Pharmaceutical Waste Management Illinois Legislation It's not just garbage to me!

Scott A. Meyers, RPh, MS, FASHP Executive Vice President Illinois Council of Health-System Pharmacists

Disclosure

• The speaker has no financial interest in any pharmaceutical waste management company or Illinois legislator.

Learning Objectives

- Develop steps to insure that your institution and department are in compliance with SB1919 the "Don't Flush" bill.
- Describe what Household Wastes are and why every pharmacy should be familiar with SB178.

Senate Bill 1919

- If you work in a hospital pharmacy, nursing home pharmacy, home care pharmacy or provide care to any skilled care facility, this bill will impact you!
- This bill is Public Act 96-0221
- It becomes effective on January 1, 2010.
- Here's what you need to know:

Senate Bill 1919 - The Don't Flush Bill

 (a) Except for medications contained in intravenous fluids, syringes, or transdermal patches, no health care institution, nor any employee, staff person, contractor, or other person acting under the direction or supervision of a health care institution, may discharge, dispose of, flush, pour, or empty any unused medication into a public wastewater collection system or septic system.

Where it applies:

 "Health care institution" means any public or private institution or agency licensed or certified by State law to provide health care. The term includes hospitals, nursing homes, residential health care facilities, home health care agencies, hospice programs operating in this State, institutions, facilities, or agencies that provide services to persons with mental health illnesses, and institutions, facilities, or agencies that provide services for persons with developmental disabilities.

What it applies to: • "Unused medication" means any unopened, expired, or excess medication that has been dispensed for patient or resident care and that is in a solid form. The term includes pills, tablets, capsules, and caplets. For long-term care facilities licensed under the Nursing Home Care Act, "unused medication" does not include any Schedule II controlled substance under federal law in any form, until such time as the federal Drug Enforcement Administration adopts regulations that permit these facilities to dispose of controlled substances in a manner consistent with this Act. **Violations** • (b) A violation of this Section is a petty offense subject to a fine of \$500. Fines collected under this Act from facilities licensed under the Nursing Home Care Act shall be deposited into the Long Term Care Monitor/Receiver Fund. Fines collected from all other health care institutions under this Act shall be deposited into the Environmental Protection Trust Fund. So What's Your Plan?

Senate Bill 178 Household Waste Drop-Off Points

- The good news is participation is voluntary!
- The Statute is in effect now.
- It is Public Act 96-0121
- Here's the highlights:

Why and some definitions

- The General Assembly finds that protection of human health and the environment can be enhanced if certain commonly generated household wastes are managed separately from the general household waste stream.
- "Household waste" means waste generated from a single residence or multiple residences.
- "Personal care product" means an item other than a pharmaceutical product that is consumed by an individual for personal health, hygiene, or cosmetic reasons. Personal care products include, but are not limited to items used in bathing, dressing or grooming.

Pharmaceutical Product

"Pharmaceutical product" means medicine
or a product containing medicine. A
pharmaceutical product may be sold by
prescription or over the counter.
"Pharmaceutical product" does not include
(i) medicine that contains a radioactive
component or a product that contains a
radioactive component, (ii) a controlled
substance.

Rules

- "Household waste drop-off point" means the portion of a site or facility used solely for the receipt and temporary storage of household waste.
- A household waste drop-off point must not accept waste other than the following types of household waste: pharmaceutical products, personal care products, batteries other than lead-acid batteries, paints, automotive fluids, compact fluorescent lightbulbs, mercury thermometers, and mercury thermostats.

More Rules

 Household waste drop-off points must be located at a site or facility where the types of products accepted at the HWDOP are lawfully sold, distributed, or dispensed. This doesn't apply to HWDOPs operated by a government or school entity, or by an association or other organization of government or school entities. HWDOPs that accept mercury thermometers can be located at any site or facility where nonmercury thermometers are sold, distributed or dispensed.

And More Rules

 HW must only be accepted from private individuals. HW must not be accepted from other persons such as owners and operators of rented or leased residencies where the household waste was generated, commercial haulers, and other commercial, industrial, agricultural, and government operations or entities.

Yes, More Rules

- If more than one type of HW is accepted, each type of HW must be managed separately prior to it packaging for off-site transfer.
- HWDOPs accepting pharmaceutical waste are required to post a sign developed by the Agency.
- HW must not be stored for longer than 90 days after its receipt, except as otherwise approved by the Agency, in writing.

More and More Rules

- Household waste(HW) must be managed in a manner that protects against releases of the waste, prevents nuisances, and otherwise protects human health and the environment.
- HW must be properly secured to prevent public access to the waste, including but not limited to, preventing access to the waste during the event's non-business hours.

Rules, Rules, Rules

- Management of the HW must be limited to the following: (i) acceptance of the waste, (ii) temporary storage of the waste before transfer, and (iii) off-site transfer of the waste or packaging for off-site transfer.
- Off-site transfer of HW must comply with federal and state laws and regulations.

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One-Day Events

- One-day HW collection events
 - Must apply in writing in advance
 - Must receive Agency approval prior to
 - No more than one day per calendar quarter
 - The Agency may require special conditions are met.
- May not collect garbage, landscape materials, controlled substances, or other wasted excluded by the Agency's approval.

What HWs Are You Worried About?

Questions???

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Pharmaceutical Waste Management Scott Meyers

Post-test question:

- 1. What is the fine for a violation of the "Don't Flush" Bill?
 - a. \$1000
 - b. \$100
 - c. \$500
 - d. \$50

Pharmaceutical Waste Management: National Regulations and Best Practices

September 12, 2009

Cynthia Reilly, B.S. Pharm. Director, Practice Development Division American Society of Health-System Pharmacists

The speaker has no conflict to disclose.

Why It Matters

- Earliest reports of pharmaceuticals in the environment were in late 90s, early 2000
 - Antidepressants
 - Estrogens and other hormonesAntibiotics
- Disposed of by:
 - Drug manufacturers
 Health care facilities
 - Patients
 - Agricultural businesses
- In general, drugs and their by-products are NOT removed by standard water treatment processes
- Impact ???
 - Endocrine disruptors
 - Sexual differentiation
 Reproduction/Growth









Who Regulates Pharmaceutical Waste Disposal?

- A. Environmental Protection Agency
- B. State and local authorities
- C. Department of Transportation
- D. A and B
- E. All of the above

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Interested Parties

- Environmental Protection Agency (EPA)
- Drug Enforcement Agency (DEA)
- · Department of Transportation
- · State and local authorities
- National Institute for Occupational Safety and Health (NIOSH)
- Occupational Safety and Health Administration (OSHA)
- Congress
- · Health care professionals
- Public



Resource Conservation and Recovery Act (RCRA)

- · Enacted in 1976
- Objective: "to promote the protection of health and the environment and to conserve valuable material and energy resources"
- Controls the generation, transportation, treatment, storage and disposal of hazardous wastes
- Establishing a framework for the management of non-hazardous waste

www.epa.gov/compliance/civil/rcra/rcraenfstatreq.html

RCRA Hazardous Waste Categories

P listed: acutely hazardous

- Arsenic trioxideEpinephrine (EXCLUDES salts)
- Nicotine
- Nitroglycerin (EXCLUDES some medicinal forms)
- Phentermine
- Physiostigmine Warfarin >0.3%

U listed

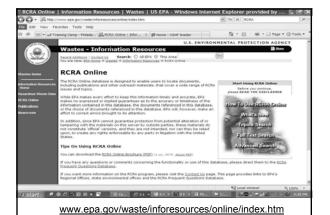
- Choral hydrateDichlorodiflouromethane - Hexachlorophene
- Lindane

- Lindane
 Paraldehyde
 Phenol
 Reserpine
 Resourcinol
 Saccharin
 Selenium sulfide
- Select chemotherapy agents (arsenic trioxide, chlorambucil, cyclophophamide, daunomycin, diethylstilbestrol, melphalan, mitomycin C, streptozocin, and uracil mustard
- Trichoromonpflouromethane
 Warfarin 0.3%



RCRA Hazardous Waste Categories (cont'd)

- Characteristic drugs:
 - Ignitable: ≥24% alcohol, low flashpoint, compressed gases (e.g., e-mycin 2% gel, some inhalers)
 - Corrosive: pH ≤ 2 or ≥ 12.5 (e.g., acetic acid)
 - Reactive: unstable under normal conditions (e.g., nitroglycerin)
 - Toxic: concentration specific (lindane 0.4 mg/L, silver sulfadiazine 5 mg/L)



Hazardous Drug LIST?

- More than 100 drugs, including hormonal agents, are described as hazardous by NIOSH, but not included on the RCRA list
- · ASHP is encouraging EPA to reconcile these lists
- · In the interim, ASHP best practices recommend managing these as hazardous

www.ashp.org/DocLibrary/BestPractices/policypositions2009.aspx. $\underline{www.ashp.org/DocLibrary/BestPractices/ASHPGuidelinesHandlingHazardousDrugs.aspx.}$

Comparison of EPA and OSHA (NIOSH) **Hazardous Drug Classification**

EPA (Resource Conservation and Recovery Act) - P listed

- U listed
- OSHA (NIOSH)
 - Largely defined by drugs listed in Appendix A in NIOSH Alert on Hazardous Drugs (2004)
- er drugs wit acteristics STATE AND LOCAL motherapy
- Ignitable
- REGULATION Sugs with the follow Corrosive
- Toxic

- Teratogenicity
 Reproductive toxicity
- Organ toxicity at low doses
- Proposed final list issued in May 2009

CAUTION: State and Local Regulations May be More Stringent than EPA!



Pharmacy Practice Concerns

- Inspections and enforcement vary by EPA region as well as state and municipality
- Fines up to \$250,000 have been reported
- Requires dedicated staff to assess and ensure compliance
- Extensive staff education, including departments external to pharmacy
- · Cost of disposal

ASHP Member Knowledge of RCRA

self-reported by director of pharmacy

	No Knowledge, %	Aware,	Basic Knowledge,	Expert Knowledge, %			
2008 N = 526	11.4	27.2	54.2	7.3			
2005 N = 510	30.9	69.1	(combined a	s aware)			

Decreased knowledge of RCRA in smaller facilities

- <100 beds: 15% to 18% report no knowledge
- >100 beds: approximately 5% report no knowledge

ASHP National Survey of Pharmacy Practice in Hospital Settings, 2005 and 2008.

		Disposed of through the regular trash (e.g. landfill)	Trash placed in segregated, colored containers (e.g., yellow, red, green) for special handling (e.g. chemical treatment, or municipal incinerator)	Trash placed in segregated black containers to be transported for incineration by a Regulated Medical Waste facility	Other
Characteristic	n	96	76	%	96
Empty or partial fill drug vials, unused tablets, unused IVs, drug packaging, or other materials used in the preparation of non-hazardous pharmaceuticals	525	22.5	55.0	18.5	4.0
Trace quantities of chemotherapy drugs (empty drug vials, drug packaging, IV tubing, or other materials used in preparation)	480	9.4	71.0	18.5	1.2
Concentrated chemotherapy drug waste (partial fill drug vials, umused IVs, umused drug syringes, or umused tablets)f	478	1.4	66.7	28.9	3.0
Trace quantities of drugs listed by NIOSH and/or EPA/RCRA, such as warfarin, nitroglycerin, nicotine, select antivirals, and physostigmine (empoty drug vials, drug packaging, IV tubing, or other materials used in preparation.)	523	25.4	50.3	21.0	3.3
Concentrated waste of drugs listed by NIOSH and/or EPA/RCRA, such as warfarin, nitroglyserin, nicotine, select antivirals, and physostigmine waste (partial fill drug vials, umsed IVs, umsed drug syringes, or	523	15.9	50.8	27.2	6.1

Staff Disposal Practices





	Disposal in	n Patient Care Ar	eas
	Similar to Pharmacy, %	Different than Pharmacy, %	Don't Know, %
2008 N = 523	82.8	6.4	10.8

- Significant training and reinforcement of education
- Better control within pharmacy department
- Leadership rests with pharmacy regardless of where the drug is used

ASHP National Survey of Pharmacy Practice in Hospital Settings, 2008.

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Types and Disposal of Pharmaceutical Wastes

- RCRA and NIOSH hazardous
- Trace-contaminated wastes
- Unclassified hazardous drugs (i.e., drugs with hazardous characteristics)
- Mixed hazardous and infectious (most vendors can not accept)
- Non-hazardous



Empty Container Exemption

- Empty containers that have held U or characteristic wastes
- Empty = trace contaminated hazardous waste
 - No more remains than 3% (by weight of total capacity of that container)
 - Containers, needles, syringes, contaminated gloves, empty IV sets
 - Does not apply to acute hazardous wastes (i.e., P-listed)
- May be disposed by regulated medical (incinerator)



P-Listed Drugs/Containers

- Nitroglycerin
 - Medicinal nitroglycerin is non-reactive; exempt from RCRA
 - State/local regulations vary
 - Some formulations may be ignitable
- Empty warfarin unit-dose packaging
- Check with state and local regulations
- Epinephrine
 - Empty syringes exempt by1994 syringe interpretation
 - Extends to other syringes holding P and U listed drugs
 - In addition, epi salts are excluded
- Some formulations, such as inhalers may be hazardous
- Sharps used in prep of these drugs must be managed as acute hazardous wastes

http://yosemite.epa.gov/osw/tcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/5file/14788.phttp://yosemite.epa.gov/osw/tcra.nsf/0c994248c239947e85256d090071175f/6a5dedf2fba24fe68525744b0045b4aff/OpenDocument

Personnel Protective Equipment/Spill Kits

- KNOWN contaminated must be managed as hazardous
 - U or P, depending on source contaminant
 - Characteristic contamination should also be managed as such (best practice)
- General use, no suspected contamination
 - Trace chemotherapy waste
 - General waste/landfill



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Controlled Substances

- · DEA requires witnessed destruction
- · RCRA-related controlled substances
 - Chloral hydrate
 - Paraldehyde
 - Phentermine
- · Additional drugs may be regulated by states
- Require shipment to a DEA <u>and</u> RCRA registered vendor
- · Sewer?
 - Small quantities; check local regulations

CHI

Generator Status

- Determined by the quantity of hazardous waste that a facility generates <u>each month</u>
- Intent is to manage AND reduce waste production
- With the exception of those generating the smallest amount of wastes, a minimization plan must be in place

 $\underline{www.hercenter.org/wastereduction/hazardouswaste.cfm}$

Qcm

What is Your Generator Status?

- A. Conditionally-Exempt
- B. Small Quantity
- C. Large Quantity
- D. Don't know

Conditionally-Exempt Small Quantity Generators (CE-SQG)

- Less than 100 kg of non-acute hazardous
- Less than 1 kg of acute hazardous waste (e.g. P-list)
- Less than 100 kg of residues or contaminated soil, waste, and other debris from the spill cleanup of acute hazardous waste
- Exempt from the Part 262 hazardous waste regulations as long as it complies with the set of regulations described in Section 261.5

 $\underline{www.hercenter.org/wastereduction/hazardouswaste.cfm}$



Small Quantity Generators (SQG)

- Between 100 kg and 1000 kg of non-acute hazardous waste
- Less than 1 kg of acute hazardous waste
- Less than 100 kg of spill residue from acute hazardous waste
- Must meet limited requirements in Part 262

www.hercenter.org/wastereduction/hazardouswaste.cfm



Large Quantity Generators (LQG)

- 1000 kg or more of non-acute hazardous waste
- 1 kg or more of acute hazardous waste
- 100 kg or more of spill residue from acute hazardous waste
- Must copy with all of Code of Federal Regulations, Chapter 40, Part 262

www.hercenter.org/wastereduction/hazardouswaste.cfm http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr262_main_02.tpl

Shipping Wastes

- · RCRA and Department of Transportation regulations Shipping manifest
 End receipt to entity that holds a federal permit
 Contractor may manage process

 - - · Verify licensure
- · Containers must be:
 - Labeled
 - Leakproof

 - SpillproofPuncture resistant
 - Non-reactive
- · Staff must have OSHA training

Uniform Hazardous Waste Manifest



www.epa.gov/epawas te/hazard/transportati on/manifest/



Universal Waste Rule

- Intended to streamline management and avoid disposal as municipal or bulk wastes
- · Characteristics:
 - small quantities from a large numbers of sources
 - low risk during accumulation and transport
- · Includes
 - batteries
 - pesticides
 - mercury-containing equipment
 - lamp bulbs

www.epa.gov/waste/hazard/wastetypes/universal/pharm.htm

Proposed Addition of Drugs to Universal Waste Rule

- EPA has proposed adding pharmaceuticals to the UWR
- Modified requirements for storage, labeling, shipment and training,
- Intent
 - Streamline collection of RCRA drugs

 - Allow take-back programs within the community Encourage disposal of ALL drugs as universal waste
- Accepted public comment through 3/09
- Would make facilities "handlers" rather than "generators"
 - Allow facilities to hold wastes for up to 1 year

 - No manifest requirement
 - Basic training requirements

www.epa.gov/waste/hazard/wastetypes/universal/pharm.htm



Universal Waste Rule (cont'd)

- · May improve compliance and reduce burden and costs
 - Requires significant staff training and oversight
 - Impact on costs?
- · ASHP comments to EPA:
 - Must address chain of ownership—cradle to grave—via manifest or other documentation
 - Diversion
 - Dumping
 - Update P- and U-lists of hazardous wastes
 - Provide education and training
 - Conduct pilot studies to determine true impact
- EPA workgroup meeting to address comments; final rule expected 2011



Potential Impact of UWR

- · Would not replace RCRA
 - States could still opt out
- · Would not preclude fines for RCRA violations
- For best practices, facilities should ensure **DOCUMENTATION** of final destruction

EPA Survey

- Study of unused pharmaceuticals from health care facilities
- Retrospective collection of 2007 data
 - Current 30-day collection is an option
- 29-page survey to assess:
 - Factors driving current practices
 - Types and amounts of drugs disposed by drain or flush
 - Alternatives to drain or flush disposal
- · Results will be used to:
 - Improve science and public understanding
 - Identifying partnership and stewardship opportunities
 - Determine economic impact of new and proposed policies
 - Take regulatory action, as appropriate

http://www.epa.gov/waterscience/guide/304m/#hsi

http://www.epa.gov/waterscience/guide/304m/2008/hsi-ltcfquestionnaire-200807.pdf

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EPA Survey (cont'd)

- ASHP comments to EPAto ↑ usefulness while ↓ the burden of data collection
 - Prospective data collection for a SHORT time (2 weeks) preferred—more reflective of current practices
 - Survey a limited number of sites representative of facility types (e.g., academic medical center, small rural hospital, oncology clinic)
 - Clarify definitions (e.g., unused, package size versus units or dose)
 - Clarify types of drug products (topicals, patient-specific extemp. IV)
 - Emphasize education versus fines
- · EPA workgroup meeting to address comments

Strategies for Completing EPA Survey

- · Surveys expected to begin fall 2009
- · 60 days to respond
- · Designate a team
 - Pharmacy
 - Nursing
 - Environmental services
 - Industrial hygiene
- · Request adequate time/resources from C-suite

Creating an Institution-Specific Plan

Managing pharmaceutical waste: A 10-step blueprint for healthcare facilities in the United States. www.h2eonline.org/docs/h2eph armablueprint41506.p



10-Step Blueprint

- #1: Waste Management Team
- #2: Overview of Regulations
- #3: Best Practices for Non-regulated Wastes
- #4: Drug Inventory Review
- #5: Minimizing Waste Production

www.h2e-online.org/docs/h2epharmablueprint41506.pdf

10-Step Blueprint (cont'd)

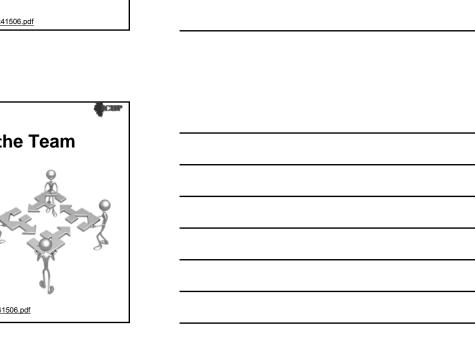
- #6: Assessment of Current Practices
- #7: Communication and Labeling
- #8: Management Options
- #9: Preparation for implementation
- #10: Program launch

www.h2e-online.org/docs/h2epharmablueprint41506.pdf

Assembling the Team

- Environmental health/safety/education
- Pharmacy
- Nursing
- Laboratory
- Research
- · Environmental services
- Infection control
- · Compliance/legal
- Facilities/engineering

www.h2e-online.org/docs/h2epharmablueprint41506.pdf



Drug Inventory Review

- Most pharmacies store 2,000 to 4,000 drug products
- · Approximately 5% are RCRA hazardous
- Up to 15% should be managed as hazardous according to best practices
- Gather drug-specific information, including vehicle information
- Document your assessment
- · This should be an ongoing process!

www.h2e-online.org/docs/h2epharmablueprint41506.pdf



CHI

Decreasing Waste Production

- · Use unit-of-use and pre-mixed packaging
- · Batch preparation
- · Buy only the amount needed—estimate usage!
- Avoid purchasing in bulk
 - disposal of unused product may negate up-front savings
- Inventory management: first-in, first-out rule
- · Establish take-back contracts
- Decrease use of aerosols and other flammable products

 $\frac{www.hercenter.org/wastereduction/hazardouswaste.cfm}{www.h2e-online.org/docs/hpn50105.pdf}$

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Assessment of Current Practices

- · Assess use and disposal practices
- · Consider all departments and units
- · Attempt to quantify
- Identify units with greatest use and generation
- · Confirm your generator status



 $\frac{www.h2e\text{-}online.org/docs/h2epharmablueprint41506.pdf}{www.hercenter.org/wastereduction/hazardouswaste.cfm}.$

Labeling and Education

- Proper disposal can avoid unnecessary costs
- Identify drugs for proper disposal
 - Labeling via dispensing software
 - Barcoding
 - Shelf stickers
- Signage in patient care areas

www.h2e-online.org/docs/h2epharmablueprint41506.pdf





Management Options

- Segregate at point of generation
 - Ideal but significant education and training
- Centralize segregation
 - Staff exposure risk
- Manage all wastes as hazardous
 - \$\$\$\$\$
- Ideal management strategy is facilityspecific

 $\underline{www.h2e-online.org/docs/h2epharmablueprint41506.pdf}$



Strategies to Decrease Waste Removal Costs

- Centralize collection to maximize volume allowance
- Decrease contractor costs by coordinating pickup with other departments or satellite facilities
- Negotiate!!!



www.h2e-online.org/docs/hpn50105.pdf

Prepare for Implementation

- · Create an action plan
- Prepare policies and procedures
- · Select vendors
- · Conduct pilot studies
- Educate and reeducate staff



www.h2e-online.org/docs/h2epharmablueprint41506.pdf

Program Launch

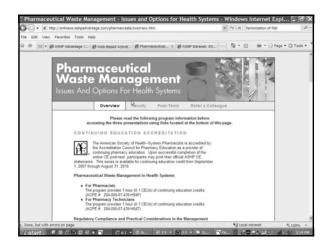
- · Initiation is not the end
- Next steps are to focus on tracking, measuring, and documenting your progress
- · Conduct audits
- · Retrain as needed



www.h2e-online.org/docs/h2epharmablueprint41506.pdf

Additional Resources

- ASHP Compounding Web Resource Center
 - ASHP Guidelines on Handling of Hazardous Drugs
 - Links to educational programming, AJHP articles, external resources
- Practice Green Health (formerly Hospitals for a Healthy Environment)
 - www.practicegreenhealth.org
 - Managing pharmaceutical waste: A 10-step blueprint for healthcare facilities in the United States
 - http://www.h2e-online.org/docs/h2epharmablueprint41506.pdf





Pharmaceutical Waste Management: National Regulations and Best Practices

Presented by Cynthia Reilly, Director, ASHP Practice Development Division ICHP Annual Meeting
September 12, 2009

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Pharmaceutical Waste Management: National Regulations and Best Practices

Presented by Cynthia Reilly, Director, ASHP Practice Development Division ICHP Annual Meeting September 12, 2009

Self-Assessment Questions

- 1. Sources of drugs in the environment include:
 - a. Healthcare facilities
 - b. Individual patients
 - c. Drug manufacturers
 - d. Agricultural businesses
 - e. All of the above
- 2. Drugs and their by-products are removed by standard water treatment processes.
 - a. True
 - b. False
- 3. Pharmaceutical wastes are regulated by:
 - a. Environmental Protection Agency
 - b. State and local authorities
 - c. Department of Transportation
 - d. A and B
 - e. All of the above
- 4. In general, which of the following regulations are more stringent?
 - a. Federal (i.e., RCRA)
 - b. State and local
- 5. Fines for RCRA violations are consistent across EPA regions.
 - a. True
 - b. False
- 6. A facility's pharmaceutical waste management team should be multidisciplinary.
 - a. True
 - b. False

7.	Approximately of a pharmacy's inventory is considered RCRA hazardous.
	b. 15%
	c. 25%
	d. 60%
8.	A drug inventory should be considered an ongoing process. a. True b. False

- 9. Strategies for decreasing waste production include all of the following except:
 - a. Buy only the amount needed
 - b. Avoid purchasing in bulk
 - c. Avoid use of these products
 - d. Establish take-back contracts
- 10. Proper inventory management techniques, such as following the first-in, first-out rule can decrease the amount of pharmaceutical wastes produced by a facility.
 - a. True
 - b. False