Current Pharmaceutical Waste Liabilities, Future Relief

Connecticut DEEP Stakeholders Meeting
June 11th, 2014
PharmEcology Services
WM Healthcare Solutions

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What Current Regulations Apply to Discarded Pharmaceuticals in Conn?

- **Environmental Protection Agency (EPA)**
  - **Resource Conservation & Recovery Act**
- **Connecticut Dept. of Energy and the Environment (CT DEEP)**
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA)
- US Department of Transportation (DOT)

RCRA:
The Defining Waste Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA and authorized states
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste

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Who Is Liable Under RCRA?

- All businesses in any sector of the economy
  - Hospitals
  - Clinics, surgery centers, physician and veterinary practices
  - Retail pharmacies
  - Retail groceries (including imbedded pharmacies)
  - Long term care facilities, assisted living facilities and LTCF provider pharmacies
- Who is exempt from RCRA?
  - Households
  - Very small group homes
  - Apartments including independent living
  - Dormitories

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If RCRA was Enacted in 1976, Why Are We First Hearing About It Now?

- First enforced within heavy industry and known sources of pollution, e.g. chemical industry, oil industry, etc.
- Slowly moving through the economy
  - Gas stations
  - Dry cleaners
- Finally started enforcing in health care in late 1990's
  - Beginning with hospitals
  - Drilling down into alternate care, retail sector
- Targeted colleges and universities in 2001
  - Encouraged self-audits
  - Effective compliance strategy

RCRA Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: Federal - FBI, Dept. of Justice

    States - State Police, Office of State's Attorney
- Corporate fines: $25,000/violation/day (CT), $37,500/violation/day (EPA)
- Personal liability: fines and/or imprisonment
- No statute of limitations
- Managers up through CEO liable

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Increased State Regulatory Enforcement of Hazardous Waste Regulations on Hospitals

- Concord Hospital located in Concord, New Hampshire fined $205,000 in December, 2012 by New Hampshire Department of Environmental Services
- Danbury Hospital located in Danbury, Connecticut fined $41,855 in September, 2012 by CT Department of Energy and Environmental Protection
- Aurora Health Care, Milwaukee, WI settles hazardous waste case for $340,000, May, 2014
- Sentara Norfolk General Hospital settles hazardous waste violations, May, 2012 for $19,920

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Increased State Regulatory Enforcement of Hazardous Waste Regulations on Retail Pharmacies

- CVS ordered to pay $13.75 million in fines to 45 cities and towns in California for improper dumping of hazardous materials and hypodermic needles.
- CVS to pay $800,000 Penalty and Correct Violations Under Agreement with CT DEEP for violating hazardous waste rules
- Walgreens must pay $16 million in fines for illegally dumping old drugs (California)
- Walmart to pay $60 million in California in a combination of civil and criminal penalties
- Save Mart Supermarkets to pay $2.5 million in California for RCRA violations
- DeMoulas Super Markets, Inc. to pay $33,736 in Massachusetts
- Safeway, Inc. to pay $600,000 civil penalty and $4.1 million in repairs to refrigeration units nationwide for leaking CFCs.
- 99 Cents Stores to pay $409,490 for illegal pesticide disposal

Hazardous Waste Federally and in CT Under RCRA

- P-listed pharmaceuticals (acutely hazardous)
  - Sole active ingredient; unused; empty containers
  - LD50 (oral) 50mg/kg

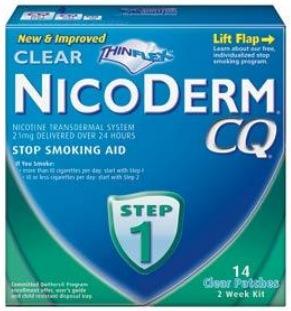
- U-listed pharmaceuticals (toxic)
  - Sole active ingredient; unused

- Pharmaceuticals that exhibit a *characteristic* of hazardous waste (D codes)
  - Ignitability D001
  - Toxicity D004 – D043
  - Corrosivity D002
  - Reactivity D003

Examples of P- and U-listed Drugs found in hospitals

P-listed Drugs

Arsenic Trioxide	P012
Epinephrine & salts (CT)	P042
Nicotine	P075
Nitroglycerin (CT)	P081
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
Warfarin ≤ 0.3%	U248

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Examples of U-listed Pharmaceuticals in Retail Pharmacies

- Chlorambucil (Chemo) U035
  - Leukeran®
- Cyclophosphamide (Chemo) U058
  - Cytoxan®
- Melphalan (Chemo) U150
  - Alkeran®
- Reserpine (Blood pressure) U200
- Selenium sulfide (Dandruff) U205
  - Selsun®, Selsun Blue®

12

Examples of U-Listed Pharmaceuticals

Chemotherapy

13

Examples of U-Listed Chemotherapy Drugs used in Hospitals, Oncology Infusion Centers

Daunomycin U059

- (Daunorubicin)

Mitomycin C U010

Streptozotocin U206

14

Characteristic of Toxicity

- 40 chemicals which must be below specific leaching concentrations
- Fails the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN
  - May 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

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Preservatives: thimerosal & m-cresol

Heavy metals: selenium, chromium and silver

16

Flu Vaccines 2013-2014

- Thimerosal Preservative D009
  - Afluria 5 ml vial multidose
  - Flulaval 5 ml vial multidose
  - Fluvirin 5 ml vial multidose
  - Fluzone 5 ml vial multidose
- Live Attenuated Virus – Biohazardous
  - Flumist Nasal Vaccine

*http://www.pharmecology.com/pedd/jsp/static/a6_news_20131011.jsp

17

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point <140°F
- Non-aqueous solutions with flash points <140° F
- Oxidizers
- Flammable aerosols
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparations
- Some alcohol-based Injections

Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- The only potentially reactive pharmaceutical is nitroglycerin, but
  - Most weak nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001
  - Unless they exhibit another characteristics, such as ignitability
  - CT has NOT accepted the exclusion for weak nitroglycerin
- Hazardous waste number: D003

19

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Definition of Empty

- To be “RCRA empty”, P-listed containers must be triple rinsed & rinsate discarded as hazardous waste; only used syringes excluded – EPA regulation (in practice, no triple rinsing)
- The EPA requires **P-listed wrappers & packaging to** be managed as RCRA hazardous waste because of the **residue** remaining in them
  - Empty nitroglycerin (CT) and epinephrine (CT) containers, warfarin bottles and wrappers, nicotine envelopes
  - Warfarin stock bottles – may count only the residue towards generator status
- U-listed and D codes: empty if **all removed that can be removed by normal means and** no more than 3%, by weight, remaining
  - For vials, can any additional drug be drawn up in a syringe?
  - For bottles, can any additional liquid be poured out?
  - Aerosols – never considered “empty”

Used vs Unused

- If a P- or U-listed drug has been used for its intended purpose, the “used” waste is no longer regulated under RCRA
  - For example, mitomycin (U010) used in a bladder instillation is “used” and if collected in a Foley bag, should be disposed in the yellow trace chemo container
  - A partial IV bag of Cytoxan (U058) is “unused” and should be disposed in a black hazardous waste container
- D code drugs are always regulated, whether “used” or not
  - Unlikely that a “used” D code drug would be available for collection

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Chemotherapy Agents

- Nine chemotherapy agents are regulated under RCRA (1 P-listed; 8 U-Listed). Examples include:
  - Arsenic trioxide P012
  - Mitomycin C U010
- Over 100 additional chemotherapy agents are not regulated under RCRA (the list was published in 1976), yet should be managed as hazardous waste.
- Examples include:
  - Cisplatin
  - Fluorouracil
  - Methotrexate
  - Taxol® (paclitaxel)

Satellite Accumulation Area vs. Storage Accumulation Area

- Satellite accumulation area:
  - Under immediate control of the operator generating the hazardous waste
  - Limits of 1 quart of P-listed waste and 55 gallons of total hazardous waste
- Storage accumulation area
  - Container must be dated when placed in storage accumulation
  - Time limits based on generator status:

    LQG: 90 days

    SQG: 180 days

    CESQG: no limit

Generator Requirements Under RCRA

- Perform waste determination for all drug products (update at least annually and have documentation on-site)
- Obtain EPA Identification Number
- Determine generator status
- Segregate drug waste into appropriate containers
- Prepare waste profile: Enables commingling of compatible hazard classes for DOT purposes
- Prepare label: Very specific DOT requirements
- Prepare Uniform Hazardous Waste Manifest: Very specific DOT requirements
- Prepare Land Disposal Restriction Form (Land Ban)

Still More Generator Requirements Under RCRA

- Contract with a state and federally permitted RCRA transporter and incineration facility - Treatment, Storage & Disposal Facility (TSDF)
- Develop written RCRA training program and conduct training (initial and annual review)
- Develop inspection schedule and inspection log
- Conduct inspections and record in log
- Maintain storage accumulation area requirements (impermeable base, secondary containment, accumulation time, containers closed when not in use, condition, etc.)
- Biennial reporting and contingency planning for LQGs
- Maintain documentation for at least three years

Determining Generator Status under RCRA

- Large Quantity Generator (LQG):
  - generates ≥ 1000 kg/month of hazardous waste, or
  - **generates > 1 kg/month P-listed waste, or**
  - **stores > 1 kg of P-listed waste at any one time.**
- Small Quantity Generator (SQG):
  - generates < 1000 kg/month but > 100 kg/month of hazardous waste; and
  - **≤ 1 kg/month P-listed waste, and**
  - **stores ≤ 1 kg of P-listed waste at any one time.**
- Conditionally Exempt Small Quantity Generator (CESQG):
  - Generates ≤ 100 kg hazardous waste/month, and
  - **≤ 1kg P-listed waste/month, and**
  - **stores ≤ 1 kg of P-listed waste at any one time.**
- [Note: CT thresholds are more stringent than federal]

Determining Generator Status in CT

- EPA published a memo on Nov. 4, 2011 attempting to more clearly define residue in a warfarin bottle or blister-pak or a nicotine envelope.
- Access EPA memo at http://www.pharmecology.com/pedd/jsp/static/a6_news_20111205.jsp
- **CT DEEP** accepts EPA position on residues and contaminated containers.
- Nicotine products damaged or outdated at the store can cause the retail pharmacy to exceed the 1 kg. limit in a given month, causing the store to become LQG for the rest of the year.

27

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Non-RCRA Hazardous
CT Regulated Waste

- Waste is neither listed nor characteristically hazardous waste
- Defined in Section 22a-448 of Connecticut General Statutes (C.G.S.)
- Must be managed by vendors who are permitted under Section 22a-454 (C.G.S.)
- Wastes include:
  - Materials containing or contaminated with PCBs (CR01)
  - Waste oil and waste soluble oil (CR02 and CR03)
  - Chemical liquids (CR04) and solids (CR05) which include all pharmaceuticals not covered under RCRA

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Non-RCRA Hazardous
CT Regulated Waste

- Waste pharmaceuticals may be CR04 (liquids) or CR05 (solids)
- Store wastes in manner similar to hazardous waste
- Picked up by permitted waste hauler (except CR05)
- Shipped using bill of lading or manifest
- For practical purposes, solids and liquids in same container so all must be shipped by permitted waste haulers

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Non-RCRA Hazardous CT Regulated Waste

- In CT, transporter and disposal facility must be permitted to take CT Regulated Waste under Section 22a-454 (C.G.S.)
- If shipped out-of-state, facility permitted to accept non-hazardous pharmaceutical waste
- Alternative: Send to Permitted Resource Recovery Facilities with Special Waste Handling Plan for CT Regulated Pharmaceutical Waste
  - Covanta facilities in Preston and Wallingford and Wheelabrator facilities in Bridgeport and Lisbon
  - Typically practical only for consolidated loads

Summary of Current CT Pharmaceutical Waste Streams

Compatible Hazardous Waste*	Aerosols	Trace Chemo (Sharps)	Trace Chemo (Soft)	Non – RCRA Hazardous Drugs	Red Sharps	Municipal Solid Waste	Sewer System
* Dual waste for sharps							

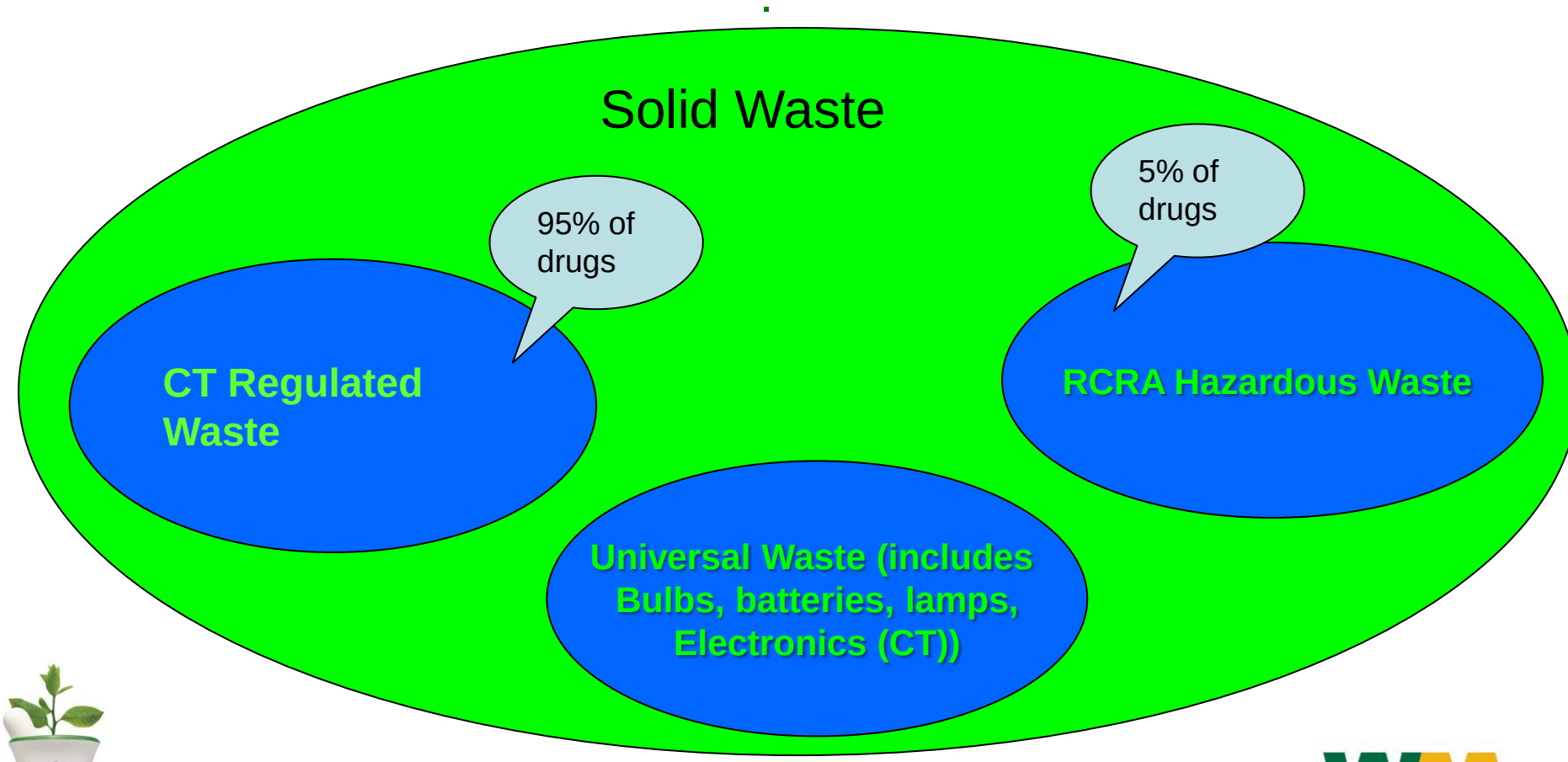
• P-listed (inc. containers)
• U-listed
• D-listed t toxic,
• Ignitable
• Bulk chemo
• Haz/Chemo spill clean up
	• Ignitable aerosols
	• Pressurized aerosols
		• Empty vials and ampules
		• Empty syringes and needles
		• Empty IVs
			• Gowns
			• Gloves
			• Tubing
			• Wipes
			• Packaging
				• All non-RCRA hazardous pharmaceutical waste
				• No biohazardous drugs
				• **No needles**
					• Empty syringes, needles, ampules (except chemo)
					• Potentially infectious drugs
						• Most packaging
						• Most empty bottles and vials
						• Most empty IVs
						• Paper
						• Plastic
						• No drugs
						• No P-waste containers
							• 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) Need DEEP Discharge Permit**
Ash		**Ash**		**Ash**	**Shredded (Most states)**		
Lined Hazardous Waste Landfill		**Lined Non-Hazardous Waste Landfill**					**Water Supply**

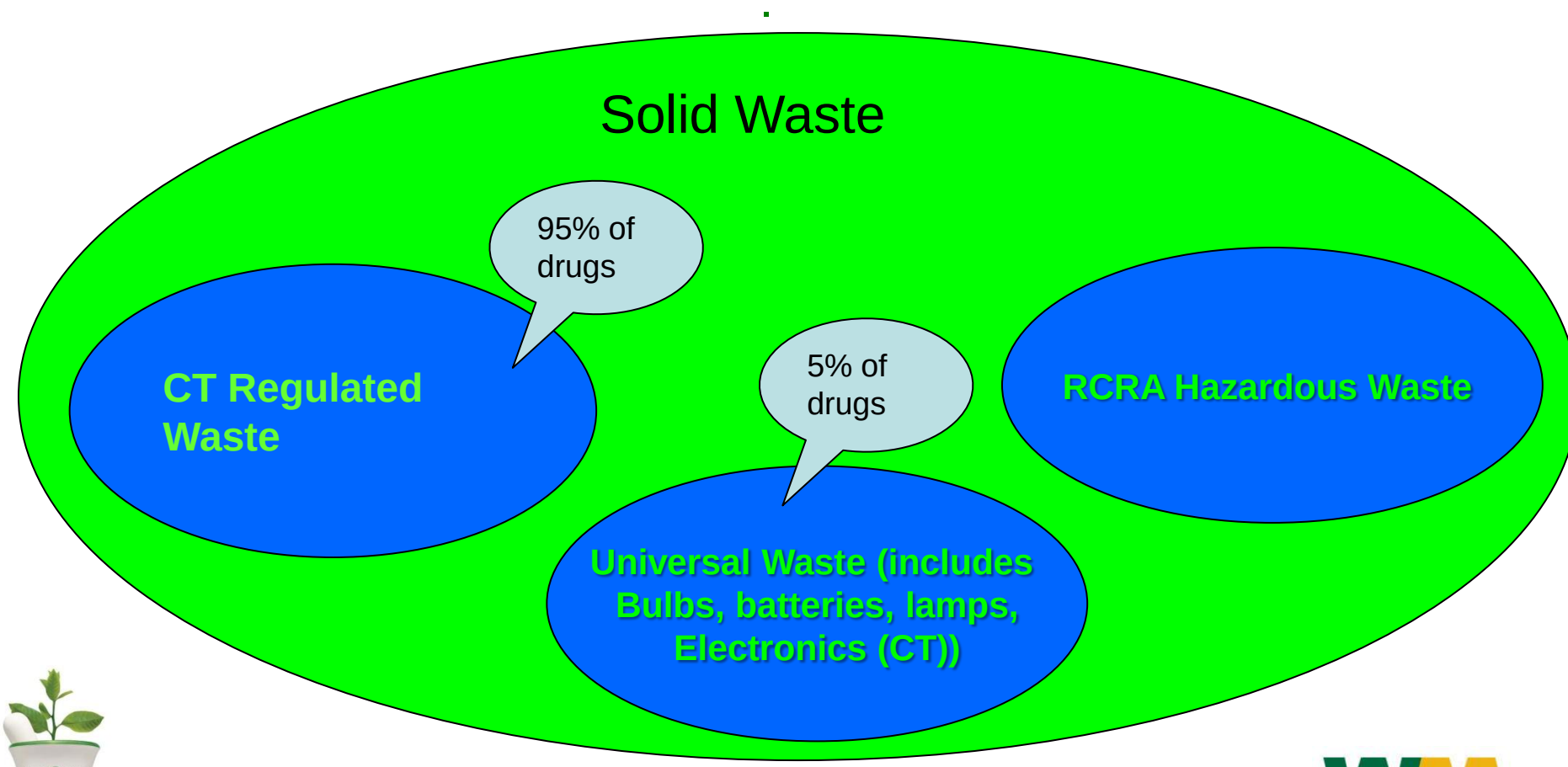
Non-Drug Hazardous Wastes (Not included in proposed UWR)

Nail polish remover
Perfumes
Sunscreen

Summary of Current Waste Classifications



Proposed Waste Classifications



What is Universal Waste?

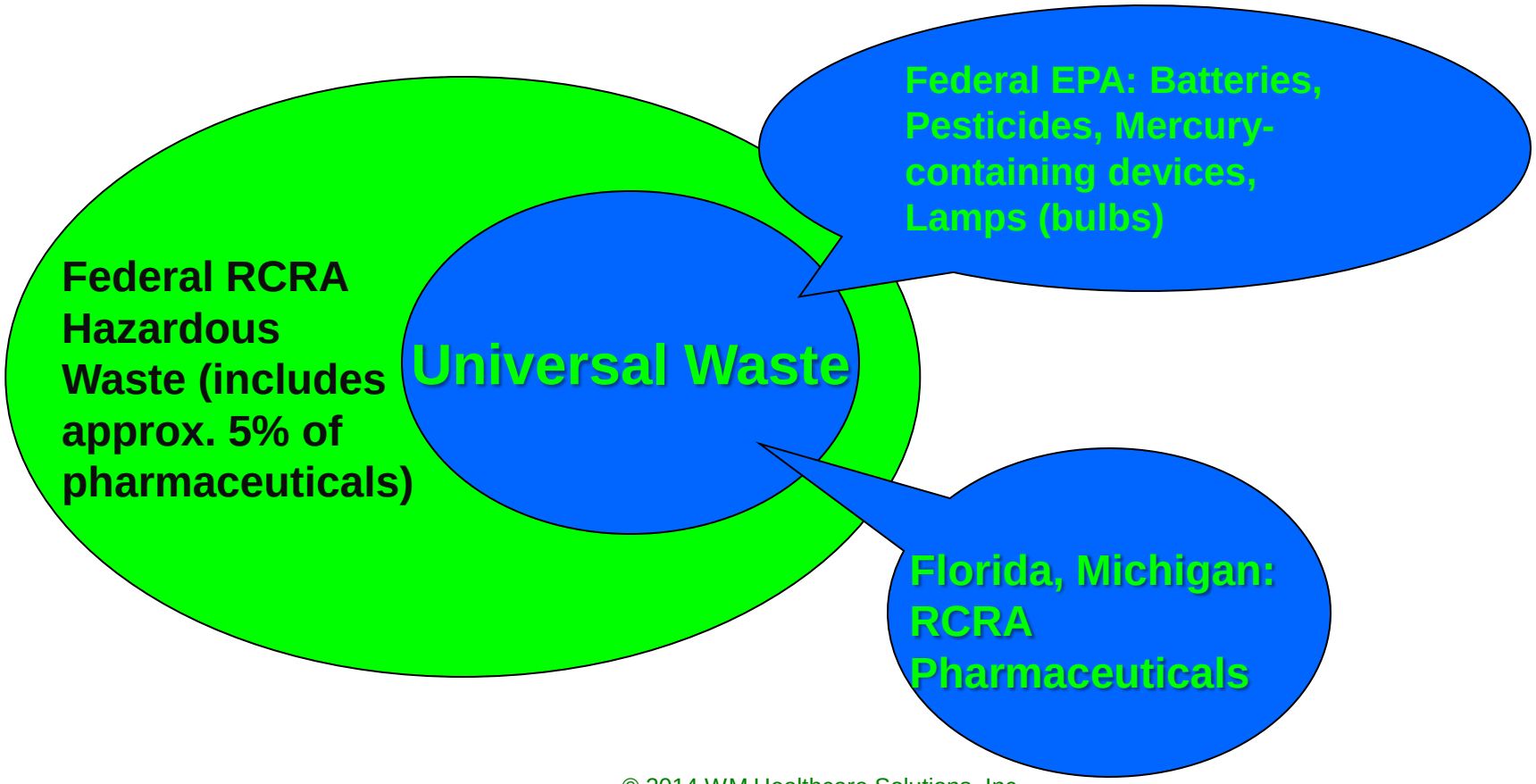
- Universal Waste Rule finalized May 11, 1995 in Federal Register
- Waste that is generated in a wide variety of settings other than industrial settings, by a vast community of sources, and may be present in significant volumes in non-hazardous waste management systems.
- Designed to promote easier collection, recycling, reuse of hazardous wastes that occur throughout the population
- Currently include lamps, batteries, mercury-containing devices, pesticides, and electronics (CT only)

General Goals of UWR

- To encourage resource conservation
- To improve implementation of current RCRA subtitle C hazardous waste regulatory program
- To separate UW from the municipal waste stream
- Maintain high regulatory standards with more flexibility

RCRA and Universal Waste

"Universal Waste" is a subset of RCRA hazardous waste.



EPA Initial Proposal to Add Pharmaceuticals to Universal Waste Rule

- Federal Register publication Dec 2, 2008 –Only applied to drug waste that meets the definition of RCRA hazardous waste
- Only intended for healthcare-type generators, not manufacturers
- Intended to streamline pharmaceutical waste management and encourage consumer take-back programs
- EPA has decided not to move forward with the UWR but is developing a new proposal "to establish appropriate standards for the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities."
- Notice of Proposed Rule Making tentatively scheduled for December, 2014
- http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm

Benefits of State-Listing Hazardous Pharmaceutical Waste as a Universal Waste

- Increase compliance rates
- Streamline the current regulations/reduce the regulatory burden
- Ensure larger quantities of hazardous pharmaceutical waste are managed properly
- Does not count towards generator status
- Do not need to use Uniform Hazardous Waste Manifest
- Longer accumulation limits (1 year vs. 90 or 180 days)
- Ability to aggregate waste at a non-RCRA TSDF

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What Makes Drug Waste Unique?
Security Issues

- Legend Pharmaceuticals (prescription only) are deliberately restricted in their availability to the consumer AND within the supply chain due to their inherently “dangerous” status regarding human use
- The street value of pharmaceuticals continues to climb due to increased drug costs and shrinking personal resources
- Waste pharmaceuticals continue to have value, including empty vials of IV admixtures that can be used for introducing counterfeit drugs back into the supply chain

What Makes Drug Waste Unique?

- Due to concerns regarding handling, storage, and counterfeiting, FDA and state regulatory authorities have multiple requirements, for example:
  - Licensure (distributors & reverse distributors)
  - Inspections
  - Background checks, drug testing
  - Physical security
  - Criminal penalties
  - “Pedigrees”
- Forward supply chain (manufacturers, distributors) working hard to develop further security measures (e.g. “track and trace” technology)

Questions?

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