmaceutical waste disposal

Review best practice and regulations for the disposal of pharmaceutical waste

Identify medications and routes for disposal of pharmaceutical waste

QUESTION FOR THE AUDIENCE

Hospital vs Ambulatory

- How many have heard about RCRA hazardous waste?
- How many people have implemented a pharmaceutical waste program?
- How many people are in the process of implementing a pharmaceutical waste program?

Which type of pharmaceutical waste does the EPA consider to be the most hazardous?

- A. P-listed
- **B.** U-listed
- C. D coded
- **D.** Controlled substances

- Which of the following are disposed in black containers?
- A. Hazardous drug waste regulated by RCRA (Plisted, U-listed, and characteristic D coded wastes)
- **B.** Bulk chemotherapy waste
- **C.** Non-hazardous pharmaceutical waste
- **D. Biohazardous waste**
- E. A and B

- Which of the following can be disposed of down the drain?
- A. D5W/NS with KCI 40meq
- **B.** A partial PCA containing morphine
- C. D5W 50ml w/ ampicillin 500mg
- **D.** An unused TPN solution
- E. A and B

Which container should you use when discarding cleanup materials from a chemotherapy spill?









<u>Partial</u> chemotherapy vial labeled with is disposed in which container?









Partial ampicillin vial with no label, is disposed in which container?







PHARMACEUTICAL WASTE

Pharmaceutical waste is:

- No longer used for its intended purpose
- Designated for discard
- Not returnable for credit

Examples:

- Partial syringes, vials, tablets, creams, inhalers, IV bags, etc
- Discontinued meds
- Hospital repacks or pre-filled syringes
- Expired or unusable compounded medications

WHY IS THIS IMPORTANT?

Environmental

- Pharmaceuticals detected in soils and surface/ground waters
- A 2002 U.S. Geological Survey found organic waste water pollutants, including many pharmaceutical product contaminants, in 80% of streams sampled in 30 states
- Impacts include:
 - Effects on oocytes and testicular cells
 - Inhibition of growth in fish and plants
- Regulatory Fines
 - Noncompliance fines of \$37,500 per day, per incident

Halford, B. Side Effects. Chemical & Engineering News. February 25, 2008. Volume 86 Issue 8. p. 13-17. Accessed 11/20/15 at http://cen.acs.org/articles/86/i8/Side-Effects.html

Boxall, A. The environmental side effects of medication. EMBO Reports. December 5, 2004. p. 1110-1116. Accessed 11/20/15 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299201/

TOP 16 HOSPITALS WITH PENALTIES SINCE 1999

CONCORD HOSPITAL	\$205,000
NASSAU UNIVERSITY MEDICAL CENTER	\$124,000
RESEARCH MEDICAL CENTER	\$105,900
BARNES JEWISH HOSPITAL NORTH	\$90,176
CHILDRENS MERCY HOSPITAL THE	\$86,043
SHAWNEE MISSION MEDICAL CTR	\$83,488
FLORIDA HOSPITAL	\$69,958
AURORA BAYCARE MEDICAL CTR	\$66,500
FORMER WALTER REED ARMY MEDICAL CENTER	\$65,000
V A MEDICAL & REGIONAL OFFICE CENTER	\$50,000
USVA WILLIAM S MIDDLETON MEMORIAL HOSPITAL	\$48,000
MOUNTAINSIDE HOSPITAL	\$45,000
CLARKSON UNIVERSITY	\$45,000
ST ANTHONYS MEDICAL CENTER	\$42,952
DANBURY HOSPITAL	\$41,855
HUNTINGTON HOSPITAL	\$40,000

RIKNET. http://www.rtknet.org. Accessed 10/25/15

- **1.** Getting Started
- 2. Understanding Regulations and Best Managements
- **3. Drug Inventory**
- **4. Assessing Current Practices**
- **5. Management Options**
- 6. Communication and Education Plan
- 7. Audit and Follow-up

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GETTING STARTED

- Designing and implementing a successful pharmaceutical waste program starts with an interdisciplinary team
- Support from Senior Leadership
- Members of a pharmaceutical waste team
 - Pharmacy Managers
 - Environmental Services
 - Safety
 - Nursing
 - Educators
 - Infection Control

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REGULATORY BODIES THAT OVERSEE PHARMACEUTICAL WASTE

- Environmental Protection Agency (EPA)
- Department of Transportation (DOT)
- Occupational Safety and Health Agency (OSHA)
- Drug Enforcement Administration (DEA)State Environmental Protection Agencies

OSHA Hazardous Drugs

-Carcinogenicity -Teratogenicity -Reproductive toxicity -Organ toxicity -Genotoxicity

Examples: -Chemotherapy -Estrogens EPA Toxic Hazardous Drugs

Examples: -Arsenic -Cyclophosphamide -Mitomycin -Warfarin -Bulk chemo EPA Pharmaceutical Waste

<u>P&U Listed Examples</u>: -Epinephrine - Nicotine

OSHA. https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html Accessed 10/25/15 EPA. http://www.gpo.gov/fdsys/pkg/CFR-2012-title40-vol27/xml/CFR-2012-title40-vol27-sec261-33.xml. Accessed 10/25/15

RCRA

Resource Conservation and Recovery Act (RCRA)

Enacted in 1976

 Governs the management of solid and hazardous waste generated in the U.S.
 Regulated by the EPA

PHARMACEUTICAL WASTE CATEGORIES

RCRA Hazardous Pharmaceutical Waste

- Best Management Practice (BMP) Hazardous
 - Non-RCRA Antineoplastic Hazardous
- Best Management Non-Hazardous
 - Controlled substances
 - Biohazardous
 - Non-hazardous sewerables
 - Non-hazardous

EPA RCRA WASTE TYPES

Listed Wastes:

- P Listed
- U Listed

Characteristic Wastes:

- Exhibit hazardous properties
 - Ignitability
 - Corrosivity
 - Reactivity

Toxicity

P LISTED WASTE













Acutely Hazardous

Pharmaceutical	Waste Code
Arsenic trioxide	P012
Epinephrine base	P042
Nicotine	P075
Nitroglycerin	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine salicylate	P188
Warfarin >0.3%	P001

P LISTED WASTE

- Empty containers
 - Triple rinsed, and
 - The rinse is managed as hazardous waste
- Bottom-line



- Empty containers which held a P Listed medication MUST be managed as hazardous waste
- Dilute concentration
- Exceptions
 - Epinephrine Salt
 - Nitroglycerin

P LISTED WASTE

Exceptions

- Epinephrine Salt
 - EPA's Memo from October 15, 2007
 - EPA determined that the score of the P042 listing does NOT include epinephrine salt
- Nitroglycerin
 - Solely listed for its reactivity characteristic
 - Removed medical grade nitroglycerin off the P list

Hale, Matt, Scope of Hazardous Waste Listing P042 (Epinephrine) Memorandum, United States Environmental Protection Agency, Office of Solid Waste, October 15, 2007. May be accessed at http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6a5dedf2fba24fe68525744b0045b4af!

U LISTED WASTE

Pharmaceutical	Waste Code	Pharmaceutical	Waste Code
Chloral hydrate	U034	Paraldehyde	U182
Chlorambucil	U035	Phenol	U188
Cyclophosphamide	U058	Reserpine	U200
Daunomycin	U059	Resorcinol	U201
Dichlorodifluoromethane	U075	Saccharin	U202
Diethylstilbestrol	U089	Selenium sulfide	U205
Hexachlorophene	U132	Streptozotocin	U206
Lindane	U129	Trichloromonofluromethane	U121
Melphalan	U150	Uracil mustard	U237
Mercury	U151	Warfarin <0.3%	U248
Mitomycin C	U010		

U LISTED WASTE



U LISTED WASTE

Empty containers

All contents have been removed

No more than 3% by weight remains

Dilute concentration

Ignitability D001
Corrosivity D002
Reactivity D003
Toxicity Multiple D Codes

Ignitability D001

- Aqueous drug formulations containing 24% or more alcohol by volume and having a flashpoint of less than 140°F or 60°C
- Liquid drug formulations containing less than 24% alcohol with a flashpoint of less than 140°F or 60°C
- Oxidizers defined by DOT

 Flammable aerosol propellants defined by DOT

Ignitability D001















Corrosivity D002

- •pH of less than or equal to 2 or greater than or equal to 12.5
- Examples:
 - Potassium hydroxide
 - Trichloracetic acid



Reactivity D003Unstable under normal conditions

Toxicity Multiple D Codes

Pharmaceutical	Waste Code	Examples
Arsenic	D004	Arsenic trioxide
Barium	D005	Barium sulfate
Cadmium	D006	Mineral preparations
Chloroform	D022	No longer commonly used
Chromium	D007	Mineral preparations
Lindane	D013	Treatment of lice, scabies
M-cresol	D024	Preservative in human insulins
Mercury	D009	Vaccines with thimerosal, eye, ear preparations
Selenium	D010	Dandruff shampoo, mineral preparations
Silver	D011	Silver sulfadiazine cream

Toxicity Multiple D Codes













Empty containers

All contents have been removed

No more than 3% by weight remains

Dilute concentration

PPE AND SPILL MATERIALS

Personal protective equipment (PPE) and spill materials

- P or U listed hazardous waste
- Characteristic waste
BEST MANAGEMENT PRACTICE HAZARDOUS PHARMACEUTICAL WASTE

Antineoplastic

- Trace
- Bulk

TRACE CHEMOTHERAPY

Trace – Residual chemotherapy waste

- •3% or less of the total volume by weight of the container
- Examples
 - Empty vials
 - Gowns
 - Gloves



- Needles and syringes
- IV tubing and empty IV bags

BULK CHEMOTHERAPY

- Bulk More than residual chemotherapy waste
 - More than 3% of the total volume by weight of the container
 - Examples
 - Used chemo spill kits
 - Partial vials, bottles and IV bags
 - Partial chemo syringe
 - Saturated PPE



BEST MANAGEMENT PRACTICE NON-HAZARDOUS PHARMACEUTICAL

- Controlled Substances
- Biohazardous
- Non-Hazardous Sewerables
- Non-Hazardous

CONTROLLED SUBSTANCES

Regulated by the DEA

Disposal method must be render the controlled substance non-retrievable

Drain disposal





U. S. Department of Justice Drug Enforcement Administration Office of Diversion Control

www.dea.gov

September 9, 2014

Dear Registrant:

On September 9, 2014, the Disposal of Controlled Substances final rule was published in the *Federal Register*. The final rule is available at <u>http://www.regulations.gov</u> and the Drug Enforcement Administration (DEA) website, <u>http://www.DEAdiversion.usdoj.gov</u>. The final rule will become effective on October 9, 2014.

These regulations implement the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act). The Disposal Act was passed in an effort to curtail prescription drug abuse by authorizing regulations that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical controlled substances. The final rule authorizes ultimate users to transfer unwanted and unused pharmaceutical controlled substances in their lawful possession to an authorized collector for safe, secure, and responsible disposal. In addition to ultimate users, long-term care facilities and persons lawfully entitled to dispose of a decedent's property may also transfer pharmaceutical controlled substances to an authorized collector for the purpose of disposal.

Destruction of Controlled Substances: The final rule implements a standard of destruction: *non-retrievable*. The process utilized to render a substance "non-retrievable" shall permanently alter the substance's physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

BIOHAZARDOUS

- Blood products and biohazardous waste
 - Examples:
 - Albumin
 - Rabies vaccine



- Needles, sharps, ampules, empty vials
- **No unused pharmaceuticals**
 - Temperature during destruction insufficient to destroy most pharmaceutical ingredients

NON-HAZARDOUS SEWERABLES

 Intravenous solutions with NO ADDITIVES may go in the sink
 Sewerable 7:

- Dextrose
- Saline
- Sterile water
- Lactated ringers
- Potassium
- Magnesium
- Calcium



NON-HAZARDOUS

Non-hazardous waste pharmaceuticals

Examples:

- Partially filled:
 - Creams
 - Ointments
 - Vials
 - Tablets/capsules
 - Liquids

No needles or biohazardous medications



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PERFORMING A DRUG INVENTORY



PERFORMING A DRUG INVENTORY

Obtain a 12 month summary of purchased records from drug wholesaler(s) including

- NDC
- Brand name
- Generic name
- Manufacturer
- Strength
- Dosage form
- Package size

Identify all ingredients found in each drug formulation including preservatives, heavy metals and alcohol

Consider all compounded products or IV admixtures

PERFORMING A DRUG INVENTORY

Compare inventory against

- P and U Listed
- Ignitability D001
- Corrosivity D002
- Reactivity D003
- Toxicity Multiple D Codes
- Review inventory for Best Practice Management
- Document your findings
- Keep your inventory updated at least quarterly or when new medications are added

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CURRENT PRACTICE

- Assess data from automatic dispensing cabinets
- Conduct interviews to assess the current disposal practices
 - Interviews should include pharmacy, all nursing units and all outpatient clinics
 - Interview should include supervisors and frontline staff
 - Discuss what drugs are being discarded and how medications are discarded

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MANAGEMENT OPTIONS

Models for managing pharmaceutical waste

- Automatic barcode drive sorting device
- Managing all pharmaceutical waste as hazardous waste
- Manually segregating waste

MANUAL SEGREGATION



No Needles

- No Trash
- No Empty containers except P-listed
- No Controlled Substances

P-listed medications

- Including wrappers or empty containers
- U-listed medications
- D-listed medications
- Spill kits of hazardous waste
- Best Management Practice Hazardous
 - Bulk chemotherapy

MANUAL SEGREGATION



No Controlled Substances

Trace chemotherapy

- Empty
 - chemotherapy IV bags, tubing
- Empty vials,
 - syringes, needles
- Gloves and gowns
- Chemotherapy packaging

MANUAL SEGREGATION



Non-hazardous pharmaceutical waste

Partial drug left

No Needles
No Trash
No Empty containers
No Controlled Substances

MANAGEMENT OPTIONS

Placement of containers

- Located near where pharmaceutical waste is generated
- In secure locations







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COMMUNICATION AND EDUCATION

- Once a model for managing pharmaceutical waste has been selected it MUST be communicated
- Communication options
 - Labeling medications
 - Using code names on medications
 - Messages on automatic dispensing units
 - Messages on the medication administration record
 - Posters

COMMUNICATION AND EDUCATION

FLOVENT 110me		arigin) injection
Warfarin History Detai	s Additional Info Comments	
MAR Note	MAR Note 5/6/2015 7:17 AKDT HIGH ALERT MEDICATION - verify dose Do Not Crush or Chew Baseline INP =00	AND
	P listed: Dispose of unused drug and/or packaging in BLACK container.	8





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AUDIT AND FOLLOW-UP

- Rounds
 - Nursing Units
 - Pharmacies
- Staff meetings
 - Reviewing findings as a group
 - Staff feedback/input
- Direct feedback to managers
- Checking bins
 - Take pictures of examples

AUDIT AND FOLLOW-UP



Which type of pharmaceutical waste does the EPA consider to be the most hazardous?

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<u>Partial</u> chemotherapy vial labeled with is disposed in which container?







Partial ampicillin vial with no label, is disposed in which container?









QUESTIONS/COMMENTS?
CONTACT INFORMATION

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- www.dea.gov. Accessed 10/25/15