Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine:
Changes for Healthcare Facilities

Bart Collinsworth
Western Region Technical Assistance
Tuesday, March 8, 2022
Presumption –
Audience has previous knowledge of hazardous waste rules...

Terms used –
- Hazardous waste determination
  - Listed
  - Characteristic
- Generator status (size)
  - Very small, Small and Large quantity generators
- DEQ id number
  - Notification and annual reporting
Terms used continued –

Pharmaceutical hazardous waste = **Hazardous waste pharmaceuticals**
Non-pharmaceutical hazardous waste = **Other hazardous waste**
Non-hazardous waste pharmaceuticals = **Pharmaceuticals that aren’t hazardous**
Pharmaceutical Rule and P075 Amendment

**P075**

- Specific listing amendment limited to….

- Food and Drug Administration approved over the counter nicotine replacement therapies

**Pharmaceutical Rule**

- Management standards for healthcare facilities & reverse distributors

- Waste and sector specific!

- Prohibits sewering and ensures best ultimate disposal
P075: Nicotine Replacement Therapies

P075 Amendment

P075^154-11-5 Nicotine & salts
(Does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
Pharmaceutical Rule: What? Who?

• Pharmaceutical hazardous waste

• Healthcare facilities
  – Small or Large Quantity Generators for *All* their hazardous waste
    • *pharmaceutical hazardous waste* & *non-pharmaceutical hazardous waste*

*hazardous waste pharmaceuticals + all other hazardous waste*

• Reverse distributors
Sector and Waste Specific

Who is subject to the new Pharmaceutical Rule?

Are you automatically in because of your total hazardous wastes AND sector?
Pharmaceutical Rule Overview

Is it a Waste?
- Yes
- No: Not regulated

Is it a Hazardous Waste?
- Yes
- No: Manage as Solid Waste

Is it a Pharmaceutical?
- Yes
  - Was it generated by a Healthcare facility?
    - Yes
      - Is the Healthcare facility a SQG or LQG? for all their HW
        - Yes
          - Must be managed under 40 CFR 266 subpart P
        - No
          - Manage as hazardous waste under 40 CFR part 262
    - No
      - Manage as hazardous waste under 40 CFR part 262

OR if Very Small Quantity Generator opts-in,
Pharmaceutical Examples (waste specific)

- Dietary supplements
- Prescription and OTC drugs
- Homeopathic drugs
- Investigational new drugs
- Residues of pharmaceuticals in non-empty containers
- PPE-contaminated with pharmaceuticals
- Cleanup material from spills of pharmaceuticals

Dental amalgam, sharps and medical waste *ARE NOT pharmaceuticals*

*Solvents??*
Pharmaceutical Hazardous Wastes

- Arsenic Trioxide (P012)
- Nicotine (P075)
- Phentermine (P046)
- Physostigmine salicylate (P188)
- Warfarin >0.3% (P001)
- Epinephrine base (P042)
- Nitroglycerin (P081)
- Physostigmine (P204)
- Chloral hydrate (U034)
- Cyclophosphamide (U058)
- Dichlorodifluoromethane (U075)
- Diethylstilbestrol (U089)
- Hexachlorophene (U132)
- Melphalan (U151)
- Mitomycin C (U010)
- Phenol (U188)
- Resorcinol (U201)
- Selenium sulfide (U205)
- Trichloromonofluoromethane (U121)
- Uracil mustard (U237)
- Chlorambucil (U035)
- Daunomycin (U059)
- Lindane (U0129)
- Mercury (U151)
- Paraldehyde (U182)
- Reserpine (U200)
- Saccharin (U202)
- Streptozotocin (U206)
- Warfarin ≤ 0.3% (U248)
### Healthcare Facilities (sector specific)

<table>
<thead>
<tr>
<th>Facility Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale distributors</td>
</tr>
<tr>
<td>Military medical logistics facilities</td>
</tr>
<tr>
<td>Hospitals and psychiatric hospitals</td>
</tr>
<tr>
<td>Health clinics, physicians’ offices, chiropractors</td>
</tr>
<tr>
<td>Optical and dental providers</td>
</tr>
<tr>
<td>Pharmacies</td>
</tr>
<tr>
<td>Long-term care facilities</td>
</tr>
<tr>
<td>Veterinary clinics</td>
</tr>
</tbody>
</table>

### Not healthcare facilities
- Pharma manufacturers
- Reverse distributors
Healthcare Facilities and Reverse Distributors

Hazardous waste pharmaceuticals

Non-creditable
Potentially creditable
Evaluated
Different Pharmaceutical Hazardous Wastes

**Non-Creditable**
- Prescription or non-prescription with no expectation of credit, and
- Broken or leaking
- Repackaged
- Dispensed
- Expired >1 yr
- Investigational new drugs
- Contaminated PPE
- Floor sweepings
- Clean-up material

**Potentially Creditable**
- Prescription with a reasonable expectation of receiving a manufacturer credit, and
- In original manufacturer packaging
- Undispensed
- Unexpired or less than 1-yr past expiration

**Evaluated**
- No further evaluation or verification of manufacturer credit is necessary
Pharmaceutical Rule: Waste Flow

Healthcare Facility

Potential creditable

Non-creditable

Reverse Distributor

Evaluated

TSDF
Notify DEQ of activity as a healthcare facility or a reverse distributor – using the site identification form within 60 days of being subject to 266 subpart P

If withdrawing as a Very Small Quantity Generator, notify DEQ using the DEQ site identification form
Must submit withdrawal before operating under 262.14 – must keep copy of withdrawal for 3 yrs from date of signature on withdrawal notification
**Notification in YDO**

### 14. Additional Regulated Waste Activities

1. **Pharmaceutical Activities** (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)
   - [ ] Yes
   - [ ] No

1a. **Withdrawing from Pharmaceutical Activities**
   - [ ] Yes
   - [ ] No

---

**Healthcare Facility**

1. **Pharmaceutical Activities** (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)
   - [ ] Yes
   - [ ] No

1a. **Withdrawing from Pharmaceutical Activities**
   - [ ] Yes
   - [ ] No

---
Withdraw in YDO

14. Additional Regulated Waste Activities

1. Pharmaceutical Activities (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)

- Yes
- No

- Healthcare Facility
- Reverse Distributor

1a. Withdrawing from Pharmaceutical Activities

- Yes
- No

- If withdrawing from pharmaceutical activities, "No" must be selected for "Pharmaceutical Activities".

- In order for a Healthcare Facility to withdraw from Subpart P, Generator Status must not equal Large Quantity Generator (LQG) or Small Quantity Generator (SQG).
# Healthcare Facilities Management Standards

<table>
<thead>
<tr>
<th></th>
<th>Non-creditable HW Pharms</th>
<th>Potentially creditable HW Pharms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification</strong></td>
<td>![Checkmark] Healthcare facilities Notify</td>
<td></td>
</tr>
<tr>
<td><strong>Labeling</strong></td>
<td>Hazardous waste Pharmaceuticals</td>
<td>None</td>
</tr>
<tr>
<td><strong>Container standards</strong></td>
<td>![Checkmark]</td>
<td>None</td>
</tr>
<tr>
<td><strong>Max accumulation time</strong></td>
<td>1- year (UW like)</td>
<td>None</td>
</tr>
<tr>
<td><strong>Biennial reporting</strong></td>
<td>*None</td>
<td>*None</td>
</tr>
<tr>
<td><strong>Employee training</strong></td>
<td>![Checkmark]</td>
<td>None?</td>
</tr>
<tr>
<td><strong>Weekly inspections</strong></td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Manifest</strong></td>
<td>![Checkmark] PHARMS or PHRM</td>
<td>None</td>
</tr>
</tbody>
</table>

*No reporting – just notify; VSQGs opt-in/withdraw
## Container Standards/Labelling - Healthcare Facility

<table>
<thead>
<tr>
<th></th>
<th>Potentially creditable</th>
<th>Non-creditable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container standards</td>
<td>*No</td>
<td>-Yes-</td>
</tr>
<tr>
<td>Labelling</td>
<td>*No</td>
<td>Hazardous waste Pharmaceuticals</td>
</tr>
</tbody>
</table>

*Remember potentially creditable definition*
# Accumulation Time - Healthcare Facility

<table>
<thead>
<tr>
<th>Potentially creditable</th>
<th>Non-creditable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accumulation time limit</strong></td>
<td><em>None</em></td>
</tr>
<tr>
<td><strong>-Yes-</strong> One year or less</td>
<td>-Label each container with date</td>
</tr>
<tr>
<td></td>
<td>-Inventory system</td>
</tr>
<tr>
<td></td>
<td>-Designated area</td>
</tr>
</tbody>
</table>

*Remember potentially creditable definition*
Employee Training - Healthcare Facility

Potentially creditable

• No

Non-creditable

• Yes - must ensure all personnel managing non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.
## Manifesting non-creditable hazardous waste pharmaceuticals

**Waste codes:**

- PHARMS
- PHRM

<table>
<thead>
<tr>
<th>No</th>
<th>Type</th>
<th>Quantity</th>
<th>Unit Wt./Vol.</th>
<th>Waste Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>DM</td>
<td>1.65</td>
<td>G</td>
<td>PHARMS 214</td>
</tr>
<tr>
<td>1</td>
<td>CF</td>
<td>2.00</td>
<td>P</td>
<td>D001 352</td>
</tr>
<tr>
<td>5</td>
<td>DM</td>
<td>6.00</td>
<td>P</td>
<td>D001 352</td>
</tr>
</tbody>
</table>
## Shipping - Healthcare Facility

<table>
<thead>
<tr>
<th></th>
<th>Potentially creditable (49 CFR parts 171-180, if Haz Mat)</th>
<th>Non-creditable (containers for shipping)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*49 CFR 171.8 – NOT a HW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging</td>
<td>-</td>
<td>49 CFR parts 172, 173 and 180</td>
</tr>
<tr>
<td>Labelling</td>
<td>-</td>
<td>49 CFR parts 172 subpart E</td>
</tr>
<tr>
<td>Marking</td>
<td>-</td>
<td>49 CFR parts 172 subpart D</td>
</tr>
<tr>
<td>Placarding</td>
<td>-</td>
<td>49 CFR parts 172 subpart F</td>
</tr>
<tr>
<td>Manifesting</td>
<td>NO</td>
<td>40 CFR 262 Subpart B</td>
</tr>
<tr>
<td>Delivery Confirm</td>
<td>receive delivery confirm</td>
<td>receive signed manifest</td>
</tr>
</tbody>
</table>
Recordkeeping – Healthcare Facility

Potentially creditable
- notification
- withdrawal
- delivery confirm
- shipping papers
- shipments received

Non-creditable
- notification
- withdrawal
- manifest
- HW determs.
- shipments received

VSQGs - for both HW Pharma and non-pharma HW:
• May send potentially creditable pharma to Reverse Distributor
• May send “*HW pharma” to another Healthcare Facility
  • HCF meets 266.502(l), 503(b)
• May send HW pharma to an LQG
  • VSQG meets 262.14(a)(5)(viii), LQG meets 262.17(f)

Long-term Care Facilities that are VSQGs:
• May dispose HW pharma, with exceptions, in on-site receptacle of a Drug Enforcement Agency authorized collector
• With 20 beds or less is presumed to be a VSQG
## Pharmaceutical Rule: Empty Containers

<table>
<thead>
<tr>
<th>Type of Container</th>
<th>RCRA Empty: Non-Acute HWP</th>
<th>RCRA Empty: Acute HWP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock/Dispensing Bottles (1 liter or 10,000 pills) and 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 If not empty, then meet <a href="https://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol2/pdf/CFR-2014-title40-vol2.pdf">40 CFR § 261.7(b)(1)</a></td>
<td>Fully Administer Contents If not empty, then manage as non-creditable HW pharma</td>
</tr>
<tr>
<td>Other Containers (includes, but is not limited to: inhalers, aerosols, neutralizers, and tubes or ointments, gels or creams)</td>
<td>Meets <a href="https://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol2/pdf/CFR-2014-title40-vol2.pdf">40 CFR § 261.7(b)(1) or (2)</a></td>
<td>Cannot be RCRA Empty. Manage as non-creditable HW pharma</td>
</tr>
</tbody>
</table>
Pharma and P075: Oregon Adoption

P075: Adopted by reference.

Pharmaceutical Rule:

• Adopted by reference, except less than 20 bed long-term care facility
  Very Small Quantity Generator presumption - OAR 340-100-0002(3)
• Tailored to Oregon state rules - OAR 340-102-0500
  • Notification on Oregon Site Identification form
  • Reverse Distributors report annually to DEQ, not biennially to EPA
  • For empty container residuals follow 110 gals not 119 gals per DEQ definitions
Benefits for Healthcare Facilities

for hazardous waste pharmaceuticals

- Accumulate on site for 1 year
- Basic training requirements
- No longer -
  - large generator for 1 kg of acute hazardous waste
  - subject to satellite accumulation area rules
  - specify hazardous waste codes on manifests
  - perform weekly inspections
  - report annually to DEQ

for hazardous waste pharmaceuticals
Prohibitions for Healthcare Facilities

for hazardous waste pharmaceuticals

- Must not be sewered
- Pharmaceutical hazardous waste must end up at a permitted hazardous waste facility for final disposal
- Only potentially creditable hazardous waste pharmaceuticals can be sent to a Reverse Distributor
Technical Assistance: Regional Contacts

**Northwest Region**
*Clackamas, Clatsop, Columbia, Multnomah, Tillamook, and Washington counties*
- Pete Anderson, 503-229-5070
- Alex Bertolucci, 503-229-5336

**Western Region**
*Benton, Coos, Curry, Douglas, Jackson, Josephine, Lane, Lincoln, Linn, Marion, Polk and Yamhill counties*
- Bart Collinsworth, 503-378-5071

**Eastern Region**
*Baker, Crook, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Klamath, Lake, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler counties*
- Brian Allen 541-633-2014