HAZARDOUS WASTE
PHARMACEUTICALS &
AMENDMENT TO THE NICOTINE
LISTING (P075)
Presentation Overview

- Why
- Definitions
- Applicability
- Management Standards
- Nicotine Waste
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
   - HW TSDF

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

3. Reverse Distributor
   - 1st Reverse Distributor
   - 2nd Reverse Distributor

WASTE MANAGEMENT & RADIATION CONTROL
3 Types of HW Pharmaceuticals

1. Non-Creditable
   - Healthcare Facility

2. Potentially Creditable
   - 1st Reverse Distributor
   - 2nd Reverse Distributor

3. Evaluated
   - No further evaluation or verification of manufacturer credit is necessary
   - HW TSDF
DEFINITIONS

* Healthcare Facility
* Reverse Distributor
Reverse Distribution of Rx HW Pharmaceuticals

1st Reverse Distributor

2nd Reverse Distributor

Potentially Creditable Pharmaceuticals*

Non-creditable Pharmaceuticals+

Healthcare Facility

HW TSDF

Non-Compliant Disposal

Sewer

* Unsold/unused pharmaceuticals that have a reasonable expectation of receiving credit from the manufacturer
+ Pharmaceuticals with no reasonable expectation of receiving credit from the manufacturer
Hazardous waste pharmaceuticals must be managed under Part 266

* Healthcare Facilities that generate **above** Very Small Quantity Generator (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, 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.
HEALTHCARE FACILITY
HAZARDOUS WASTE DETERMINATIONS

- **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
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
<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>pharmaceuticals &amp; commingling with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hazardous waste pharmaceuticals</td>
<td></td>
<td></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

* 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>Stock/Dispensing Bottles (1 liter or 10,000 pills) &amp; Unit-dose containers</td>
<td>Remove contents</td>
<td>Remove contents</td>
</tr>
<tr>
<td>Syringes</td>
<td>Fully depress plunger</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td>IV Bags</td>
<td>Fully administer contents or § 261.7(b)(1)</td>
<td>Fully administer contents</td>
</tr>
<tr>
<td>Other Containers</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
LONG-TERM CARE FACILITIES

- 20 beds or fewer
- On-site collection receptacles
- Greater than 20 beds
SHIPPING HW PHARMACEUTICALS

**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

HCF/Pharmacy

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
NICOTINE
Nicotine is an acute hazardous waste that is listed as P075 due to its acute toxicity.

* P075 - Nicotine, and salts; this listing does not include patches, gums and lozenges that are FDA approved over-the-counter nicotine replacement therapies

* Unused formulations of nicotine are still considered P075 when discarded, including:
  - E-liquids/e-juices in e-cigarettes, cartridges, or vials
  - Prescription nicotine (e.g., nasal spray, inhaler)
  - Legacy pesticides containing nicotine
  - Nicotine used in research and manufacturing
NICOTINE REPLACEMENT THERAPIES

- EPA has concluded that nicotine patches, gums and lozenges do not meet the regulatory criteria for acute hazardous waste.
- Nicotine patches, gums and lozenges can be discarded as non-hazardous waste.

≠ P075