Presentation Overview

- Why
- Definitions
- Applicability
- Management Standards
Pharmaceutical Rule Adopted by Utah – Effective Date September 14, 2020
1. Tailored regulations to prevent diversion to black market
2. Eliminate intentional sewering of hazardous waste pharmaceuticals
DEFINITIONS

- Pharmaceutical
- Hazardous Waste Pharmaceutical
3 Types of HW Pharmaceuticals

1. Non-Creditable
   - Broken or leaking
   - Repackaged
   - Dispensed
   - Expired >1 yr
   - Investigational new drugs
   - Contaminated PPE
   - Floor sweepings
   - Clean-up material
3 Types of HW Pharmaceuticals

1. Non-Creditable

2. Potentially Creditable
   - Original manufacturer packaging (except recalls)
   - Undispensed
   - Unexpired or less than 1-yr past expiration

3. Reverse Distributor

HW TSDF

WASTE MANAGEMENT & RADIATION CONTROL
POTENTIALLY CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS POLL
3 Types of HW Pharmaceuticals

1. Non-Creditable

2. Potentially Creditable

3. Evaluated

First Reverse Distributor

Second Reverse Distributor

Healthcare Facility

HW TSDF

No further evaluation or verification of manufacturer credit is necessary.
DEFINITIONS

* Healthcare Facility
* Reverse Distributor
Hazardous waste pharmaceuticals must be managed under Part 266

- Healthcare Facilities that generate above VSQG amounts of hazardous waste
- All Reverse Distributors
Healthcare Facilities and Reverse Distributors **MAY NOT** sewer Hazardous Waste Pharmaceuticals

Hazardous wastes that are DEA controlled substances are also subject to the sewer prohibition

The sewer prohibition is effective **NOW**
HEALTHCARE FACILITY MANAGEMENT STANDARDS

- Notification
- Training
- Hazardous Waste Determinations
  - Commingling
- Non-creditable Hazardous Waste Pharmaceuticals
- Potentially Creditable Hazardous Waste Pharmaceuticals
Facilities that are not required to submit a biennial report must have notified by **November 14, 2020**

Facilities that are required to submit a biennial report may notify on normal biennial report reporting cycle by **March 1, 2024**

*If required you should have submitted a biennial report this year on March 1, 2022.*
All personnel managing non-creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.
Hazardous Waste Determinations: must determine whether a waste pharmaceutical is a hazardous waste pharmaceutical

Commingling: may accumulate hazardous and non-hazardous waste pharmaceuticals in the same container
HAZARDOUS WASTE PHARMACEUTICALS WASTE DETERMINATIONS POLL
HEALTHCARE FACILITY
Hazardous Waste Pharmaceuticals

Non-creditable hazardous waste pharmaceuticals

- Label “Hazardous Waste Pharmaceuticals”
- Containers that are structurally sound and compatible
- Closed and secured
- Accumulate for 1 year

Potentially creditable hazardous waste pharmaceuticals

- No labeling, containers standards or accumulation time
### HEALTHCARE FACILITY STANDARDS

<table>
<thead>
<tr>
<th></th>
<th>Non-creditable HW Pharms</th>
<th>Potentially Creditable HW Pharms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Container Standards</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Maximum Accumulation Time</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Hazardous waste determinations*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Over-managing non-hazardous...</td>
<td>Allowed</td>
<td>Allowed</td>
</tr>
<tr>
<td>Include hazardous waste pharmaceuticals on BR</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Not required for either type if managing all pharmaceutical waste as hazardous*
EMPTY CONTAINERS POLL
Applies to any/all containers for hazardous waste pharmaceuticals

Residues remaining in “RCRA Empty” containers are not regulated as hazardous waste

No Triple Rinsing
## Empty Container Standards

### “RCRA Empty”

<table>
<thead>
<tr>
<th></th>
<th>Non-acute HW Pharms</th>
<th>Acute HW Pharms*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stock/Dispensing Bottles</strong> (1 liter or 10,000 pills) &amp; Unit-dose containers</td>
<td>Remove contents</td>
<td>Remove contents</td>
</tr>
<tr>
<td><strong>Syringes</strong></td>
<td>Fully depress plunger</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td><strong>IV Bags</strong></td>
<td>Fully administer contents or § 261.7(b)(1)</td>
<td>Fully administer contents</td>
</tr>
<tr>
<td><strong>Other Containers</strong></td>
<td>§ 261.7(b)(1) or (2)</td>
<td>Can not be RCRA empty</td>
</tr>
</tbody>
</table>

*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
VSQG HEALTHCARE FACILITIES

- Cannot sewer pharmaceuticals
- Pharmaceutical Rule Empty Container Standards apply
- Can opt into Subpart P
- Comply with VSQG requirements & optional provisions of Subpart P

WASTE MANAGEMENT & RADIATION CONTROL
LONG-TERM CARE FACILITIES

- 20 beds or fewer
- On-site collection receptacles
- Greater than 20 beds
Potentially Creditable

* Manifest and hazardous waste transporter are **NOT** required
* Common carrier is ok
* Delivery confirmation required

Non-creditable & Evaluated

* Manifest & hazardous waste transporter required
* TSDF required
* Healthcare Facility - use “PHARMS” on manifest
* Reverse distributor - use hazardous waste codes on manifest
FLOW OF HW PHARMACEUTICALS

- Maximum transfers allowed between RDs
- 180 days after evaluation allowed at each RD

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF
REVERSE DISTRIBUTOR MANAGEMENT STANDARDS

- Potentially Creditable Hazardous Waste Pharmaceuticals ONLY
- Notification
- Inventory
- Accumulation
REVERSE DISTRIBUTOR
MANAGEMENT STANDARDS

Potentially creditable hazardous waste pharmaceuticals

- No specific labeling or container standards
- Not included on biennial report

Evaluated hazardous waste pharmaceuticals

- Designate onsite accumulation area
- Labeling
- Weekly inspections
- Container standards
- Training & Contingency Plan
- Hazardous waste codes prior to transport
- Include on Biennial Report