MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

and Amendment to the P075 Listing for Nicotine

HAWAII HAZARDOUS WASTE PROGRAM

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CAUTION: OVERVIEW ONLY
<table>
<thead>
<tr>
<th>Part of rule</th>
<th>Applicability</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sewer ban</td>
<td>Healthcare Facilities &amp; Reverse Distributors</td>
<td>August 21, 2019</td>
</tr>
<tr>
<td>P075 listing amendment</td>
<td>All generators</td>
<td>June 25, 2020</td>
</tr>
<tr>
<td>Empty container definition</td>
<td>All generators</td>
<td>June 7, 2021</td>
</tr>
<tr>
<td>40 CFR 266 subpart P</td>
<td>Healthcare Facilities &amp; Reverse Distributors</td>
<td>June 7, 2021</td>
</tr>
</tbody>
</table>
SEWER BAN

- Effective August 21, 2019
- Hazardous waste pharmaceuticals may not be sewered
- Applies to all healthcare facilities, including VSQGs
- EPA and DOH discourage sewering of any pharmaceuticals by any entity
## EMPTY CONTAINER DEFINITION

<table>
<thead>
<tr>
<th>Stock/dispensing bottles (up to 1 liter or 10,000 pills) and unit-dose containers</th>
<th>Non-acute HW Pharms</th>
<th>Acute HW Pharms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove contents</td>
<td>Remove contents</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Syringes</th>
<th>Fully depress plunger</th>
<th>Fully depress plunger</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IV bags</th>
<th>Fully administer contents Or §261.7(b)(1)</th>
<th>Fully administer contents</th>
</tr>
</thead>
</table>

| Other containers | §261.7(b)(1) or (2) | Can not be RCRA empty |
Reverse distribution - Rx HW pharms

1st Reverse Distributor

Potentially creditable pharmaceuticals

Non-creditable pharmaceuticals

Healthcare Facility

2nd Reverse Distributor

HW TSDF

Non-Compliant Disposal

Sewer
Reverse logistics - Non-Rx pharms, retail items

Reasonable expectation of use/reuse or reclamation

No reasonable expectation of use/reuse or reclamation

Hazardous waste pharmaceuticals

Donate  Sell  Recycle  Repair  HW TSDF  Non-Compliant Disposal  Sewer
Pharmaceutical

- any drug or dietary supplement for use by humans or other animals
- electronic nicotine delivery system (ENDS)
- liquid nicotine/e-liquid packaged for retail sale for use in ENDS
### Pharmaceutical

- Dietary supplements
- Prescription drugs
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers
- PPE contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals

Does **NOT** include:

- Dental amalgam
- Sharps
- Medical waste
- Electronic nicotine delivery systems (ENDS), e.g., e-cigarettes, vaping pens
- Nicotine e-liquid/juice packaged for retail sale for use in ENDS, e.g., pre-filled cartridges or vials
Pharmaceuticals NOT subject to RCRA regulation:

- Reasonable expectation of being legitimately used/reused or reclaimed
- Recalled*
- Under preservation order, or during an investigation or judicial proceeding*
- Investigational new drugs*
- Household waste pharmaceuticals, including collected DEA controlled substances (with conditions in §266.506)

* Become subject to Subpart P when decision is made to discard
Any person that is lawfully authorized to:

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
Any person that is lawfully authorized to:

(1) Provide...care...of a human or animal...; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals
Healthcare facility

Includes, but is not limited to:
- Wholesale distributors
- Third-party logistics providers (‘3PLs’) that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians’ offices
- Optical and dental providers
- Chiropractors
- Long-term care facilities**

Does **NOT** include:
- Pharmaceutical manufacturers
- Reverse Distributors
- Reverse Logistics centers
- ENDS Retailers

Ambulance services
Pharmacies
Long-term care pharmacies
Mail-order pharmacies
Retailers of pharmaceuticals
Veterinary clinics & hospitals
Hazardous waste

Non-pharmaceutical HW

Non-HW pharmaceutical

Pharmaceutical
Hazardous waste

Non-pharmaceutical HW

Potentially creditable HW
HW pharmaceutical → pharmaceutical

Non-creditable HW pharmaceutical

Non-Rx

Non-HW pharmaceutical

Pharmaceutical

Rx
3 Types of HW Pharmaceuticals

1. Non-Creditable
   - Dispensed
   - Broken or leaking
   - Repackaged
   - >1 year expired
   - Investigational new drugs
   - Free samples
   - Residues
   - Floor sweepings
   - Contaminated PPE
   - Spill clean-up material
3 Types of HW Pharmaceuticals

1. Non-Creditable

- In original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1 year expired

2. Potentially Creditable

- Healthcare Facility
- Permit TSDF
- 1st Reverse Distributor
- 2nd Reverse Distributor
3 Types of HW Pharmaceuticals

1. Non-Creditable

Healthcare Facility

2. Potentially creditable

1st Reverse Distributor

3. Evaluated

No further evaluation/verification of manufacturer credit is necessary

Permitted TSDF

2nd Reverse Distributor
COMMON HW PHARMS

- D001: usually due to alcohol content
- D002
- P-listed: arsenic trioxide, nicotine, phentermine, physostigmine, physostigmine salicylate, warfarin >0.3%
- U listed: chloral hydrate, chloroform, formaldehyde, lindane, paraldehyde, phenol, reserpine, saccharin, selenium sulfide
- U-listed chemo: mitomycin, chlorambucil, cyclophosphamide, melphalan
DETERMINING APPLICABILITY

1. Count all hazardous waste → applicability of subpart P
   - Include HW pharms
   - **Include potentially creditable HW pharms**
   - Include non-pharm HW
   - Include all types of Universal Waste
   > 100 kg/mo HW or > 1 kg/mo acute HW → subject to subpart P

2. Count only HW subject to chapter 11-262.1 → generator category for notification and 11-262.1 regulations
   - Exclude HW pharms
   - Exclude UW
NON-HW PHARMS TO MANAGE WITH CARE

- More than one active ingredient on the P- or U-list
- Chemotherapy agents characterized as bulk wastes
- Meets NIOSH hazardous drug criteria
- LD50 ≤ 50 mg/kg
- Carcinogenic or endocrine disrupting compounds
- Vitamin/mineral preparations containing heavy metals
Once subject to subpart P, all healthcare facilities are regulated the same

Healthcare facilities operating under subpart P do not have to:

- Track monthly generation of HW pharmaceuticals
- Segregate acute and non-acute HW pharmaceuticals

Healthcare facilities managing all waste pharmaceuticals as HW do not have to keep documentation of HW determinations
GENERAL REQUIREMENTS

- Notification by August 6, 2021 (within 60 days of effective date, June 7)
- Employee training
- Hazardous waste determinations
- Reporting and recordkeeping
  - 3 years
  - Exception reporting (60 days)
- Spill response
ON-SITE ACCUMULATION

For non-creditable pharmaceuticals:

- Label “Hazardous waste pharmaceuticals”
- Containers
  - Structurally sound, compatible with contents, lack evidence of leakage spillage, or damage
  - Special requirements for ignitable/reactive
  - Closed
  - Secured in a manner than prevents unauthorized access to contents
- Maximum accumulation time 1 year
SEGREGATE NON-COMBUSTIBLE

- Metal bearing wastes prohibited from dilution in a combustion unit
- Label with hazardous waste codes

- D004-D011 arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver
- P012 arsenic trioxide
- U151 mercury
- U205 selenium disulfide
LIQUIDS AND AEROSOLS

- Sealed plastic bag or other outer container
- Reduce the risk of spills and release
## ON-SITE ACCUMULATION

<table>
<thead>
<tr>
<th>HEALTHCARE FACILITY</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>Max accumulation time</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>HW determinations*</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Not required if all pharmaceutical waste is managed as hazardous waste*
SHIPPING: NON-CREDITABLE

- To RCRA permitted TSDF
- Use a HW transporter & HW manifest
  - PHARMS or PHRM on manifest in item 13
  - Segregate metal bearing wastes prohibited from dilution in a combustion unit and label with HW codes
- Keep records for 3 years
To Reverse Distributor

Neither manifest nor HW transporter required (can use common carrier)

Shipper must receive delivery confirmation from reverse distributor
  - 35 days from date the shipment was sent
  - Electronic delivery confirmation okay

Keep records for 3 years
Count all hazardous waste – both HW pharmaceuticals & non-pharmaceutical HW

- Remain subject to §262.14
- Subject to subpart P ONLY for:
  - Sewer prohibition
  - Empty containers
  - Optional provisions of §266.504
Can send potentially creditable HW pharmaceuticals to reverse distributor

Can send HW pharmaceuticals to a healthcare facility under control of the same person

A VSQG long-term care facility can dispose of its HW pharmaceuticals (but not its DEA controlled substances) in an on-site collection receptacle that complies with DEA regulations
To receive and manage HW pharmaceuticals from a VSQG healthcare facility, a healthcare facility must:

- Be under the control of the same “person” OR supply the VSQG with pharmaceuticals
- Operate under 40 CFR Part 266 subpart P & manage the received pharmaceuticals under subpart P
- Keep records of shipments received for 3 years
## COMPARING VSQG CONSOLIDATION

<table>
<thead>
<tr>
<th>Subpart P VSQG consolidation</th>
<th>Generator Improvements Rule VSQG consolidation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be used by VSQG healthcare facilities only for HW pharms</td>
<td>Can be used by VSQG healthcare facilities for both HW pharms and non-pharmaceutical HW</td>
</tr>
<tr>
<td>Fewer conditions</td>
<td>More conditions</td>
</tr>
</tbody>
</table>
| Receiving healthcare facility must be:  
  • under the control of the same person as the VSQG, or  
  • the supplier of the pharmaceuticals | Receiving facility must be:  
  • under the control of the same person as the VSQG |
| Receiving healthcare facility does not have to be an LQG | Receiving facility must be an LQG |
A VSQG WHO OPTS IN

- Opt in/opt out notification
- Must comply with all subpart P standards for healthcare facilities
- Cannot use the optional provisions in section 266.504
  - Subpart P consolidation
- Still has to keep track of monthly generation amounts for non-pharmaceutical waste to verify VSQG status
<table>
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<tr>
<th>Management Standard Elements</th>
<th>Standards for Healthcare Facilities</th>
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<tbody>
<tr>
<td></td>
<td>Potentially Creditable</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• No standards</td>
</tr>
<tr>
<td></td>
<td>• No time limit</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping to Reverse Distributor</td>
<td>• Confirmation of delivery</td>
</tr>
<tr>
<td></td>
<td>• Common carrier</td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>Non-Creditable</td>
</tr>
<tr>
<td></td>
<td>• UW-like standards</td>
</tr>
<tr>
<td></td>
<td>• 1 year maximum</td>
</tr>
<tr>
<td>Shipping to TSDF</td>
<td>• Manifest (PHARMS or PHRM)</td>
</tr>
<tr>
<td></td>
<td>• HW transporter</td>
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</tbody>
</table>
HW pharmaceuticals that are also DEA controlled substances
CONDITIONAL EXEMPTION

- Sewer ban
- Collected, stored, and transported, in compliance with DEA requirements
- Destroyed by a method DEA has deemed in writing to meet their non-retrievable standard OR combusted at a permitted:
  - Large or small municipal waste combustor
  - Hospital, medical and infectious waste incinerator
  - Commercial and industrial solid waste incinerator
  - Hazardous waste combustor
RESOURCES

- DOH HW rules page & guidance
- EPA pharms rule website
  - Rule
  - FAQ
- Recorded webinar by EPA
- EPA guidance for managing pharms
RESOURCES

- **Healthcare Environmental Resource Center (HERC)**
  - Provides pollution prevention and environmental compliance assistance information for the healthcare sector.
  - Receives funding from EPA through the National Compliance Assistance Centers program

- **Guidance for safe disposal of household waste pharmaceuticals**

- **Retail strategy & reverse logistics policy**
Special thanks to Marcus Rivas at EPA Region 7 for sharing his slides, which were used to develop this presentation. nk

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