Resource Conservation and Recovery Act (RCRA)

Pharmacy Waste Management: An Emerging Issue

Presented by U.S. EPA, Region 7
Waste Enforcement and Materials Management Branch

to the Missouri Recycling Association (MORA) Conference
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Pharmacy Waste Management: An Emerging Issue

Presenter:

Stacie Tucker
Environmental Scientist

Compliance Officer at U.S. EPA, Region 7
Air and Waste Management Division (AWMD),
Waste Enforcement and Materials Management Branch (WEMM)
Goals of Presentation

- Assist MORA members gain a better understanding of the Resource Conservation and Recovery Act (RCRA).

- Provide an overview of the RCRA Program, specifically on waste determinations, waste handling, and waste disposal of pharmaceutical wastes.
Purpose of Presentation

- Overview of pharmaceutical waste management from the regulatory perspective
  - Why these wastes need to managed properly.
  - What needs to be done to meet the regulations.

- Briefly discuss the proposed pharmaceutical amendment to the Universal Waste Rule (UWR)
  - Impact on how to manage pharmaceutical wastes
  - The proposed pharmaceutical amendment to the UWR is tentatively scheduled to be finalized in 2011.
Why do Pharmaceutical Wastes need to be managed?

- Pharmaceutical wastes are regulated by RCRA Subtitle C

- RCRA Subtitle C - hazardous waste regulations (40 CFR 260 - 279)
  - Generators – LQG, SQG, and CESQG
  - Transporters
  - Treatment, storage, and disposal facilities (TSDF)
### RCRA Subtitle C: Hazardous Waste Management

<table>
<thead>
<tr>
<th>Generator Status</th>
<th>Monthly Hazardous Waste Generation Rate (kilograms)</th>
<th>Monthly Acute Hazardous Waste Generation Rate (kilograms)</th>
<th>Maximum storage amount of hazardous waste (kilograms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LQG</td>
<td>&gt; 1,000</td>
<td>&gt; 1</td>
<td>N/A</td>
</tr>
<tr>
<td>SQG</td>
<td>Between 100 and 1,000</td>
<td>&lt;1</td>
<td>6,000</td>
</tr>
<tr>
<td>CESQG</td>
<td>&lt;100</td>
<td>&lt;1</td>
<td>1,000</td>
</tr>
</tbody>
</table>
How does RCRA Subtitle C affect how Pharmaceutical Wastes are managed?

- RCRA Subtitle C is managed by authorized states and EPA

- Iowa is the only state that is not currently authorized to manage any portion of the RCRA Subtitle C program

- The state program must be fully equivalent to, no less stringent than, and consistent with the federal program

  - Contact the EPA or your state with questions about compliance

  - **Always** check with your state for additional compliance requirements
What is a “Hazardous Waste?”

- Hazardous waste is a waste with properties that make it dangerous or capable of having a harmful effect on human health or the environment.

- All wastes must be solid wastes before they are considered hazardous wastes.
RCRA Characteristic Hazardous Wastes

Ignitability  Corrosivity  Reactivity  Toxicity
RCRA Listed Hazardous Wastes

- Non-Specific Sources (F)
- Specific Sources (K)
- Discarded Commercial Chemical Products, Off-Specification Species, Container Residues, and Spill Residues Thereof (P and U)
How are Pharmaceutical Wastes classified as Hazardous Wastes?

- **P-listed hazardous wastes**
  - Manufactured chemical listed by its generic name
  - Epinephrine: P042
  - Nicotine, & salts: P075

- **U-listed hazardous wastes**
  - Specific chemicals identified as toxic
  - Mercury: U151
  - Benzene: U019

- **Commercial Chemical Product (CCP)**

- **Sole active ingredient**
Key EPA Resources for Managing Pharmaceutical Wastes

- **EPA websites:**
  - [http://www.epa.gov/compliance/civil/rcra/index.html](http://www.epa.gov/compliance/civil/rcra/index.html)
  - [http://www.epa.gov/compliance/civil/rcra/rcraenfreq.html](http://www.epa.gov/compliance/civil/rcra/rcraenfreq.html)

- **RCRA Online database:**
  - [http://www.epa.gov/wastes/inforesources/online/](http://www.epa.gov/wastes/inforesources/online/)
  - RO # 14788 – clarification of the epinephrine syringe interpretation, extended to other P- and U-listed drugs
  - RO # 13718 – epinephrine syringe interpretation
  - RO # 14778 – scope of HW listing for epinephrine (P042), references older RCRA Online documents
  - RO # 13530 – commercial chemical product (CCP) definition in 40 CFR 261.33
  - RO # 14012 – definition of CCPs for solid waste vs. HW determination
  - RO # 14654 – nitroglycerine under mixed-rule and derived-from rule
  - RO # 13622 – nitroglycerin pills as CCPs
What are Pharmaceutical Wastes?

- Commercial Chemical Product (CCP), 40 CFR 261.33(d)
  1. Pure, unused chemical having the generic name in the P- or U-list
  2. Manufacturing chemical intermediates that have those names
  3. Off-spec variations of the pure chemical or chemical intermediates
  4. Residues of these chemicals in containers that do not meet the definition of “RCRA empty”
  5. Clean-up residue and debris resulting from spills of these chemicals
  6. Sole active ingredient
  7. Technical grade of the chemical
  8. Manufacturing process wastes
What needs to be done to meet the Pharmaceutical Waste management regulations?

- Waste Identification
- Recordkeeping and reporting requirements
- Disposal requirements
Compliance Issues with Pharmaceutical Wastes

- Waste Identification
  - Failure to make a hazardous waste determination on a waste stream is RCRA’s No. 1 violation!

  40 CFR 262.11
Disposal Requirements

- Storage and Disposal Requirements for:

<table>
<thead>
<tr>
<th>Generator Size</th>
<th>Storage Time Limits</th>
<th>Disposal Paperwork</th>
</tr>
</thead>
<tbody>
<tr>
<td>LQG</td>
<td>90 days</td>
<td>Manifest</td>
</tr>
<tr>
<td>SQG</td>
<td>180/270 days</td>
<td>Manifest or Tolling Agreement (for reclaimed wastes)</td>
</tr>
<tr>
<td>CESQG</td>
<td>---</td>
<td>40 CFR 261.5(f)(3) and 40 CFR 261.5(g)(3)</td>
</tr>
</tbody>
</table>

- LDRs (40 CFR 268)
Proposed changes to Pharmaceutical Waste Management

- Brief discussion of the proposed pharmaceutical amendment to the Universal Waste Rule (UWR)
Background: What Is the Universal Waste Rule?

- The universal waste program is an alternate set of regulations which streamlines hazardous waste management standards for certain hazardous wastes that have been federally designated as universal wastes (UW)
  - Generators have the option of managing these wastes as HW under RCRC subtitle C or as UWs

- So, what does this mean?
  - A universal waste is still a hazardous waste, but the generator requirements are simplified in order to:
    - Promote the collection of these wastes
    - Promote the proper recycling, treatment or disposal of these wastes
  - UWs still need to be disposed of at permitted hazardous waste treatment, storage and disposal facilities
What Are the Current Federal Universal Wastes?

- Batteries, pesticides, Mercury-containing equipment (MCEs), and lamps
  - States can have additional hazardous wastes in their UW programs

Why are these wastes special?

- Compared to other hazardous wastes, these wastes are relatively low-risk during accumulation and transport
- They are frequently generated in a wide variety of settings
- They are generated by a vast community
- Present in significant volumes in non-hazardous waste management systems (e.g., households)

Proposal to Add Hazardous Pharmaceutical Wastes to UWR

- In December 2008, FR notice was published
  - Comment period extension was published January 30, 2009
  - Commenting period ended March 4, 2009

- Applies to RCRA hazardous pharmaceutical wastes
  - P and U listed wastes (see 40 CFR 261.33(e) and (f))
  - Characteristic wastes
    - Ignitability, corrosivity, reactivity and toxicity (see 40 CFR 261.21-24)

- Proposed rule applies to pharmacies, hospitals, doctors’ and dentists’ offices, ambulatory care centers, outpatient care centers, residential care facilities, vet clinics and other facilities that generate this type of waste
Proposed Requirements
(As compared to current generator requirements)

- Increased accumulation threshold
  - SQHUW = <5,000 kg total of UW at any time
  - LQHUW = ≥5,000 kg total of UW at any time
- No EPA ID number for SQHUW
- No manifesting requirements for handlers
  - LQHUW have basic recordkeeping requirements; no tracking required for SQHUW
- Increased storage time
  - 1-year storage
- Basic training requirements
- Transporters
  - No manifest requirement and consequently no EPA ID number.
Comments Received

- Over 100 comments received (9 requesting extension)
  - Trade associations
  - States
  - RDs/waste management
  - Hospitals
  - POTWs
  - Municipalites
  - NGOs
  - Federal Agencies
  - Miscellaneous
Comments

- General support for the rule

- 3 states oppose (CO, MN and WI)
  - Rule is unnecessary
    - education and enforcement is key
    - Need healthcare facility (HCF)-specific regulations
  - Rule will not encourage better waste management
  - Rule removes the paper trail regulators depend on
  - Pharmaceuticals do not meet the criteria of a UW
Major Issues/Concerns of Supporters

- **Security**
  - no manifests and/or EPA IDs
  - Closed containers
  - Labels
  - Handler thresholds/accumulation times

- **Non-compliance**
  - Need education/enforcement
  - Still cheaper to mismanage

- **Outdated listings**
  - Rule covers only a small percentage of approved drugs

- **Reverse distributors**

- **DEA**
## Appendix: UW vs. Subtitle C (handlers)

<table>
<thead>
<tr>
<th>Quantity Handled by Category</th>
<th>Universal Waste Requirements</th>
<th>Generator Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small Quantity Handler of Universal Waste (SQHUW)</td>
<td>Large Quantity Handler of Universal Waste (LQHUW)</td>
</tr>
<tr>
<td></td>
<td>accumulate &lt; 5,000 kg (11,000 lb) on site at any one time</td>
<td>accumulate 5,000 kg (11,000) or more on site at any one time</td>
</tr>
<tr>
<td>EPA ID #</td>
<td>Not required</td>
<td>Required</td>
</tr>
<tr>
<td>On-Site Accumulation Limit</td>
<td>&lt; 5,000 kg</td>
<td>No quantity limit</td>
</tr>
</tbody>
</table>
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<th>Generator Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small Quantity</strong></td>
<td><strong>Large Quantity</strong></td>
<td><strong>Conditionally</strong></td>
</tr>
<tr>
<td>Handler of Universal</td>
<td>Handler of Universal</td>
<td>Exempt Small Quantity</td>
</tr>
<tr>
<td>Waste (SQHUW)</td>
<td>Waste (LQHUW)</td>
<td>Generator (CESQG)</td>
</tr>
<tr>
<td><strong>Storage Time Limit</strong></td>
<td>1 year, unless for proper</td>
<td>1 year, unless for</td>
</tr>
<tr>
<td>(without a storage</td>
<td>recovery, treatment, or</td>
<td>proper recovery,</td>
</tr>
<tr>
<td>permit)</td>
<td>disposal</td>
<td>treatment, or disposal</td>
</tr>
<tr>
<td><strong>Manifest</strong></td>
<td>Not required</td>
<td>Not required, but</td>
</tr>
<tr>
<td></td>
<td></td>
<td>must keep basic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>shipping records</td>
</tr>
<tr>
<td><strong>Personnel Training</strong></td>
<td>Basic training</td>
<td>Basic training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>geared toward employee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>responsibilities</td>
</tr>
</tbody>
</table>
Appendix: UW vs. Subtitle C (transporters)

<table>
<thead>
<tr>
<th></th>
<th>Universal Waste Transporters</th>
<th>Hazardous Waste Transporters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance with Department of Transportation (DOT)</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>EPA ID Number</td>
<td>none</td>
<td>yes</td>
</tr>
<tr>
<td>Allowance to Store up to 10 days at a Transfer Facility</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Manifest Requirements</td>
<td>none</td>
<td>yes</td>
</tr>
<tr>
<td>Response to Releases</td>
<td>yes</td>
<td>yes, with more complex requirements</td>
</tr>
</tbody>
</table>
Any overview questions?
Who do I contact at EPA?

- National Superfund/EPCRA/RCRA Hotline
  1-800-424-9346

- EPA Region 7 Oil and Chemical Spill Hotline
  913-281-0991

- Iowa EPA Region 7 Environmental Action Line
  1-800-223-0425

- Lisa Lauer, EPA, Headquarters
  Office of Resource Conservation and Recovery (ORCR)
  703-308-7418
Additional questions, specific concerns, or comments?

Stacie Tucker  
RCRA Compliance Officer  
U.S. EPA, Region 7  
AWMD/WEMM  
Office: (913) 551-7715  
Fax: (913) 551-9715  
Tucker.Stacie@epa.gov