EPA Regulations for Hazardous Waste Pharmaceuticals
Washington State Medicine Take-back Summit

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Outline

- Examples of HW Pharmaceuticals
- RCRA HW that are also DEA Controlled Substances
- Household Hazardous Waste Exemption
- DEA Authorized Collection Receptacles
- EPA Recommendation & Future Regulation
- State Considerations
Examples of HW Pharmaceuticals

- **Listed hazardous wastes**
  - P-listed (acute HW): Warfarin, Nicotine, etc.
  - U-listed: Mitomycin C, Chlormal hydrate, Lindane, Selenium sulfide, Cyclophosphamide, etc.

- **Characteristic hazardous wastes**
  - Ignitable (D001): Preparations with >24% alcohol
  - Toxicity (D004-D043): if present above certain concentrations in the leachate during TCLP test
    - m-Cresol (preservative in insulin)
    - Mercury (preservative thimerosal)
    - Selenium (multi-vitamins)
    - Chromium (multi-vitamins)
    - Silver (burn creams)
Examples of HW Pharmaceuticals

- The chemical names on the P- and U-list are different than the drugs’ brand names and generic names, for example -
  - If you are a pharmacist: Brand name Trisenox
  - If you speak RCRA: Arsenic trioxide = P012

- The characteristic hazardous wastes (D001-D043) are descriptive:
  - Do not give any indication which specific drugs might exhibit a characteristic and
  - Can vary for different forms of the same drug, for example -
    - Fentanyl sublingual spray is dissolved in alcohol – D001 (ignitable)
    - Other forms of fentanyl are not hazardous waste
There are a few RCRA hazardous wastes that are also DEA controlled substances:

- Chloral hydrate (U034)
- Fentanyl sublingual spray (D001)
- Phenobarbital (D001)
- Testosterone gels (D001)
- Valium injectable (D001)
Household Hazardous Waste Exemption

- Hazardous waste generated at residences is exempt from RCRA regulation
  - “Household hazardous waste” = HHW
  - 40 CFR 261.4(b)(1)
- The exemption continues to apply even when the HHW is collected
Since the waste collected in a DEA authorized collection receptacle is from a residence (ultimate user), EPA would consider it to be exempt from RCRA as HHW.

Pharmacies cannot use the collection receptacles for their own hazardous waste pharmaceuticals.

Pharmacies must manage their own hazardous waste pharmaceuticals separately.
EPA’s Current Recommendation

- EPA recommends that pharmaceuticals collected at take-back events or collection programs should be incinerated at a permitted
  - municipal solid waste combustor, for example:
    - Spokane, WA
    - Marion County, OR
  - Or hazardous waste combustor, for example:
    - Clean Harbors in UT
    - Veolia or Clean Harbors in TX

- See EPA’s recommendation in memo
  - September 26, 2012
  - RCRA Online # 14833
Proposed Rule: 2 Conditional Exemptions

1. Hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation

- Conditions for exemption:
  - Must be managed in accordance with all DEA regulations
  - Must be combusted at a permitted/interim status:
    - municipal solid waste combustor or
    - hazardous waste combustor
Proposed Rule: 2 Conditional Exemptions

2. Authorized collectors of DEA controlled substances that co-mingle them with pharmaceuticals that are exempt household hazardous waste (HHW) would be exempt from RCRA regulation

- Conditions for exemption:
  - Must be managed in accordance with all DEA regulations
  - Must be combusted at a permitted/interim status:
    - municipal solid waste combustor or
    - hazardous waste combustor
States May be Different

- **State hazardous** waste regulations may still apply for collected HHW
  - States can be more stringent

- **State solid** waste regulations may apply for collecting waste
  - States may require licensing or permitting to be a solid waste collector
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- **Resources**
  - [http://hwpharms.wikispaces.com](http://hwpharms.wikispaces.com)