Connecticut Department of Energy and Environmental Protection

Proposal to State-list Hazardous Waste Pharmaceuticals as a Universal Waste

September 26, 2014

Presented by Michele DiNoia , Senior Sanitary Engineer

Conference for Sharing Sustainable Solutions for Healthcare Facilities

Hosted by Yale-New Haven Hospital

Universal Waste Rule

- Universal Waste Rule (UWR) finalized on May 11, 1995.
- Streamline hazardous waste management standards to ease regulatory burden.
- Facilitate collection and proper recycling or treatment.
- Includes lamps, batteries, mercury-containing devices, pesticides, and electronics (some states including CT), and pharmaceuticals (FL & MI).

EPA Proposal

- EPA published a proposal to add hazardous waste pharmaceuticals to UWR on December 2, 2008.
- Due to unfavorable comments, EPA decided to not finalize the 2008 proposal.
- Developing a new proposal for healthcare-related facilities.
- Scheduled to be published in December 2014.

WEED Proposal

- Fall of 2013, WEED announced proposal to State-list hazardous waste pharmaceuticals as a UW.
- History of non-compliance.
- Available literature.
- Impact to the environment.
- Question is “How should we go about State-listing hazardous pharmaceutical waste as a universal waste?”

Stakeholders

- Formed stakeholders group in fall of 2013.
- 20 stakeholders/8 alternates.
- Assist in the development of the regulations.
- Represent the interest and views of a particular stakeholder.
- Provide valuable input.

Stakeholders

- Members represent hospitals, independent and retail pharmacies, long-term healthcare facilities, reverse distributors, veterinarians, universities, pharmaceutical manufacturers, transporters, waste management/consulting, DCP/Drug Control Division, and CT Dept. of Public Health.

- Asked to respond to several key issues as a starting point.

Key Issues

- How should the terms “pharmaceutical” and “pharmaceutical universal waste” be defined?
- Should drugs from latest NIOSH Publication and/or the OSHA Technical Manual be managed as a universal waste?
- How much training and what type of training should be required?
- Should containers of hazardous waste pharmaceuticals be kept closed?
- What type(s) of tracking records should be required to be kept?

Key Issues

- Other key issues from stakeholders –
  - How does reverse distribution fit into the proposal?
  - Who owns medication at long term care facilities?
  - Nicotine patches and gum.
  - Security concerns.

Stakeholders Group/Webpage

- Stakeholder meetings are held the second Wednesday of the month at DEEP Hqtrs.
- Meetings are open to the public.
- Stakeholders working on language for their draft of proposed UW regulations.
- WEED created pharmaceutical webpage.
- Link for webpage - http://www.ct.gov/deep/cwp/view.asp?a=2718&q=535950&deepNav_GID=1967

Pharmaceutical UW Stakeholders Group Webpage

- Meeting schedule, agendas, presentations.
- Stakeholder list.
- Universal Waste Rule.
- EPA's 2008 proposal and comments.
- Hazardous Waste Management Regulations.
- Other state's UW regulations and policies.
- Useful guidance documents.
- Association websites.

Pharmaceutical Waste

- All waste pharmaceuticals are a solid waste.
- Hazardous waste is a subset of solid waste.
- Universal waste is a subset of hazardous waste.
- Estimated that 5% of pharmaceutical waste is hazardous. Must be managed as RCRA hazardous waste.
- About 95% of waste pharmaceuticals are considered a solid waste and must be managed as a Connecticut non-RCRA waste.

Hazardous Pharmaceutical Waste

- "P"-listed or acute hazardous waste.
- "U"-listed hazardous waste.
- Characteristic hazardous waste -
  - Ignitable D001
  - Corrosive D002
  - Reactive D003
  - Toxic D004 – D043
- Florida published a list of pharmaceuticals that are potentially hazardous waste in December 2007.

Characteristic of Ignitability

- Liquid with flash point < 140 degrees Fahrenheit.
- A solid that can cause a fire and sustain combustion.
- A compressed gas.
- An oxidizer.
- Examples –

  Rubbing alcohol, amyl nitrate, Clindamycin Topical Solution, Paclitaxel prior to dilution, alcohol-based gels, pressurized aerosol inhalers with flammable propellants, etc.

Characteristic of Toxicity

- Flu vaccines in multi-dose vials only due to thimerosal preservative (mercury D009).
- Veterinary drugs containing merbromin (D009).
- Human insulin due to m-cresol (D024) preservative.
- Silver Sulfadiazine cream, silver nitrate (silver D011 and D001).
- Multivitamins and mineral supplements (chromium D007, selenium D010).

Examples of “P”-listed Pharmaceuticals

• Warfarin >3%	P001
• Arsenic Trioxide	P012
• Epinephrine & salts	P042
• Nicotine & salts	P075
• Nitroglycerin	P081
• Physostigmine salicylate	P188
• Physostigmine	P205

Examples of "U"-listed Pharmaceuticals

- Mitomycin C U010
- Chlorambucil U035
- Cyclophosphamide U058
- Daunomycin U059
- Lindane U129
- Melphalan U150
- Reserpine U200
- Selenium Sulfide U205
- Warfarin <3% U248

Empty Containers

- November 4, 2011 memo from EPA.
- http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/14827.pdf
- Regulatory status of “containers” that held “P”-listed pharmaceuticals.
- “Container” = bottle, vial, blister pack, or wrapper.
- The residue remaining in the container is a hazardous waste unless the container is empty.

Empty Containers

- Three ways that a container that held an acute hazardous waste is considered “empty” –
  - “Container” has been triple rinsed, or
  - “Container” has been cleaned by another method shown in scientific literature to be equivalent, or
  - The inner liner has been removed.
- Do not triple rinse! Rinsate a hazardous waste.
- Count only the residue toward generator status.
- Manage the “container” as a hazardous waste.

Determining Generator Status

Large Quantity Generator (LQG) –

generates ≥ 1000 kg/month of hazardous waste, OR

generates > 1 kg/month "P"-listed waste, OR

stores > 1 kg of "P"-listed waste at any one time.

Small Quantity Generator (SQG) –

generates > 100 kg/month but < 1000 kg/month of hazardous waste, AND

generates ≤ 1 kg/month "P"-listed waste, AND

stores ≤ 1 kg/month "P"-listed waste at any one time.

Conditionally Exempt Small Quantity Generator (CESQG) –

generates ≤ 100 kg/month of hazardous waste, AND

generates ≤ 1 kg/month "P"-listed waste, AND

stores ≤ 1 kg/month "P"-listed waste at any one time.

[Note: CT requirements are more stringent than federal requirements.]

LQG Requirements

- Hazardous waste determinations (update annually and have documentation on-site).
- EPA Identification number.
- Manifest and land disposal restriction documents.
- Exception reporting.
- Container marking.
- Labeling of containers (also DOT requirements).
- Container management.

LQG Requirements

- Inspection schedule and logs.
- Inspections (daily, weekly, monthly).
- Personnel training (initial and annual).
- Contingency planning.
- Biennial waste reporting.
- Use only permitted transporters.
- Recordkeeping (maintain for at least 3 years)
- Use TSDFs.

Universal Waste Advantages

- Does not count toward generator status.
- Longer accumulation limits (1 year vs. 90 or 180 days).
- EPA Identification number not required.
- Do not need to use a hazardous waste manifest (within CT).
- Personnel training is less rigorous (duty specific).
- Recordkeeping is not as extensive.

Universal Waste Advantages

- Inspections not required, but good idea.
- Biennial reporting not required.
- May aggregate waste at a non-RCRA TSDF.
- Generator status may change from LQG to SQG or even CESQG (when pharmaceutical waste a UW).
- For SQGs, generator status may change to CESQG (pharmaceutical waste).

Flow of Hazardous Waste Pharmaceuticals - 3 Problem Areas

Potentially Creditable Pharmacy Drugs (20%)

Non-creditable Floor Waste & Pharmacy Drugs (80%)

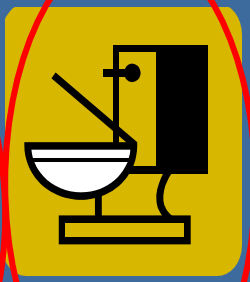
Healthcare Facility/ Pharmacy

1st RD

2nd RD

HW TSDF

Non-Compliant Disposal ≈40-50%



Sewer ≈20%

Flow of Hazardous Waste Pharmaceuticals

Notes:

- Information presented in the previous slide was provided by Kristin Fitzgerald of EPA Headquarters at a meeting with EPA and states held on June 4, 2014.
- The percentages are based on estimates EPA received via consultations with industry.
- The percentages are part of a DRAFT economic analysis that will be done in conjunction with EPA's new proposed rule, and will be subject to review and comment when the rule is published.

Hospitals

- WEED inspected 15 hospitals since 2006.
- 20% of the hospitals found to be in compliance.
- 80% of the hospitals in non-compliance.
- Informal enforcement actions (Notices of Violation) issued to 65% of the hospitals.
- Formal enforcement actions with payment of civil penalty (Consent Order and Referral to the AGO) for 15% of the hospitals.

Hospitals

- Violations included –
  - Hazardous Waste Determinations
  - EPA Identification number
  - Storing waste on-site beyond allowable 90 or 180-days
  - Container management
  - Marking/labeling
  - Inspection schedule and/or log
  - Inspections
  - Failure to correct deficiencies found during inspections

Hospitals

- Personnel training
- Recordkeeping
- Contingency planning
- Biennial reporting
- Universal Waste
- Recyclables

VISIT the Pharmaceutical Universal Waste Stakeholders Group Webpage

http://www.ct.gov/deep/cwp/view.asp?a=2718&q=535950&deepNav_GID=1967

Michele DiNoia
Waste Engineering and Enforcement Division
(860) 424-3816
Michele.DiNoia@ct.gov

Connecticut Department of Energy and Environmental Protection