Hazardous / Non-Hazardous Pharmaceutical Waste Disposal

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Concept of “Green Pharmacy” Gaining Attention

“Cradle-to-Grave” Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health.

EPA auditing 480 hospitals in 2013; Rx waste
States beginning to focus on management of waste pharmaceuticals
Florida
Washington State
Minnesota
Michigan
Colorado

Intersecting regulatory agencies
EPA, DEA, OSHA, State Boards of Pharmacy, CDPHE

Wastage of Raw Materials from Manufacturing Process
Wastage at the Distributor/Pharmacy/Healthcare Facility
Wastage at the LTCF or other residential facility
Expired Pharmaceuticals
Wastage at the Consumer Level
Metabolites Entering Wastewater

USGS Water Quality Study*

First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants
139 streams in 30 states, analyzed for 95 different OWCs
82 of the 95 detected in at least one sample
One or more OWCs found in 88% of stream samples
13% of sites had more than 20 OWCs

Low sperm counts (50% reduction since 1939)
Infertility
Genital deformities
Hormonally triggered human cancers
Neurological disorders in children
Hyperactivity
Attention deficit
Developmental & reproductive problems in wildlife
What is RCRA and Why Does it Matter?
- Federally based program created by Congress in 1976. EPA added language/requirements and rolled out across the US in the early 1980’s. Colorado is an EPA Authorized State that administers RCRA with EPA oversight.
- Contains strict definitions of hazardous waste; different from OSHA, NIOSH, etc.
- RCRA hazardous waste pharmaceuticals generally require incineration at RCRA incinerator (only 10 nationwide, none in Colorado).
- Non-RCRA pharmaceutical waste is regulated too, but not as strictly.

Definition of a Hazardous Waste (4 CCR 1007-3, Section 261.3)
A hazardous waste is a solid, a liquid or a contained gaseous material that is no longer used and that no longer serves the purpose for which it was produced, and could pose dangers to human health and the environment after it is discarded.

Hazardous Waste Generators
- Must determine what wastes are RCRA hazardous wastes.
- Must ensure that the hazardous waste is disposed of at a permitted hazardous waste disposal facility.
- Other requirements apply depending on the generator category.
- Requirements apply as soon as waste is generated.

Where Have Waste Drugs Gone in the Past?
- Primarily concerned with rendering drugs unrecovurable
  - In dumpsters, municipal trash
  - Made slurries, sewered
  - Burned in hospital incinerators
- No training in pharmacy curriculum on EPA regulations
Where are Waste Drugs Going Today?
- Sewer System
  - Unused, partial IVs, including antibiotics
  - Compounding residues
  - Liquids
- Red Infectious Waste Sharps Containers, Bags
- Yellow or White Chemotherapy Sharps Containers, Bags

Reverse Distribution: Current Scenarios
- Decision to discard is made at the pharmacy
  - By pharmacy
  - By a contracted company
  - Pharmacy (hospital) becomes the waste generator
- Decision to discard is made at the reverse distributor
  - Reverse Distributor becomes the waste generator

Benefits of a Comprehensive Hazardous Waste Disposal Plan
- Environment of Care Performance Improvement Initiative
  - New 2004 Standards – see both Medication Management and Environment of Care
- Reduces EPA liability and risk exposure to a minimum
- Protects employees and patients
- Demonstrates responsible care in dealing with hazardous substances, hazardous wastes

Resources
- RCRA Online: www.epa.gov/rcraonline
- RCRA Hot Line: 1-800-424-9346
- Improper Discard of Toxic Drugs Hurts Environment: Leads to Fines. AJHP, Vol. 58, #17 September 1, 2001 pp 1576-1578
- CDPHE Contact: Dan Goe (303)692-3341

QUESTIONS?