Pharmaceutical Waste Management: Current Concepts

ACPE UAN 0107-0000-10-004-L04-P & 0107-0000-10-004-L04-T 0.1 CEU/1.0 Hr.

Activity Type: Knowledge-Based

Program Objectives for Pharmacists & Technicians: Upon completion of this program, participants should be able to:
1. Summarize issues and challenges in the disposal of pharmaceutical and hazardous waste in the pharmacy.
3. Describe other regulations surrounding the proper disposal of pharmaceutical wastes.
4. Define effective practice strategies for management of pharmaceutical and hazardous waste that you can apply in your institution.

Speaker: Firouzan “Fred” Massoomi, PharmD, FASHP, received his Doctor of Pharmacy Degree from the University of Kansas School of Pharmacy, Lawrence, Kansas, 1990. His post-doctoral education included the completion 1 year of a 2 year ACCP-Accredited Fellowship in Infectious Diseases and Pharmacokinetics at the Universite Laval Laboratoire de Pharmacocinetique in Quebec City Quebec Canada 1991; completed an ACCP-Accredited Residency in Clinical Pharmacokinetics at Saint Joseph Hospital & Creighton University School of Pharmacy and Allied Health Professionals, Omaha, Nebraska in 1992. His current position is acting Pharmacy Operations Coordinator with the Department of Pharmacy at Nebraska Methodist Hospital in Omaha, Nebraska. A position he has held since 1996.

Dr. Massoomi has lectured nationally on implementation strategies for compliance with USP 797, proper hazardous drug management as outlined in the Centers for Disease Control’s National Institute of Occupational Safety and Health Alert, and, proper disposal of hazardous drug waste as outlined by the Environmental Protection Agency’s Resource and Conservation Act of 1976.

Through numerous presentations and publications, Dr. Massoomi has shared his passion for the practice of pharmacy with the goal of promoting the important role that individual pharmacist play in public safety. Dr. Massoomi was honored with the Health-System Pharmacist of the Year award from the Nebraska Pharmacists Association and the United Way Health-system Volunteer of the Year Award for his work with emergency preparedness for city of Omaha and State of Nebraska in 2004, selected as a Fellow for the American Society of Health-System Pharmacists in 2006, and, awarded Innovative Pharmacist of the Year by the Nebraska Pharmacists Association in 2007. In 2009, Dr. Massoomi testified in front to the House of Representatives, Committee on Natural Resources, Subcommittee of Insular Affairs, Oceans, and Wildlife as a panel member for “Overdose: How Drugs and Chemicals in Water Supplies and the Environment are Harming our Fish and Wildlife”.

Speaker Disclosure: Firouzan “Fred” Massoomi reports he has no actual or potential conflicts of interest in relation to this program. The speaker has indicated that off-label use of medications will not be discussed during this presentation.
Pharmaceutical Waste
Cradle to Grave

Firouzan 'Fred' Massoomi, Pharm.D., FASHP
Pharmacy Operations Coordinator
Nebraska Methodist Hospital
Omaha, Nebraska
Fred.Massoomi@nmhs.org

March 2008, Multiple series
5 month investigation highlighted that 80% of 139 sampled streams in 30 states contaminated
As part of work conducted by the United States Geological Survey (USGS)
Contaminated with estrogen disruptors, anticonvulsants, antibiotics, mood stabilizers
Implicates consumer as primary source

September 14, 2008
Health facilities flush 250 million pounds of drugs a year
Listed as a major source of most toxic and most concentrated forms of pharmaceuticals
DEA implicated as major hurdle for proper disposal

Pending Legislation
- Drug Free Water Act of 2009
  - Introduced into the House on January 7, 2009
  - EPA Task Force regarding proper disposal of unused drugs
- Safe Drug Disposal Act of 2009
  - Introduced into the House on February 25, 2009
  - Amend Controlled Substances Act to provide for the disposal of controlled substances by ultimate users and care takers through State take-back disposal programs
  - To amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing
- Secure & Responsible Drug Disposal Act of 2009
  - Introduced into the House on March 5, 2009
  - To amend the Controlled Substances Act to enable consumer take-back programs

Oversight of Drugs and Wastes
- United States Pharmacopoeia (USP)
- Occupational Safety and Health Association (OSHA)
- United States Environmental Protection Agency (USEPA)
- Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Food & Drug Administration (FDA)

Regulated Pharmaceutical Waste
- Resource Conservation and Recovery Act
  - RCRA
  - Regulated by the EPA since 1976
- Listed chemicals
  - P-list (acutely hazardous)
  - U-list (toxic, ignitable, corrosive, reactive)
- Characteristic chemicals
  - AKA D-list
    - Ignitability (D001)
    - Corrosivity (D002)
    - Reactivity (D003)
    - Toxicity (D number specific to chemical)
  - **NOTE: primary drug may not be what is listed!

EPA Defined Hazardous Drugs
- P-listed
- U-listed

http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr261_05.html
Exemptions are State Specific

- EPA guidance on exemptions
  - Nitroglycerin
  - Epinephrine Salts
- States who do NOT allow exemptions
  
<table>
<thead>
<tr>
<th>Nitroglycerin</th>
<th>Epinephrine salts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut</td>
<td>Connecticut</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Hawaii</td>
</tr>
<tr>
<td>Maine</td>
<td>New York – exempted 7/15/09</td>
</tr>
<tr>
<td>Michigan</td>
<td>Washington</td>
</tr>
</tbody>
</table>

*Florida, Michigan, Minnesota, Washington

EPA Defined Hazardous Drugs

D-Listed Characteristic Chemical Waste

<table>
<thead>
<tr>
<th>Code</th>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>D004</td>
<td>Arsenic</td>
<td>5 mg/L</td>
</tr>
<tr>
<td>D005</td>
<td>Barium</td>
<td>100 mg/L</td>
</tr>
<tr>
<td>D022</td>
<td>Chloroform</td>
<td>6 mg/L</td>
</tr>
<tr>
<td>D007</td>
<td>Chromium</td>
<td>5 mg/L</td>
</tr>
<tr>
<td>D024</td>
<td>M-Cresol</td>
<td>200 mg/L</td>
</tr>
<tr>
<td>D013</td>
<td>Lindane</td>
<td>0.4 mg/L</td>
</tr>
<tr>
<td>D009</td>
<td>Mercury</td>
<td>0.2 mg/L</td>
</tr>
<tr>
<td>D101</td>
<td>Selenium</td>
<td>1 mg/L</td>
</tr>
<tr>
<td>D011</td>
<td>Silver</td>
<td>5 mg/L</td>
</tr>
</tbody>
</table>

Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Attorney General, Grand Jury
- Corporate fines
  - $37,500 per violation/day
- Personal liability
  - fines and/or imprisonment
- No statute of limitations
- Managers up through CEO
- Not taken seriously by hospitals due to no consistent survey process and no enforcement agency like CMS for reimbursement

Employee Safety is PRIORITY

- OSHA
  - Standard (29 CFR part 1910 – 1200)
  - Hazard Communication Standard
    - "Right to know"
    - Provides a definition for hazardous chemicals (drugs)
    - Requires adequate training and employee safety programs
    - Personal Protective Equipment use
- Hazardous Waste Operations and Emergency Response (HAZWOPER)
  - Standard (29 CFR 1910.120)
  - Safe guards workers who manage hazardous waste
  - Chemicals/drugs, needles/sharps
  - Liability falls on source of hazardous waste
  - Contracted services employees

EPA’s Status

- Facility Survey NOT to be conducted
- Publish “Best Management Practices for Health Care Facilities” for 2010
- Work within EPA, with our Federal partners, and stakeholders in developing this draft guidance
- Universal Waste Rule proposal
  - Summarization of comments 2010


What is hazardous?

- WHO’s International Agency for Research on Cancer IARC 1986
  - Prepare and publish in the form of monographs, critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures.
  - IARC Group I – III Human Carcinogens 29 drugs
- Department of Transportation Hazardous Materials Transportation Law
  - Any substance or material that is considered to have the capability to cause an unreasonable risk to human health or safety or the environment when transported in commerce, used incorrectly, or if not properly stored or contained is considered a hazardous material.
- Occupational Safety & Health Administration Hazard Communication Standard
  - any chemical that is a physical hazard or a health hazard for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees
- National Institute for Occupational Safety & Health NIOSH 2004
  - Drugs are classified as hazardous drugs if studies in animals or humans indicate their potential to cause cancer, developmental or reproductive toxicity, or harm to organs
  - Carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity, at low doses, genotoxicity, structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the listed criteria

Source: www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr261_00.html ASHP 1990; OSHA 1995, 1999
Define Formulary Hazards

- Collaborative formulary assessment
  - NIOSH Appendix A & IARC
- Continuous assessment of Risk and Stream

Department of Transportation

- Protect human health and the environment
- The responsibility lies with the shipper
- Waste stream determination and manifest is responsibility of generator/shipper
- Reverse-tracers!!!!!!

http://www.pnnec.org/hazardmaterial/manifest_videomedia.html

Controlled Substance Waste

Proper Disposal

- No CSA definition of "waste"
- No distinction between expired, contaminated controlled substances and saleable product
- Accountability required of all controlled substances

Getting Started

- Consistent system for managing RX waste
  - Think Cradle to Grave do not think silo
  - Incorporate ALL regulations
  - Identify best practices
- Dedicated work team
- Perform gap analysis
- Design compliance plan

Pharmaceutical Waste Team

- Primary
  - Hospital administration
  - Pharmacy Lead
  - Risk Management
  - Environmental Services
- Secondary
  - Infection Control
  - Safety Officer
  - Facility Management
  - Purchasing leads
  - Pharmaceuticals
  - Surgical supplies
  - Central supplies
  - Physician office managers

Pharmacy Waste Stream Methodologies

1. Model I: Manual Segregating at Point of Generation
2. Model II: Automatic Sorting Device
3. Model III: Centralizing Segregation
4. Model IV: Managing All Drug Waste as Hazardous
**Model I**

**Manual Sorting of Regulated Waste**

- Entire inventory has been manually analyzed
  - New drugs have to added to the system
- Items are labeled
  - During receiving process or electronically
- Regulated drugs are dispensing in colored bag

- Combination

**Model II**

**Electronic Sorting of Regulated Waste**

- Electronically logging managed waste
- All United States NDCs
- Barcode segregation
- Cart and wall configuration
- Alerts staff when full
- Completes required USEPA and DOT manifests

“Scan Dispose Close”

www.vestara.com

**Model III**

**Centralizing Segregation**

- All pharmaceutical waste is collected in hazardous waste containers
- Mixed waste is removed to the central hazardous waste storage accumulation area
- Sorting is done by hazardous waste vendor or trained hospital staff based on analysis of the inventory

- NOTE: the generator (HOSPITAL) is liable for contracted employee harm

Source: Charlotte A. Smith, R. Ph., M.S., PharmEcology, WM Healthcare Solutions, Inc.

**Model IV**

**Managing All RX Waste as Hazardous**

- Easiest, most expensive
- Need to sort out characteristic wastes
  - Toxic, Corrosive, Ignitable, Reactive
- Inventory for waste codes for manifesting
- Storage space issues

**Implementation of Program**

- Staff education training
  - Posters and placards
  - Unit based training
- Staff hands on training
  - Handlers to movers to shippers
- Pilot program
  - Assess effectiveness processes
  - Gain user feedback
  - Policies and Procedure
- Establish rollout process
  - Housewide vs. staged
  - Health-system wide

**Education Strategies**

- Define key stakeholders
- Channel education through primary conduits
  - Written Versus Electronic
  - Initial training for all hospital staff
    - Existing staff
    - New staff at orientation
- Mandatory annual competency assessment
  - Continuous
**Assessment of Compliance**

**Trash Rounds**
- Random audits for compliance
  1. Check staff knowledge
  2. Check waste containers
  3. Track quantities
  4. Track costs
  5. Document process and results

**Staff Processes**
- Check Streams

**Waste Segregation Cost**

<table>
<thead>
<tr>
<th>Biohazardous (Regulated Medical)</th>
<th>Blood products, sharps, items contaminated with liquid blood, etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous &amp; Non-Hazardous</td>
<td>Empty chemotherapy vials, syringes, IVs, tubing, gowns, packaging, gloves, etc.</td>
</tr>
<tr>
<td>RCRA Hazardous</td>
<td>Bulk chemo in vials, unused IV’s, P, U, toxic &amp; ignitable Overtly contaminated gowns, glove, chemo spill clean up materials</td>
</tr>
<tr>
<td>RCRA Biohazardous</td>
<td>$1.00/pound</td>
</tr>
</tbody>
</table>

**RX Waste Management Survey**

- Pharmacy Purchasing & Products October 2009
  - 205 Hospital Pharmacist Surveyed
    - 75% pharmacy directors
    - 31% 100 beds; 21% 101-200; 17% 201-300
    - 18% Awareness of EPA Facility Survey
    - 29% of facilities spend <$20,000 on waste
    - Challenges to regulatory compliance:
      - 62% lack of in-house expertise
      - 51% lack of budget
      - 49% lack of storage
      - 41% lack of informative resources
      - 21% lack of administrative support

**RX Waste Management Survey**

- Current Compliance
  - 53% RCRA Hazardous
    - 31% listed Warfarin >0.3% as RCRA
    - 32% listed regular trash and 28% red sharps
    - 22% listed flu vaccine/thimerosal as RCRA
    - 17% regular trash and 49% red sharps
  - 91% Controlled substances
  - 89% Hazardous Chemotherapy
  - 7% very satisfied
  - 24% satisfied
  - 35% not satisfied
  - 38% had used a wasted management consultant

**TJC Wants to Know How Your Facility Manages Pharmaceutical Waste**

- How is pharmaceutical waste from your patient care units disposed of?
- How are unused non-chemotherapy IVs or other compounded fluids disposed of?

Source: Inside the Joint Commission, 2009 Pharmaceutical Waste Survey

**Pharmaceutical Waste Resources**

- Regional Environmental Protection Agency
- American Society of Health Systems Pharmacists
- State of Florida PharmWaste List Serve
  - Pharmwaste@lists.dep.state.fl.us
- Group Purchasing Organizations
- Hospitals for a Healthy Environment H2E
- PharmEcology Group, LLC: www.pharmeology.com
- Vestara, LLC
- www.saftersolutions.com
- Hospital Waste Haulers
- Reverse Distributors