WMSS PharmEcology

Pharmacy Technicians' Role in Managing Hazardous Drugs and Hazardous Waste Pharmaceuticals

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THINK GREEN®

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WASTE MANAGEMENT

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Objectives:

1. Define hazardous pharmaceutical waste according to EPA Resource Conservation and Recovery Act (RCRA)
2. Describe the Controlled Substances Act (CSA) and differentiate between accepted methods of disposal for controlled substances in "inventory" versus "wastage“
3. Compare and contrast National Institute for Occupational Safety and Health (NIOSH) hazardous drug handling to EPA hazardous waste disposal

Resource Conservation and Recovery Act (RCRA)

Why Is A Pharmaceutical Waste Management Plan Important?

Regulations, Fines, and Negative Media Attention

Environmental Concerns

Risks to Unborn and Newborn

Why Is A Pharmaceutical Waste Management Plan Important? (Cont.)

- EPA and state environmental protection agencies increasing enforcement
  - Fines at the federal level up to ***$40,779*** per violation per incident per day plus additional latitude for "economic benefit"
  - Activity in various states
  - Civil and criminal liability

Why Is A Pharmaceutical Waste Management Plan Important? (cont.)

- The Joint Commission now auditing on pharmaceutical waste management practices
  - Environment of Care Standards
  - Medication Management Standards
    - MM.01.01.03 The organization safely manages high-alert and hazardous medications
    - MM.03.01.01 Medication Storage and Security
      - EP4 The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, wasting, security, disposition and return to storage
      - EP3 Medications stored in secure areas to prevent diversion and locked when necessary
      - EP6 Prevent unauthorized persons from obtaining medications
      - MM.05.01.11 EP2 Dispensing practices and recordkeeping including anti-diversion strategies

Effects of Chronic Exposure to Prozac

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

Control

38 ppb Prozac

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

Hazardous Waste Under RCRA

- **P-listed pharmaceuticals (acutely hazardous)**
  - Sole active ingredient; unused; empty containers
  - LD50 (oral) 50mg/kg
  - Examples: nicotine, warfarin
- **U-listed pharmaceuticals (toxic)**
  - Sole active ingredient; unused
  - Examples: cyclophosphamide, mitomycin, lindane, selenium sulfide
- **Pharmaceuticals that exhibit a *characteristic* of hazardous waste (D codes)**
  - Ignitability D001
  - Toxicity D004 – D043
  - Corrosivity D002
  - Reactivity D003

Examples of P-Listed Pharmaceutical Waste

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

* Salts excluded federally as of Oct. 15th, 2007
** Excluded from the P list federally
***Salts excluded federally, first communicated October, 2010

Examples of U-Listed Pharmaceutical Waste

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

Characteristics of Toxicity

- 40 chemicals which must be below specific leaching concentrations
- Fails the Toxicity Characteristic Leaching Procedure (TCLP)
- Concentrated selenium and chromium usually fail the TCLP
- Must evaluate IVs, such as TPN
  - Usually come out of regulation due to dilution (chromium, selenium)
- Examples of potentially toxic pharmaceutical ingredients:
  - Chromium D007
  - m-Cresol D024
  - Mercury (Thimerosal) D009
  - Selenium D010
  - Silver D011

Characteristics of Ignitability

- Aqueous solution containing 24% alcohol or more by volume and flash point < 140º F
- Non-aqueous solutions with flash points < 140º F
- Oxidizers
- Flammable aerosols e.g. Kenalog Aerosol Spray
- Hazardous waste code D001
- Examples:
  - Rubbing alcohol
  - Topical preparation: clindamycin phosphate
  - Some injections: paclitaxel
  - Silver nitrate sticks

How Is Pharmaceutical Waste Generated at a Healthcare Facility?

- Sterile and non-sterile compounding
- Partially used vials, syringes, IVs, etc.
- Pressurized aerosols
- Creams, ointments, gels
- Unused repacks (Unit Dose)
- Spills and breakage
- Patients' personal medications left behind
- Outdated pharmaceuticals

Defining “Hazardous” in a Hospital

- **EPA Hazardous Waste:** meets one of the definitions of hazardous waste federally or at the state level; must be a waste
- **OSHA Hazardous Drug**: a risk to employees due to occupational exposure; may be a product or a waste
  - NIOSH 2016 Hazardous Drug List/USP 800
- **DOT Hazardous Material**: a risk to health and safety while in transit; may be a product or a waste
- **Biohazardous**: meets the definition of an infectious risk at the state level; may be a product or a waste
  - Regulated medical waste, includes some drug e.g. albumin

Waste Characterization

- Starts with the Pharmacy Department
- Usually a consultant performs an inventory analysis based on the pharmacy's purchase history or formulary
  - Must identify in pharmacy and train pharmacy staff
  - Must identify to nurses and train nursing staff

Label	Description
P	P-listed hazardous pharmaceutical waste
	Other "compatible" hazardous wastes, including most toxic and ignitable waste items, including those categorized as PharmE Hazardous®
AERO	Ignitable aerosols and pressurized aerosols which need to be shipped separately from other hazardous waste
OXID	This section lists the few, if any, silver nitrate applicators or other oxidizers which might appear on the floor in a finished dosage form.
ACID	This section lists the few, if any, corrosive acid items, which might be stocked in a finished dosage form.
BASE	This section lists the few, if any, corrosive bases, which might be stocked in a finished dosage form.
BIO	Biohazardous items, such as those that contain albumin or a live attenuated virus, which need to be disposed of in a red sharps biohazardous container

Summary of Recommended Pharmaceutical Waste Streams

Compatible Hazardous Waste

RCRA
- P-listed
- U-listed
- D-coded
- Compatibles

Bulk chemo

Haz/Chemo spill clean-up

NO NEEDLES

Aerosols/ Unused Silver Nitrate

Pressurized aerosols

Unused silver Nitrate sticks (used sticks in trash)

Controlled Substance Inventory

Reverse Distribution

Controlled Substance Wastage

Sequestering Device

Non-Hazardous Pharm Waste

All non-RCRA, non-PharmE Hazardous

NO NEEDLES

Trace Chemo (Sharps)

Empty chemo vials, IVs ampules, syringes and needles

NO BULK CHEMO

Trace Chemo (Soft)

PPE
Tubing
Wipes
Packaging

NO BULK CHEMO

Red Sharps

Bio-hazardous drugs

Empty syringes with needles

NO OTHER 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

When is an Outdated Drug a Waste?

- Historical EPA guidance: 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

Reverse Distribution: When to Use It

Potentially Creditable Product:

- Original manufacturer package
- Unopened
- In-date or expired
- Recalled products

Non-returnable Waste:

- Compounded products by the pharmacy (e.g. antibiotic minibags and syringes)
- Repackaged products
- Partially used products

Controlled Substances Act (CSA)

The Controlled Substances Act

- Enacted in 1970 and enforced by the Drug Enforcement Administration (DEA)
- DEA is within the Dept. of Justice
- Restricted access to controlled substances to those registered to manufacture, distribute, prescribe or dispense such products.
- All regulated substances are placed into one of five “schedules”

Controlled Substance Schedules

- Schedule I: Drugs with no recognized medical use and high abuse potential (marijuana now in transition)
  - Heroin, LSD, methaqualone, peyote
- Schedule II: Medical use but high abuse potential
  - Hydrocodone/acetaminophen (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl (Duragesic), dextroamphetamine (Dexedrine), (Adderall), and methylphenidate (Ritalin)
- Schedule III: moderate to low potential for physical and psychological dependence
  - Tylenol with codeine, ketamine, anabolic steroids, testosterone
- Schedule IV: low potential for abuse and low risk of dependence.
  - Alprazolam (Xanax), carisoprodol (Soma), propoxyphene (Darvon), (Darvocet), diazepam (Valium), lorazepam (Ativan), pentazocine (Talwin),
- Schedule V: drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.
  - Guiafenesin & codeine(Robitussin AC), diphenoxylate & atropine (Lomotil)

The DEA Disposal Regulation

- Published September 9th, 2014; took effect October 9th, 2014
- Requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users
- Regulations implement the Secure and Responsible Drug Disposal Act of 2010
- Expands options for take-back events
- Creates mail-back programs and collection receptacle options

The DEA Disposal Regulation

- Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies and hospitals/clinics with on-site pharmacies to voluntarily participate

- Pharmacies (Retail and hospital/clinic) are authorized to maintain collection receptacles at long term care facilities

- Reorganizes and consolidates regulations on disposal and role of reverse distributors

Healthcare Sectors Impacted by DEA Changes

- **Registrant Disposal**
  - Hospitals, clinics, physicians, veterinarians, dentists
  - Retail Pharmacies including LTCF Provider Pharmacies
  - Reverse Distributors
- **Non-Registrant Disposal**
  - **"Ultimate User" collection programs, including law enforcement**
    - Mail-back
    - Receptacles (kiosks)
    - Single day events
  - **"Ultimate User" long term care facilities (LTCFs)**
    - Receptacles provided and managed by retail pharmacies

Registrant Disposal Concerns Expressed to DEA

- Definition of “non-retrievable” limited to incineration
- Ability to render a drug “non-retrievable” in an institutional setting
- Ability to transfer drug wastage to a reverse distributor for incineration from an institutional setting
- Requirement to double witness the destruction of the CS until it is rendered non-retrievable

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 (take-back kiosk)
- Controlled substances from the pharmacy's inventory cannot be disposed in a receptacle for ultimate user collection (take-back kiosk)
- All destruction must be in accordance with Federal, State, tribal, and local laws and regulations

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

Challenging Issue: RCRA Regulated Controlled Substance

- DEA requires reverse distribution of outdated controlled substances (pharmacy inventory)
  - Transfer between DEA registrants
    - Reverse Distributors can be DEA registrants
- If your state does not allow hazardous waste to be reverse distributed, this creates a grey area for controlled substances that are hazardous waste.
  - DEA registrant and TSDF permitted vendor
  - Veolia, Clean Harbors, Heritage, others?

Preventing Diversion in the Nursing Unit

- Sequester the drug “wastage” in a device such as Cactus, Rx Destroyer, or other commercially available device
- Determine if any controlled substances being “wasted” are hazardous waste
  - If yes: place used cartridges or containers in a black hazardous pharmaceutical waste container
    - Chloral hydrate U034
    - Alcoholic formulations: e.g. diazepam injection, undiluted
  - If no: place used cartridges or containers in a white/blue non-hazardous pharmaceutical waste container
- DO NOT place unsequestered CS wastage in any waste containers, including red sharps! Too much opportunity for diversion throughout the storage, transport and disposal chain of command

Examples of Controlled Substance Sequestration Systems

Cactus Smart Sink®

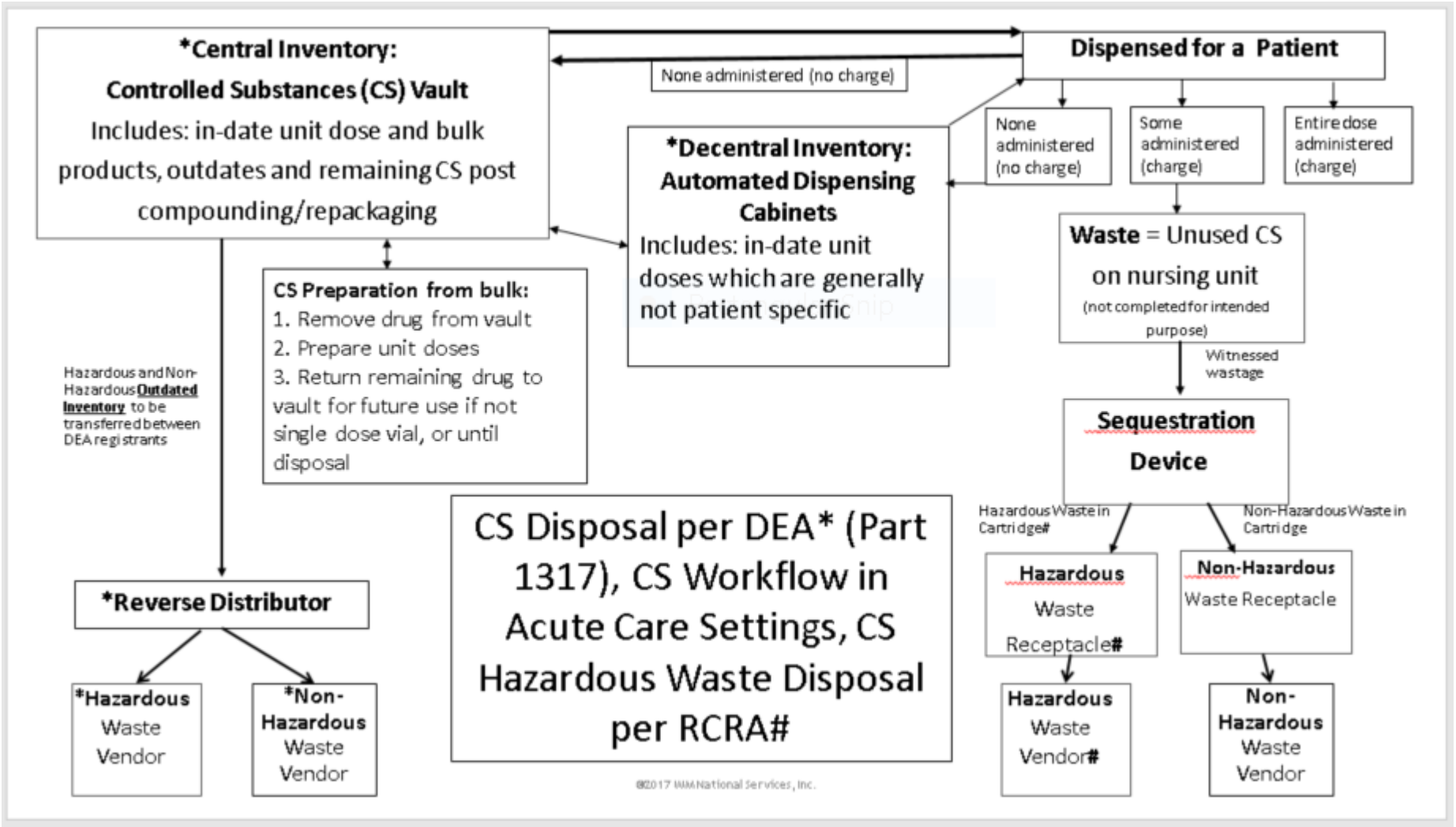
Rx Destroyer™

Can Controlled Substance Wastage Be Drain Disposed in the Nursing Unit?

- Yes, if….
  - Your state allows it
  - You checked with your POTW
  - Your organization allows it

- Best Management Practice: sequestration device

DEA: Management of Controlled Substances

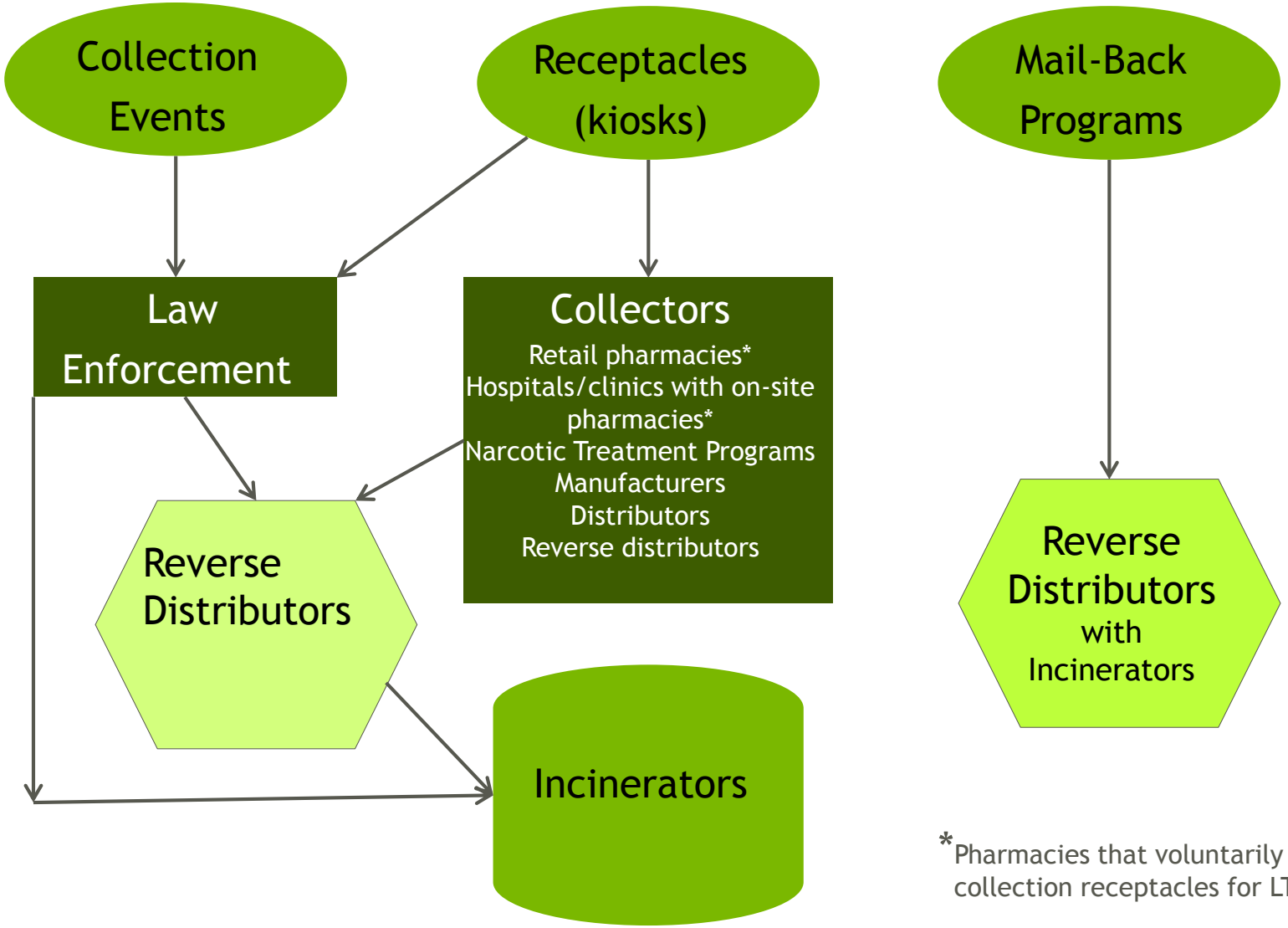


Summary of Controlled Substance Disposal in Healthcare Facilities

- If in the pharmacy's inventory, the controlled substance must be sent to a reverse distributor.

- If the controlled substance has been dispensed to a patient, any remaining drug can be sequestered in a device and the device placed in either the white/blue non-hazardous waste container or the black hazardous waste container and managed by the appropriate waste vendor

CS Disposal: Impact on Ultimate User Options



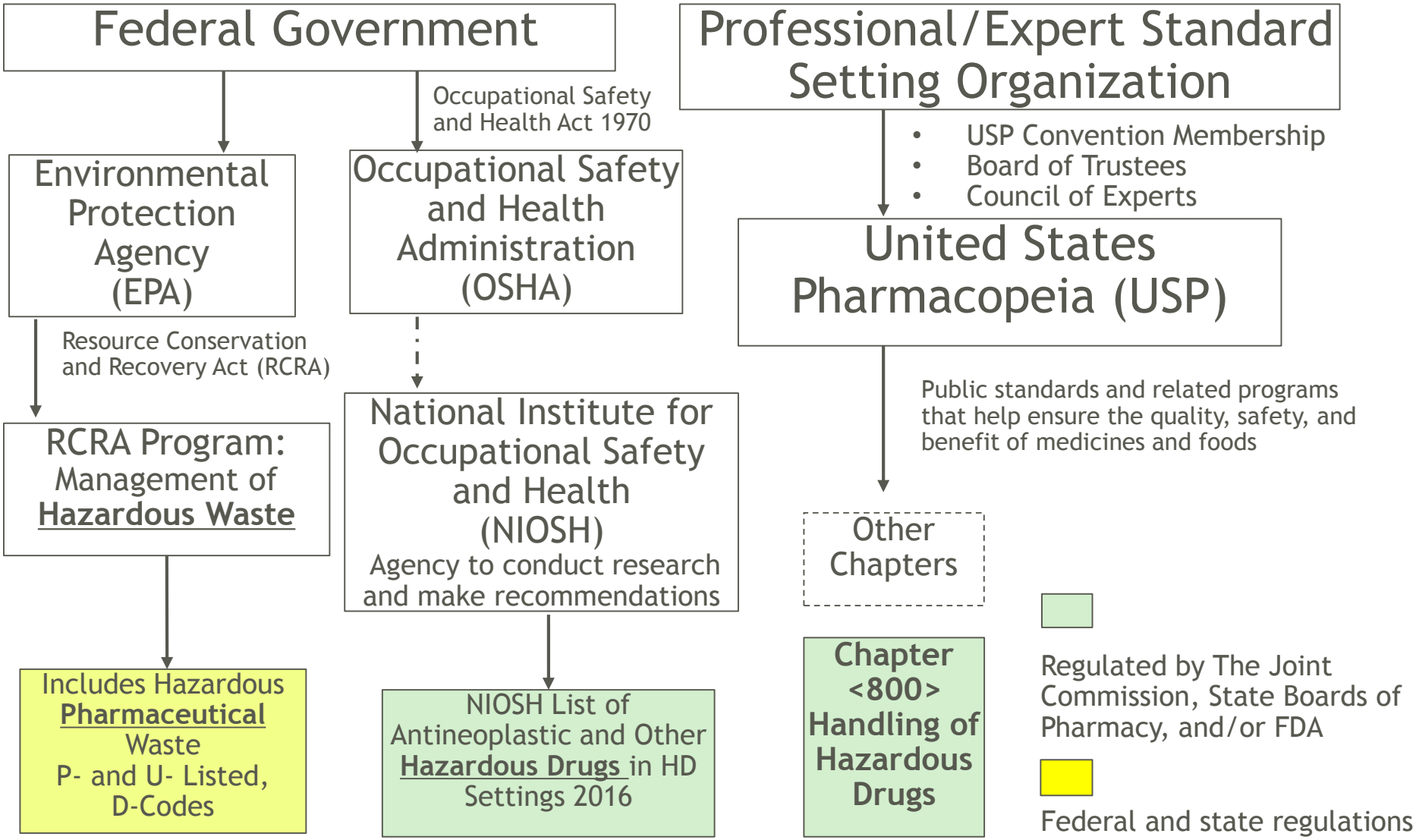
*Pharmacies that voluntarily manage collection receptacles for LTCF's

USP <800> Hazardous Drug Handling

Protecting the Environment (EPA RCRA) vs. the Employee (OSHA)

- EPA’s Mission is to protect human health and the environment.
  - Resource Conservation and Recovery Act, RCRA (40 CFR 260 – 262)
    - Defines hazardous waste in the US and applies to all businesses
    - Approximately 5% of drugs and drug formulations in the marketplace become a RCRA hazardous waste when discarded
    - The generator of this hazardous waste is highly regulated as are the treatment, storage and disposal facilities (TSDF) that perform final disposition such as incineration
- OSHA's Mission is to assure safe and healthful working conditions for working men and women by setting and enforcing standards

Relationship between: EPA, RCRA, OSHA, NIOSH, USP



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  - Examples: nicotine, warfarin
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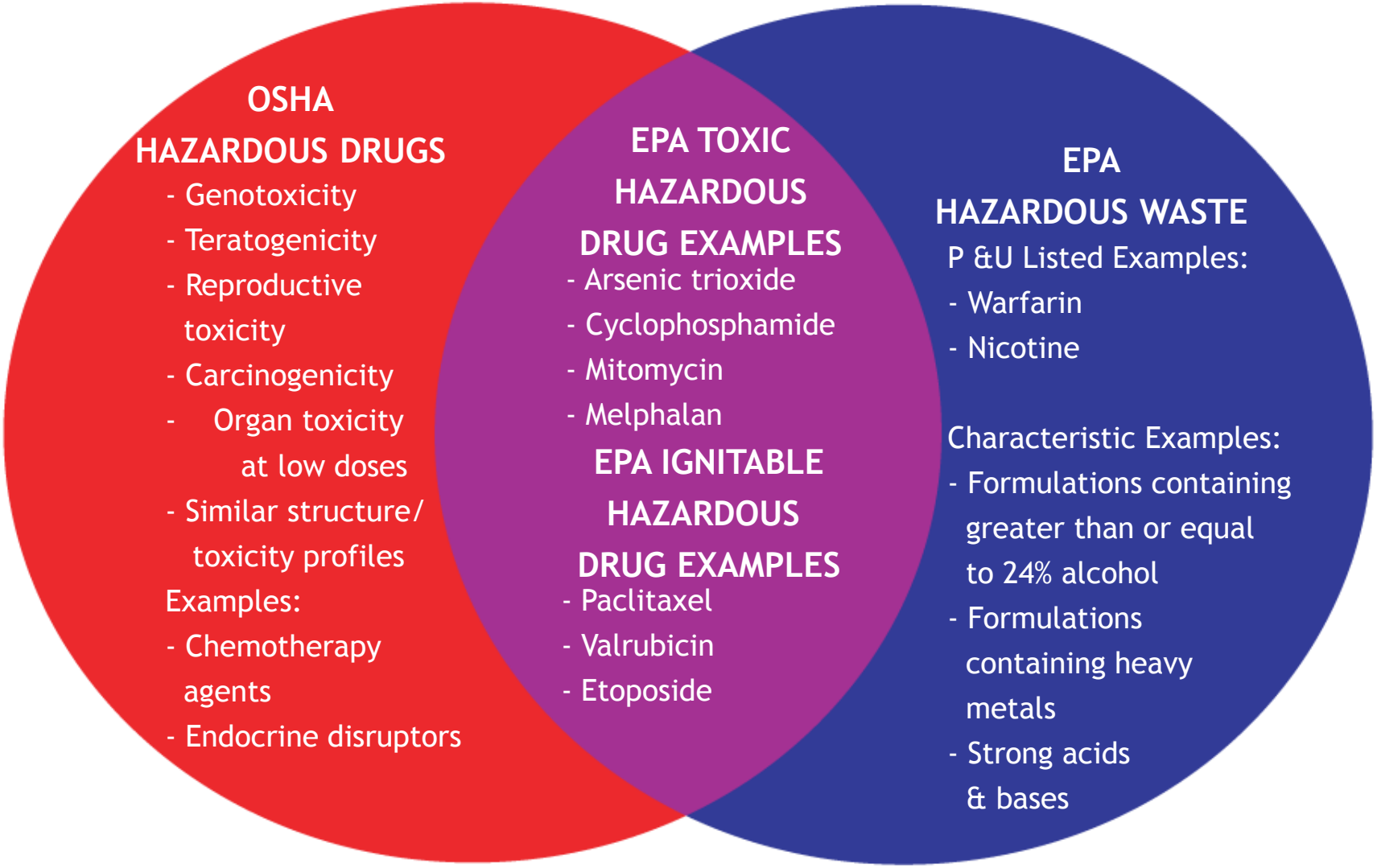
  - Examples: cyclophosphamide, mitomycin, lindane, selenium sulfide
- **Pharmaceuticals that exhibit a *characteristic* of hazardous waste (D codes)**
  - Ignitability D001
  - Toxicity D004 – D043
  - Corrosivity D002
  - Reactivity D003

Criteria of OSHA/NIOSH Hazardous Drugs

Hazardous drugs are capable of causing serious effects including:

- Carcinogenicity
- Organ toxicity at low doses
- Reproductive toxicity
- Genotoxicity
- Teratogenicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

Hazardous Waste vs. Hazardous Drugs Where EPA and OSHA Meet



Pharmaceutical Hazardous Waste (HW) vs. Hazardous Drug (HD)

HD and/or HW	EPA CODE	FULL/PARTIAL	EMPTY	ADMIN SET
Warfarin (HD = HW)	P-listed	Black	Black	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 3	Black	Black	Trash
HD and/or HW	**EPA CODE**	**FULL/PARTIAL**	**EMPTY**	**ADMIN SET**
Arsenic Trioxide (HD = HW)	P012	Black for vial	Black for vial	Black (IV bag, IV tubing)
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 1	Black	Black for vial, IV bag, IV tubing	Trace chemo unless overtly soiled then Black
HD and/or HW	**EPA CODE**	**FULL/PARTIAL**	**EMPTY**	**ADMIN SET**
Nicotine (HW ≠ HD)	P-listed	Black	Black	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	NA	Black	Black	Trash
HD and/or HW	**EPA CODE**	**FULL/PARTIAL**	**EMPTY**	**ADMIN SET**
Divalproex (HD ≠ HW)	Non-haz	White/Blue	Trash	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 2	White/Blue	Trash	Trash

RCRA Hazardous Waste vs. USP <800>

- **Implementation Date:**
  - **RCRA:** Effective since 1980
  - **USP <800>:** Anticipate December 1, 2019
- **Objective/goal:**
  - **RCRA:** Defines hazardous waste (HW) disposal
  - **USP <800>:** Standards established to protect the environment and the safety of the patient, employee during all phases of hazardous drug (HD) handling
- **Toxicity Characterization:**
  - **RCRA (wastage):** P-, U-listed and D codes (characteristic);
  - **USP <800> (drugs):** NIOSH 2016 HD List (Table 1, 2 and 3) based on definitions of genotoxicity, teratogenicity, reproductive toxicity, carcinogenicity, organ toxicity at low doses, similar structure and toxicity profiles

RCRA Hazardous Waste vs. USP <800> (cont.)

- **Regulated or audited by:**
  - **RCRA:** EPA, TJC/DNV, state regulations, DOT
  - **USP <800>:** FDA, TJC/DNV, State Board of Pharmacy
- **Develop specific list:**
  - **RCRA:** waste categorization of all drugs to determine waste streams
  - **USP <800>:** hazardous drug list formulated by comparing formulary to latest published NIOSH list of HDs with the addition of potentially HDs based on toxicity profile as part of the formulary addition process
- **Multidisciplinary teams:**
  - **RCRA:** Pharmacy, Nursing, Environmental Services
  - **USP <800>:** Pharmacy, Nursing, Environmental Services (waste disposal and transportation),Leadership, Respiratory Therapy, Medical staff from ED and OR, Quality at a minimum

RCRA Hazardous Waste vs. USP <800> (cont.)

- **Phases/processes:**
  - **RCRA:** waste disposal, transportation
  - **USP <800>:** receiving, storage, preparation, administration, waste disposal (all phases)
- **Equipment:**
  - **RCRA:** waste containers
  - **USP <800>:** PPE, engineering controls, waste containers
- **Storage:**
  - **RCRA storage of HW:** containers, satellite accumulation area, central accumulation area
  - **USP <800> storage of HD:** negative pressure room, refrigerator

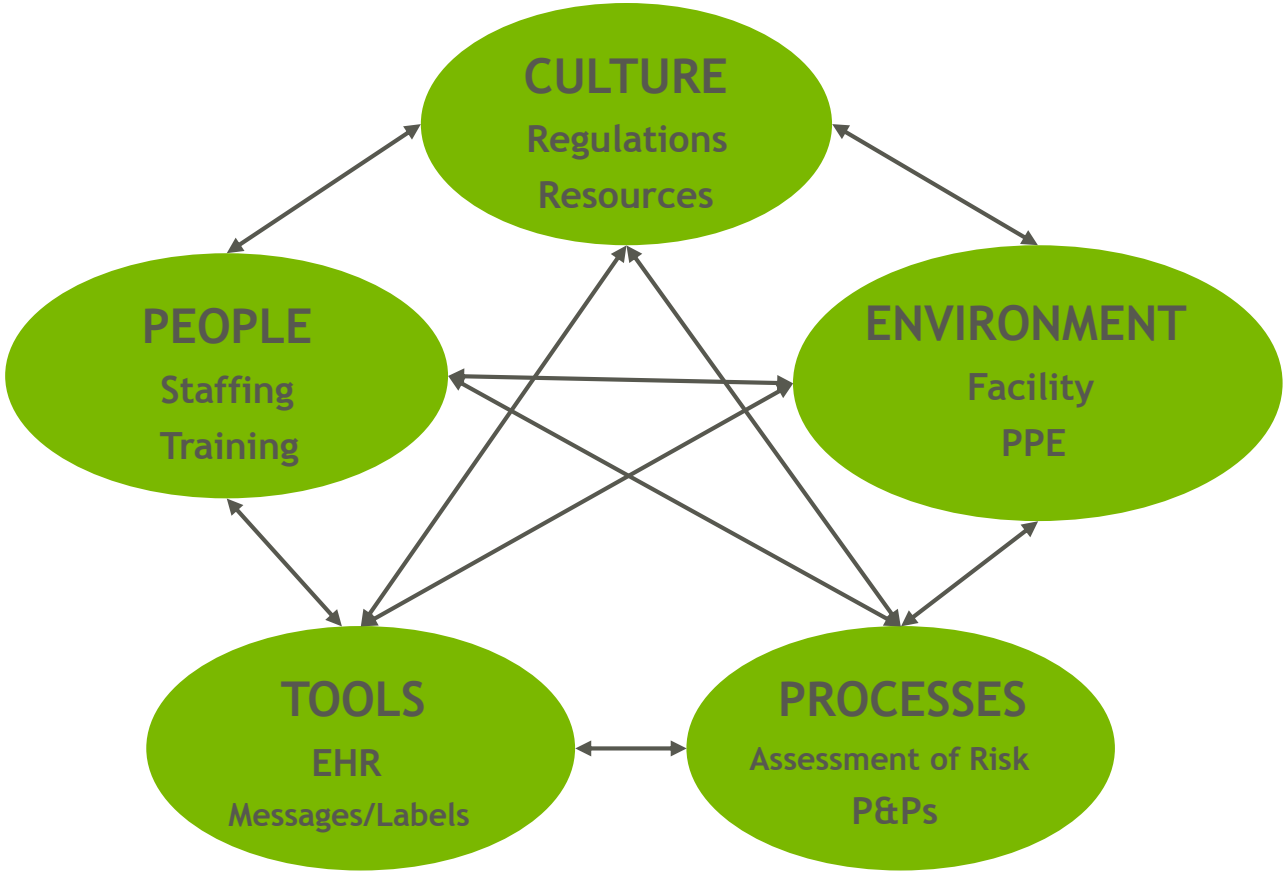
RCRA Hazardous Waste vs. USP <800> (cont.)

- **Communication:**
  - **RCRA:** labeling/messaging via ADC and eMAR defining disposal, waste charts
  - **USP <800>:** labeling/messaging via ADC and eMAR defining PPE handling requirements during preparation and administration
- **Education/training/competency/documentation:**
  - **RCRA:** typically pharmacy, nursing and EVS, HAZWOPER (LQG)
  - **USP <800>:** anyone and everyone who comes in contact with the HDs is required to be trained and demonstrate competency prior to working with the HDs and with applicable changes
- **Policy and Procedures:**
  - **RCRA:** Emergency Preparedness and Planning, Contingency Plan Quick Reference Guide (LQG)
  - **USP <800>:** specific policies are required to be established, implemented and monitored

RCRA Hazardous Waste vs. USP <800> (cont.)

- **Spill management:**
  - **RCRA:** spill kit availability, plan, communication
  - **USP <800>:** spill kit availability, plan, communication, documentations of event and personal contamination treatment, waste disposal
- **Hazardous communication plan:**
  - **RCRA:** emergency preparedness plan (LQG)
  - **USP <800>:** standard operating procedure (required)
- **Record keeping:**
  - **RCRA:** generator status, waste determinations, profiles, manifests
  - **USP <800>:** HD List, Assessment of Risk, SDSs, medical surveillance, training and competency, alternate containment strategies

USP <800> Requires a System Change



Opportunities for Pharmacy Technicians (PT)

- Hazardous waste pharmaceutical under RCRA
  - Labeling and message in pharmacy and for nursing
  - Management of waste containers
- Controlled Substance management under CSA
  - Preventing diversion
  - Managing waste
  - Inventory control
- USP <800>
  - System management: every aspect of USP <800> presents opportunities for PTs (Team participation, P&P, Training, Technology/messaging/labeling, Environment compounding)
  - Every phase of the handling of HDs cycle is the responsibility of PTs except administration and waste disposal

Summary:

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2. Describe the Controlled Substances Act (CSA) and differentiate between accepted methods of disposal for controlled substances in "inventory" versus "wastage“
3. Compare and contrast National Institute for Occupational Safety and Health (NIOSH) hazardous drug handling to EPA hazardous waste disposal

References:

USP <800> Hazardous Drugs – Handling in Healthcare Settings

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NIOSH Hazardous Drug Alert

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ASHP Guidance on Handling Hazardous Drugs

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx?la=en&hash=E0DF626948227B0F25CAED1048991E8E391F2007

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http://www.aha.org/advocacy-issues/letter/2014/141006-let-disposal.pdf

https://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf

EPA RCRA Hazardous Waste Management System, Identification and Listing of Hazardous Waste, Generator Regulations

https://www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-regulations#haz