Pharmaceuticals and the Universal Waste Rule

Connecticut DEEP Stakeholders Meeting
February 5, 2014
PharmEcology Services
WM Healthcare Solutions
Legal Disclaimer

This presentation is solely for educational purposes and provides only a general description of various regulatory requirements. For a complete description, please consult the relevant federal and state regulatory statutes. Nothing in this presentation constitutes legal advice and you should not legally rely on any information provided in this presentation. We make no warranty, express or implied, with respect to such information and disclaim all liability resulting from any use or reliance of this information.
Current Waste Classifications

Solid Waste

- CT Regulated Waste
- RCRA Hazardous Waste
- Universal Waste (includes Bulbs, batteries, lamps, Electronics (CT))

95% of drugs
5% of drugs

© 2014 WM Healthcare Solutions, Inc.
Proposed Waste Classifications

Solid Waste

- Universal Waste (includes Bulbs, Batteries, Lamps, Electronics (CT))
  - 95% of drugs
- CT Regulated Waste
  - 5% of drugs
- RCRA Hazardous Waste

© 2014 WM Healthcare Solutions, Inc.
RCRA: The Defining 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
- Households are exempt
RCRA Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Attorney General, Grand Jury

- 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
Federally Regulated Hazardous Waste 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

<table>
<thead>
<tr>
<th>P-listed Drugs</th>
<th>U-listed Drugs (partial list)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic Trioxide</td>
<td>Chloral hydrate (CIV)</td>
</tr>
<tr>
<td>Epi &amp; salts (CT)</td>
<td>Chlorambucil</td>
</tr>
<tr>
<td>Nicotine</td>
<td>Cyclophosphamide</td>
</tr>
<tr>
<td>Nitroglycerin (CT)</td>
<td>Daunomycin</td>
</tr>
<tr>
<td>Physostigmine Salicylate</td>
<td>Melphalan</td>
</tr>
<tr>
<td>Warfarin &gt;0.3%</td>
<td>Mitomycin C</td>
</tr>
<tr>
<td>Warfarin ≤ 0.3%</td>
<td>Streptozotocin</td>
</tr>
<tr>
<td></td>
<td>Lindane</td>
</tr>
<tr>
<td></td>
<td>Selenium Sulfide</td>
</tr>
<tr>
<td></td>
<td>Warfarin</td>
</tr>
</tbody>
</table>

© 2014 WM Healthcare Solutions, Inc.
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
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
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 (Clindamycin Topical Solution)
- Many alcohol-based gels
- Pressurized aerosol inhalers with flammable propellants
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Preservatives: thimerosal & m-cresol

Heavy metals: selenium, chromium and silver
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

➢ 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
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)
Hazardous Drugs vs. Hazardous Waste
Where OSHA & EPA Meet

OSHA HAZARDOUS DRUGS
- Genotoxicity
- Teratogenicity
- Reproductive toxicity
- Carcinogenicity
- Organ toxicity at low doses

Examples:
- Chemotherapy agents
- Endocrine disruptors

EPA TOXIC HAZARDOUS DRUG EXAMPLES
- Arsenic trioxide
- Cyclophosphamide
- Mitomycin
- Melphalan

EPA IGNITABLE HAZARDOUS DRUG EXAMPLES
- Paclitaxel
- Valrubicin
- Etoposide

EPA/CT HAZARDOUS WASTE
P&U Listed Examples:
- Epinephrine & salts
- Warfarin
- Nicotine
- Nitroglycerin

Characteristic Examples:
- Formulations containing greater than or equal to 24% alcohol
- Formulations containing heavy metals
- Strong acids & bases

© 2014 WM Healthcare Solutions, Inc.
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
  - ≤ 1 kg P-listed waste/month, and
  - stores ≤ 1 kg of P-listed waste at any one time.
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/or federally permitted RCRA 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
DOT Hazardous Waste Labels and Shipping Descriptions

- DOT shipping description for compatible hazardous waste (flammable/toxic)
  - UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II

- The DOT hazardous waste label is provided and completed by the hazardous waste vendor at the time of pick up based on the waste profiles

- The generator is ultimately responsible for the appropriate shipping preparations and labeling
Hazardous Waste Label Example

- Facility Name
- Facility Address (Street, City, State, Zip)
- Phone Number
- EPA Identification Number
- Waste Codes
- Accumulation Start Date
- Description of Contents (chemical name)
Uniform Hazardous Waste Manifest

- May be completed by the generator or the hazardous waste vendor
- Must be signed by employee who has received DOT hazardous material training
- Make a copy and send to WEED (Waste Engineering & Enforcement Division) within 7 days
- Top copy must be returned by vendor within 35 days; match to generator copy and save for 3 years
- If not received in 45 days, must notify WEED

© 2014 WM Healthcare Solutions, Inc.
A Quick Primer on Incinerators

- **Municipal (Resource Recovery Facility)**
  - Permitted to burn municipal “garbage”
  - Generates electricity from combustion
  - Usually not permitted to handle infectious waste
  - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions

- **Medical Waste**
  - Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
  - May be permitted to accept non-hazardous pharmaceutical waste

- **Hazardous Waste**
  - Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
  - High temperature, molecular bonds broken
  - Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 6-part Uniform Manifest
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

© 2014 WM Healthcare Solutions, Inc.
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

© 2014 WM Healthcare Solutions, Inc.
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

Lined Non-Hazardous Waste Landfill

Ash

Lined Hazardous Waste Landfill

Water Supply

© 2014 WM Healthcare Solutions, Inc.
What is Universal Waste?

- Universal Waste Rule finalized May 11, 1995 in Federal Register

- 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
“Universal Waste” is a subset of RCRA hazardous waste.
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)
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)
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 now scheduled for August, 2014
- [http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm](http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm)
Unresolved Issues

- Can generators ship potentially creditable outdated drugs that become RCRA hazardous to reverse distributors under the new UWR?
- Will UW vendors be required to provide a copy of the Uniform Manifest sent to the TSDF back to the original handler to document proper destruction?
- How will pharmaceutical UW handlers be permitted?
- What is an appropriate DOT Shipping Description?
- Will SQHUW be required to notify/obtain an EPA ID no.?
- What training will be required?
- Will chemotherapy agents be included?
Questions?

Charlotte A. Smith, R. Ph., M.S.
Senior Regulatory Advisor

[email]

1-877-247-7430