Pharmaceutical Waste Management
Are We There Yet?

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Which Pharmacy Class Did We Learn This In?
Associated Press Announces Concerns In US Drinking Water

- **March 2008**
  - 5 month investigation highlighted that 80% of 139 sampled streams in 30 states contaminated
    - Contaminated with estrogen disruptors, anticonvulsants, antibiotics, mood stabilizers
    - Implicates consumer as primary source
  
  *Source: USA Today March 2008*

- **September 2008**
  - Health facilities flush 250 million pounds of drugs a year
    - DEA implicated as major hurdle for proper disposal

*Source: USA Today September 2008*

- **March 03, 2011**
  - Integrity of the US water supply noted
Pharmaceuticals in drinking water

- Tested positive for pharmaceuticals
- Tested negative for pharmaceuticals
- Test results pending

* In Virginia Beach, pharmaceuticals were found in source water but not in treated drinking water.
** Drinking water in Austin, Texas, was tested for only one prescription drug, a synthetic birth control chemical.

NOTE: All places include some surrounding areas except: Albuquerque, N.M.; Arlington, Texas; Long Beach, Calif.; Los Angeles; New Orleans.

SOURCES: Drinking water providers' responses to Associated Press questions; AP review of scientific literature.
Senate & House Hearings on Drugs in Water

- **Senate Hearing**
  - April 15th, 2008
  - Senators Barbara Boxer, Frank Lautenberg

- **House Committee on Transportation and Infrastructure**
  - Subcommittee on Water Resources and Environment
  - September 19th, 2008

- **House Committee on Insular Affairs, Oceans, and Wildlife Oversight**
  - June 9, 2009
    - “Overdose: how drugs and chemicals in water supplies and the environment are harming our fish and wildlife”

- **Senate Hearing: Special Committee on Aging**
  - June 30, 2010
    - “Drug Waste and Disposal: When Prescriptions Become Poison”
Pending Legislation

- **Drug Free Water Act of 2009**
  - EPA Task Force regarding proper disposal of unused drugs

- **Safe Drug Disposal Act of 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 – PASSED**
  - To amend the Controlled Substances Act to enable consumer take-back programs
  - Excludes Long-term care facilities

Slide courtesy of Charlotte Smith
Health facilities, NY settle over drug-flushing

Posted: Jan 12, 2010 12:11 PM CST
Updated: Jan 13, 2010 4:37 AM CST

By MARCUS FRANKLIN
Associated Press Writer

NEW YORK (AP) - New York Attorney General Andrew Cuomo announced a settlement Tuesday with five health care facilities that flushed pharmaceutical waste into the New York City watersheds.

Cuomo reached agreements with the two hospitals and three nursing homes that disposed of painkillers, antibiotics, antidepressants, hormones and other pharmaceuticals through toilets and sinks and into the watersheds, his office said. The flushes potentially put about 9 million people's drinking water at risk, Cuomo said.

The three watersheds - the Croton, Catskill and Delaware - cover nearly 2000 square miles and drain into reservoirs and lakes providing drinking water to New York City's roughly 8 million residents and another 1 million in several northern counties - nearly half the state's 19.4 million residents.

The hospitals and nursing homes are located within the watershed in Putnam and Delaware counties north of New York City.
Regulatory Bodies for RX Wastes

- **US Environmental Protection Agency**
  - 1976 Resource Conservation Act (RCRA)
  - Federal & State Specific Regulations

- **Local Publicly Owned Treatment Works (POTWs)**
  - Permission has to be granted to dump/pour
  - Local Regulations

- **Occupational Safety and Health Agency**

- **Drug Enforcement Agency**
  - Controlled Substances Act of 1984
  - NO SPECIFIC guidance on destruction only accountability
Regulatory Bodies for RX Wastes

- **Department of Transportation**
  - HAZWOPER from OSHA
  - Hazardous Waste Transportation regulations

- **Food and Drug Administration**
  - 27 drugs with package insert disposal recommendations
  - Assisted White House policy for public disposal

Examination Bodies for RX Wastes
Almost two thirds of hospitals have been inspected by their state boards or the EPA in the past three years with 48% questioned about RCRA compliance. Reflecting pharmacies’ lack of confidence in this area, 30% of facilities received recommendations.

N=343 Rx Directors

How did the EPA get involved?

- Creation of EPA 1970
  - Prior to loose standards on disposal regulations
  - Lack of environmental protection

- EPA's mission is to protect human health and to safeguard the natural environment—air, water, and land—upon which life depends

Cuyahoga River, OH

Fire History
What Drug Waste is Regulated?

- **Solid Waste Disposal Act of 1965**
  - “encourage environmentally sound methods for disposal of household, municipal, commercial, and industrial refuse”

- **Amended in 1976 Resource Conservation and Recovery Act (RCRA)**
  - “Protect human health and the environment from the potential hazards of waste disposal”
  - Love Canal, NY 1978

Hooker Chemical company - dumped 20,000 tons - contaminated water and soil

$400mil to clean-up

What was the real cost?
Regulated Pharmaceutical Waste

- Resource Conservation and Recovery Act
  - RCRA
  - Listed chemicals
    - P-list (acutely hazardous)
    - U-list (toxic, ignitable, corrosive, reactive)
  - Characteristic chemicals
    - AKA D-list

- Controlled Substances

- And, what ever your state says!
EPA Defined Hazardous Drugs

<table>
<thead>
<tr>
<th>P-listed</th>
<th>U-listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>P012 Arsenic Trioxide</td>
<td>U034 Chloral Hydrate</td>
</tr>
<tr>
<td>P042 Epinephrine</td>
<td>U035 Chlorambucil</td>
</tr>
<tr>
<td>P075 Nicotine</td>
<td>U044 Cloroform</td>
</tr>
<tr>
<td>P081 Nitroglycerin</td>
<td>U058 Cyclophosphamide</td>
</tr>
<tr>
<td>P204 Physostigmine</td>
<td>U059 Daunomycin</td>
</tr>
<tr>
<td>P188 Physostigmine salisylate</td>
<td>U075 Dichlorodifluromethane</td>
</tr>
<tr>
<td>P001 Warfarin &gt;0.3%</td>
<td>U089 Diethylstilbestrol</td>
</tr>
<tr>
<td></td>
<td>U122 Formaldehyde</td>
</tr>
<tr>
<td></td>
<td>U129 Lindane</td>
</tr>
<tr>
<td></td>
<td>U150 Melphalan</td>
</tr>
<tr>
<td></td>
<td>U151 Mercury</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>U010 Mitomycin C</td>
</tr>
<tr>
<td></td>
<td>U182 Paraldehyde</td>
</tr>
<tr>
<td></td>
<td>U188 Phenol</td>
</tr>
<tr>
<td></td>
<td>U200 Reserpine</td>
</tr>
<tr>
<td></td>
<td>U201 Resorcinol</td>
</tr>
<tr>
<td></td>
<td>U202 Saccharine</td>
</tr>
<tr>
<td></td>
<td>U205 Selenium</td>
</tr>
<tr>
<td></td>
<td>U206 Streptozocin</td>
</tr>
<tr>
<td></td>
<td>U237 Uracil Mustard</td>
</tr>
<tr>
<td></td>
<td>U248 Warfarin &lt;0.3%</td>
</tr>
</tbody>
</table>

http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr261_05.html
## EPA Defined Hazardous Drugs

### D-Listed Characteristic Chemical Waste

- Ignitability (D001)
- Corrosivity (D002)
- Reactivity (D003)
- **Toxicity**

### NOTE: primary drug may not be what is listed!

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug</th>
<th>Limit</th>
<th>Unit</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>D004</td>
<td>Arsenic</td>
<td>5</td>
<td>mg/L</td>
<td>Dual</td>
</tr>
<tr>
<td>D005</td>
<td>Barium</td>
<td>100</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D007</td>
<td>Chromium</td>
<td>5</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D024</td>
<td>M-Cresol</td>
<td>200</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D013</td>
<td>Lindane</td>
<td>0.4</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D009</td>
<td>Mercury</td>
<td>0.2</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D101</td>
<td>Selenium</td>
<td>1</td>
<td>mg/L</td>
<td></td>
</tr>
<tr>
<td>D011</td>
<td>Silver</td>
<td>5</td>
<td>mg/L</td>
<td></td>
</tr>
</tbody>
</table>

www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr261_00.html
Exemptions are State Specific

- EPA guidance on exemptions
  - Nitroglycerin  Federal Register: May 16, 2001 (Volume 66, Number 95)
  - Epinephrine Salts  USEPA Memo Dated 10/07/2007

- 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
California Control of RX Wastes

- California Department of Public Health 1996
  - California Department of Toxic Substance Control
- Medical Waste Management Act
  - Chapter 11, Title 22, California Code of Regulations (22 CCR)
  - “the generator of the waste is ultimately responsible for proper classification of waste streams”
    - “Medical Waste (CA-only pharmaceuticals) must be treated through incineration
- Prohibits sewing and landfilling of CA-Hazardous drugs
  - Label “Incinerate Only”
- Dispose at a regulated medical waste
- Guidance letter on sewing RX Wastes
  - Solutions in IV bags containing *only* saline solution, lactate, nutrients such as glucose (e.g., D5W), vitamins, and added salts such as potassium and/or other electrolytes
  - Liquid and solid pharmaceutical wastes, such as IV bags containing biologically active materials (e.g., antibiotics, painkillers, and antineoplastics) and controlled substances
California Hazardous RX Waste

- CAL-Hazardous
  - Criteria is an LD50 of 2500 mg/kg or less
  - Acute aquatic 96-hour LC50 < 500mg/liter
- “Carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative, persistence in the environment”
- No complete list of drugs like RCRA
- Best Practice
  - segregate and incinerate all non-RCRA pharmaceuticals as Cal-Hazardous
GOP Proposes $1.6 Billion Cut to EPA Budget, Defends $4 Billion in Oil Subsidies

by Marian Wang
ProPublica, Feb. 10, 2011, 11:25 a.m.

Republicans unveiled a budget plan on Wednesday that proposed a $1.6 billion cut to the Environmental Protection Agency, an agency whose authority they have sought to curtail, while business trade groups have complained about the burden placed on them by agency regulations. Politico also reported that the GOP’s proposal would hit the Energy Department hard, with a proposal to cut energy efficiency and renewable energy programs in half.

Rep. Fred Upton, chairman of the House Energy and Commerce Committee, has said he favors gutting EPA’s authority to regulate greenhouse gas emissions with a “legislative fix” rather than simply denying it funds. (See our overview of Upton’s positions on energy.) He told the Wall Street Journal that his disagreement with the EPA is: “You don’t subsidise different forms of power -- you let the market run on its own.”
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

Eastern Kansas Health Care System August 18, 2009
- What $51,501 civil penalty & $482,069 supplemental project
- Violations
  - No hazardous waste determinations
  - No proper hazardous waste containers
  - No documentation of inspection of hazardous waste storage
  - No documentation of personnel training
  - Unpermitted on-site incineration of hazardous waste
  - Unlawful shipping of hazardous waste
Notification At The C-Suite
Healthcare RCRA Violations

Breakout of RCRA Violations from Hospital Disclosures

- Generator Requirements: 12%
- ID of HW: 23%
- Universal Waste: 18%
- General Facility Standards: 16%
- Container Management: 21%
- UST: 2%
- Accumulation Time: 2%
- Manifest: 6%
- Universal Waste: 18%

Slide courtesy of John Gorman, USEPA Region 2
EPA’s Current Status

- Facility Survey **NOT** to be conducted….yet!
  - Latest ASHP survey of 450 hospitals: 35% EPA visits

  - EPA-821-R-10-006; Aug 26, 2010
  - Comments due: November 6, 2010

- Work within EPA, with our Federal partners, and stakeholders in developing this draft guidance

- Universal Waste Rule proposal
  - Summarization of comments 2010

- DOT regulations (49 CFR)
- Primary role is public safety
- The responsibility lies with the shipper
  - (49 CFR 173.22)
  - Hazard classification, description, and packaging (173.22)
  - Proper marking, placards and labeling (172.300)
  - Waste stream manifest is responsibility of shipper
  - Segregation into defined waste streams (173.21)
  - On-site personnel training (172.702 & 172.704)
# DOT Manifest for Transport

## Standard US form

- **Page 1**
  - Main form (left)

- **Page 2**
  - “Designated Facility to Generator State”

- **Page 3**
  - “Designated Facility to Generator Copy”

- **Page 4**
  - “Designated Facility Copy”

- **Page 5**
  - “Transporter” copy

- **Page 6**
  - “Generator’s Initial Copy”

[Visit the DOT Manifest for Transport](http://www.pneac.org/hazwastemanifest/manifest_video/manifest.html)
Why The DOT Cares

DOT Reverse tracers on shipped wastes
If a site ships hazards without proper documentation
* Carrier must report it or
* Carrier can be prosecuted with the shipper
Controlled Substance Waste

Proper ACCOUNTABILITY is key!

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

- Reverse Distributors
  - Need to be DEA Registrants to remove CS
  - CAUTION on sending waste

Source: Mark W. Caverly, Chief; DEA Office of Diversion Control
**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
  - Nursing Lead
  - Risk Management
  - Environmental Services

- **Secondary**
  - Infection Control
  - Safety Officer
  - Facility Management
  - Purchasing leads
    - Pharmaceuticals
    - Surgical supplies
    - Central supplies
  - Physician office managers
Formulary Assessment of Waste

- Collaborative formulary assessment
  - NIOSH Appendix A & IARC
  - State and Federal regulations
  - Waste hauler process

- Continuous assessment of Risk and Stream

<table>
<thead>
<tr>
<th>DRUG - GENERIC (BRAND)</th>
<th>CLASS OF MEDICATION</th>
<th>ROUTES/FORMS</th>
<th>COMPANY</th>
<th>PREGNANCY CATEGORY</th>
<th>MSDS</th>
<th>BSC</th>
<th>HAZ CLASS (1-4)</th>
<th>WASTE STREAM</th>
<th>RCRA Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldesleukin (Proleukin)</td>
<td>ONC</td>
<td>INJECTABLE</td>
<td>Chrion</td>
<td>C</td>
<td>YES</td>
<td>Yes</td>
<td>Class 1</td>
<td>YELLOW</td>
<td>N</td>
</tr>
<tr>
<td>Alemtuzumab (Campth)</td>
<td>ONC</td>
<td>INJECTABLE</td>
<td>Berlex</td>
<td>C</td>
<td>YES</td>
<td>Yes</td>
<td>Class 1</td>
<td>YELLOW</td>
<td>N</td>
</tr>
<tr>
<td>Alitretinoin (Panretin)</td>
<td>Retinoid</td>
<td>TOPICAL, GEL</td>
<td>Ligand</td>
<td>D</td>
<td>YES</td>
<td>Yes, if altered</td>
<td>Class 1</td>
<td>YELLOW</td>
<td>N</td>
</tr>
<tr>
<td>Altretamine (Hexalen)</td>
<td>ONC</td>
<td>ORAL, CAPSULE</td>
<td>MGI</td>
<td>D</td>
<td>YES</td>
<td>Yes, if altered</td>
<td>Class 1</td>
<td>YELLOW</td>
<td>N</td>
</tr>
</tbody>
</table>
### AMC-SCC Formulary characterization

<table>
<thead>
<tr>
<th>AMC SCC FORMULARY CHARACTERIZATION BY NDC</th>
<th>#</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2,700</td>
<td>100%</td>
</tr>
<tr>
<td>Scheduled drugs (DEA or NYS regulated)</td>
<td>129</td>
<td>4.8%</td>
</tr>
<tr>
<td>RCRA</td>
<td>118</td>
<td>4.4%</td>
</tr>
<tr>
<td>Characteristic (D)</td>
<td>72</td>
<td>2.7%</td>
</tr>
<tr>
<td>Ignitable (D001)</td>
<td>38</td>
<td>1.4%</td>
</tr>
<tr>
<td>Mercury D009)</td>
<td>11</td>
<td>0.4%</td>
</tr>
<tr>
<td>Acutely Toxic (P) Note 3 of the 36 are epinephrine salts regulated by NY but Not US EPA</td>
<td>36</td>
<td>1.3%</td>
</tr>
<tr>
<td>Listed (U)</td>
<td>10</td>
<td>0.4%</td>
</tr>
<tr>
<td>DoT listed (aerosols)</td>
<td>9</td>
<td>0.3%</td>
</tr>
<tr>
<td>Cytotoxic - Chemo (EPA/OSHA &amp; NY DEC) Includes U &amp; P listed</td>
<td>87</td>
<td>3.2%</td>
</tr>
<tr>
<td>RMW (biohazards)</td>
<td>73</td>
<td>2.7%</td>
</tr>
<tr>
<td>Not Currently Regulated (e.g., endocrine disrupters, steroids, antibiotics, antipsychotics, depressants, etc)</td>
<td>2,426</td>
<td>90%</td>
</tr>
</tbody>
</table>
76% of hospitals have compiled a hazardous drug list, with 72% of those reviewing drugs from all departments including radiology and nuclear medicine, while 69% included off-formulary drugs in this review.
Think of All Areas Where Hazardous Drugs AreHandled

- Pharmacy
- Compounding
- Hospital Hazardous Drug Contact Points
- Housekeeping
- Oncology Unit
- Operating Room
- Surgeon
- Patient Unit - ICU
- Courier
- Ophthalmologist
- Housekeeping
- Radiologist
- Interventional Radiology
- Medical Office Building
- Dock/Pharmacy Receiving
- HD Storage & Compounding
- HD Storage
RX Waste Stream Options

1. **Model I: Manual Segregating at Point of Generation**

2. **Model II: Automatic Devices**

3. **Model III: Centralizing Segregation**

4. **Model IV: Managing All Drug Waste as Hazardous**

5. **Exclusive Model: Controlled Substances**
Red Sharps Containers

- “Unused pharmaceuticals should not be disposed of with biohazardous waste”
  - Autoclaving
- Non-hazardous not sewerred
- Sent to a medical waste incinerator
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

Used with permission: Leslie Durrant, R.Ph., BCPS
Model II
Electronic Devices for RX Waste

EcoREX™
- eLogging managed waste
- All United States NDC#s
- Barcode segregation
- Alerts staff when full
- Completes DOT manifests
  www.vestara.com

Smart Sink™
- Solid and liquid wastes
- Renders unusable unrecoverable
- Tamper evident, notification
- Wall mount, COW mount
- No electrical interfaces
  www.cactusllc.net
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 an analysis of the inventory
- NOTE: the generator (HOSPITAL) is liable for contracted employee harm

Source: Charlotte A. Smith, R. Ph., M.S.,
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
What About Hazardous Drug Spill Management?

Formal Spill Kit
- Homegrown vs. commercial
- Location of kits
- Training

Spill Notification
- Restricted area vs. Public
- Isolation of area (vapors)
- Documentation of event

Dispose as EPA Waste not Yellow
Implementation of Program

- Pilot program
  - Gain user feedback
  - Policies and Procedure

- Establish rollout process
  - Unit to house wide to system wide

- Initial training for all hospital staff
  - Existing staff
  - New staff at orientation

- Mandatory annual competency assessment
  - Continuous
85% have processes in place to identify hazardous drugs, with stickers and automated alerts being the most common approaches.
Segregate the wastes of Drugs & Dispose of in appropriate containers

<table>
<thead>
<tr>
<th>Sharps</th>
<th>BioHaz</th>
<th>CHEMO</th>
<th>RCRA HAZARDOUS Black Container</th>
<th>Non-Regulated Trash</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needles</td>
<td>Non-Chemo vials</td>
<td>Empty Chemo vials</td>
<td>ALL partial Chemo Dose vials</td>
<td></td>
</tr>
<tr>
<td>Broken Glass</td>
<td>IVIG vials/bags</td>
<td>Chemo packaging &lt;boxes, PIs&gt;</td>
<td>Drugs on EPA P &amp; U list</td>
<td></td>
</tr>
<tr>
<td>Ampules</td>
<td>Albumin vials/bags</td>
<td>Chemo mats not involved with spills</td>
<td>1. Chlorambucil</td>
<td></td>
</tr>
<tr>
<td>Other sharps</td>
<td>Blood factor vials</td>
<td>Chemo Gloves</td>
<td>2. Cyclophosphamide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Syringes</td>
<td>PhaSeal devices</td>
<td>3. Daunomycin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IV Bags and Tubing</td>
<td></td>
<td>4. Melphalan</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5. Mitomycin C</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6. Streptozotocin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7. Arsenic Trioxide</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8. Idarubicin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>9. Carmustin including Gliadel</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10. Uracil mustard</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>11. Anything used 4 chemo spill</td>
<td></td>
</tr>
</tbody>
</table>

**Drugs on EPA P & U list**
1. Chlorambucil
2. Cyclophosphamide
3. Daunomycin
4. Melphalan
5. Mitomycin C
6. Streptozotocin
7. Arsenic Trioxide
8. Idarubicin
9. Carmustin including Gliadel
10. Uracil mustard
11. Anything used 4 chemo spill

Everything Else NOT contaminated
1. Packaging
2. IV wraps
3. Syringe packaging
4. PhaSeal packaging
5. Gauzes
6. Gowns
7. Masks
8. Paper
9. Labels, etc.

Contact Service Center for questions: XXX-XXX-XXXX
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
Pharmacists are least confident with their methods for managing RCRA-regulated waste, despite improvements over last year when just 25% reported full compliance with RCRA.
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Cost ($/pound)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biohazard Infectious (Regulated Medical)</td>
<td>Blood products, sharps, items contaminated with liquid blood, etc.</td>
<td>$0.01/pound</td>
</tr>
<tr>
<td>Hazardous &amp; Non-Hazardous</td>
<td>Empty chemotherapy vials, syringes, IVs, tubing, gowns, packaging, gloves, etc.</td>
<td>$0.10/pound</td>
</tr>
<tr>
<td>RCRA Hazardous</td>
<td>Bulk chemo in vials, unused IV’s, P, U, toxic &amp; ignitable</td>
<td>$1.00/pound</td>
</tr>
<tr>
<td>RCRA Biohazardous</td>
<td>Overtly contaminated gowns, glove, chemo spill clean up materials</td>
<td>$1.20/pound</td>
</tr>
</tbody>
</table>
Most facilities are spending over $20,000 a year to manage their waste and 78% predict further increases for next year.

N=343 Rx Directors
TJC Is Interested

How is pharmaceutical waste from your patient care units disposed of?

- In red sharps containers: 53%
- Hazardous pharmaceutical waste container: 53%
- Down the drain: 30%
- In the trash: 17%
- Other, please specify: 14%
- Non-hazardous pharmaceutical waste container: 14%

How are unused non-chemotherapy IVs or other compounded fluids disposed of?

- Hazardous pharmaceutical waste container: 38%
- Poured down the drain: 34%
- Other, please specify: 25%
- Non-hazardous pharmaceutical waste container: 17%

Methodist Hospital November 17, 2010
- What MM visit to pharmacy to see waste process
- What MM visit with home health to see fentanyl patch waste
- What EC requested copies of past years DOT manifest

Source: Inside the Joint Commission, 2009 Pharmaceutical Waste Survey
It Doesn't Stop At The Hospital Door

Watauga County Take Back program May 2010

Source: http://drugtakebackday.com/index.php
Pharmacy Associations Step up
Only for the public.....

SMART DISPOSAL
A Prescription for a Healthy Planet

A few small steps can make an important difference in safeguarding lives and protecting the environment.

Follow your medication prescriber’s instructions and use all medications as instructed. If you do not use all of your prescribed or over-the-counter medication, you can take a few small steps to make a huge impact in safeguarding lives and protecting the environment by disposing of unused medicines properly:

1. DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain. *
2. Be Proactive and Dispose of Unused Medication In Household Trash. When discarding unused medications, ensure you protect children and pets from potentially negative effects:
   a. Pour medication into a sealable plastic bag. If medication is a solid (pill, liquid capsule, etc.), add water to dissolve it.
   b. Add kitty litter, sawdust, coffee grounds for any material that mixes with the medication and makes


Medicines play an important role in treating certain conditions and diseases, but they must be taken with care. Unused portions of these medicines must be disposed of properly to avoid harm to wildlife, pets, and people.

Source: www.smarxtdisposal.net
Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA’s website.

- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government’s household trash and recycling service and ask if a drug take-back program is available in your community.

- If a drug take-back or collection program is not available:
  1. Take your prescription drugs out of their original containers.
  2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
  3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
Take-Back Programs
From the public for the public……

Source: takebackyourmeds.org

Source: rxdisposalkits.com
DEA Wants to Help
After public outcry….

National Take Back Initiative Collection Site Search
The 2nd National Prescription Drug Take Back Day
Saturday, April 30, 2011
10:00 am - 2:00 pm

Enter your zip code or County/City/State to see Collection Sites near you.

Check back often; sites are added daily.

More information on the National Take Back Initiative

Source: www.dea.gov
## Comparison of programs of other countries

<table>
<thead>
<tr>
<th>Program</th>
<th>Volume Collected</th>
<th>Pharmacy Participation</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>France Cyclamed</td>
<td>13,169 tonnes</td>
<td>90%</td>
<td>Industry, pharmacies and wholesalers (4,872,530 euros in 2006)</td>
</tr>
<tr>
<td>Since: 1993</td>
<td>0.21 kg/capita</td>
<td>*0.09 kg/capita</td>
<td></td>
</tr>
<tr>
<td>Australia RUM</td>
<td>377 tonnes</td>
<td>100%</td>
<td>Federal government ($1 to $1.5 million/year)</td>
</tr>
<tr>
<td>Since: 1999</td>
<td>0.01 kg/capita</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal Valormed</td>
<td>630 tonnes</td>
<td>98.5%</td>
<td>Pharmaceutical Stakeholder Groups (eco-fee applied to all packaging)</td>
</tr>
<tr>
<td>Since: 2001</td>
<td>0.05 kg/capita</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain SIGRE</td>
<td>2,624 tonnes</td>
<td>100%</td>
<td>Pharmaceutical industry (eco-fee applied to all packaging)</td>
</tr>
<tr>
<td>Since: 2003</td>
<td>0.06 kg/capita</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden Apoteket</td>
<td>1019 tonnes</td>
<td>100%</td>
<td>Federal government (national pharmacy) (1,444,441 euros in 2006)</td>
</tr>
<tr>
<td>Since: 1970</td>
<td>0.1 kg/capita</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Weight may include packaging, sharps, etc. *Exclude packages*
Pharmaceutical Waste Resources

- Regional Environmental Protection Agency
- American Society of Health Systems Pharmacists
  - Pharmaceutical Waste CE
  - Waste Guide for pharmacists
- State of Florida PharmWaste List Serve
  - Pharmwaste@lists.dep.state.fl.us
- Group Purchasing Organizations
- Practice Greenhealth (H2E)
- Specialized hazardous waste management companies
- Hospital Waste Haulers
- Reverse Distributors
Pharmaceutical Waste Management

Are We There Yet?