

# EPA Regulations for Hazardous Waste Pharmaceuticals

Washington State Medicine Take-back Summit

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# Outline

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- ▶ 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

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## ▶ Listed hazardous wastes

- ▶ P-listed (acute HW): Warfarin, Nicotine, etc.
- ▶ U-listed: Mitomycin C, Chloral 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

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- ▶ 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

# RCRA & DEA Overlap

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- ▶ 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

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- ▶ 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

# DEA Authorized Collection Receptacles

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- ▶ Since the 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 can not use the collection receptacles for their own hazardous waste pharmaceuticals
- ▶ Pharmacies must manage their own hazardous waste pharmaceuticals separately

# EPA's Current Recommendation

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- ▶ 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

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- I. 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

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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

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- ▶ 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

# CONTACT INFO & RESOURCES

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- ▶ **Resources**

- <http://www2.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals>

- <http://hwpharms.wikispaces.com>