



Michigan Department of Environmental Quality &
Michigan Health and Hospital Association



Pharmaceutical Waste Management Webinar



July 26, 2012



Housekeeping



- All lines will be muted
- Questions can be sent to us via the question/chat box
- We will record webinar and post online



DEQ



**Christine Grossman
Waste Specialist
Office of Environmental Assistance**



Environmental Assistance Center



Phone: 1-800-NO2-WASTE
(1-800-662-9278)

Hours: 8:00 AM to 4:30 PM
Monday – Friday

Compliance Assistance Services Include:

Air
Waste
Water
Site Clean-up

Environmental Audit Privilege
Brownfield Redevelopment
Release Reporting
Permit Coordination



MHA



Sheila Finch
Executive Director, Environment of Care
Detroit Medical Center



MHA



Lisa Hardesty
Environment of Care and Sustainability Officer
Bronson Methodist Hospital



MHA



Steve Smith
Pharmacy Director
Karmanos Cancer Center



Webinar Topics



- **History MHA Guide Development**
- **MHA Guide Overview**
- **Developing a Pharmaceutical Waste Program - 10 Step Process**
- **Panel Question & Answers**



Why Do I Need to Know All of This?



Hazardous waste and liquid industrial waste regulations...

- ✓ **Apply to all businesses, including municipalities, hospitals, & service industries, not just manufacturing industries**
- ✓ **Are written broadly to address hazards posed by all waste streams**

Approximately 15% of pharmacy's inventory meets the definition of hazardous waste



Why Do I Need to Know All of This?



Mixing different waste types:

- changes the handling/disposal requirements
- can have significant disposal cost implications
- can result in exposure or non-compliance liabilities

Understanding the management requirements for common health care wastes is key to compliance, reducing liabilities, and reducing costs



MHA Guide History



Sheila Finch, Detroit Medical Center



Historical Review



- **MHA Michigan Green Health Care Committee formed a Pharmacy Sub-Committee in 2009**
- **Pharmacy Sub-Committee collectively found it difficult to apply the hazardous waste regulations to the relatively small quantities of pharmaceutical generated in health care**
- **Pharmacy Sub-Committee generated a list of common pharmaceutical related violations at hospitals**



Common Health Care Violations



- **Failure to characterize waste and retain records of evaluation**
- **Improper segregation of pharmaceutical hazardous waste and regulated medical waste**
- **Improper disposal of unused pharmaceutical**
- **Failure to retain manifest documentation for at least 3 years from waste shipment**
- **Lack of land disposal restriction documentation**



Common Health Care Violations



- **Improper labeling of hazardous waste containers**
 - ✓ **Lacking hazardous waste code**
 - ✓ **Lacking accumulation/storage start date**
- **Failure to perform weekly hazardous waste storage area inspections**
- **Failure to move satellite containers to storage area within 3 days of being full**
- **Failure to keep containers closed when not in use**



Historical Review



- **Pharmacy Sub-Committee compiled a list of questions related to pharmaceutical and medical waste handling**
- **Pharmacy Sub-Committee sought a meeting with DEQ to discuss and resolve questions and the challenges in proper pharmaceutical waste handling and disposal in health care**



Engaging DEQ



October 2009:

- Meeting request sent to DEQ Director to meet with health care representatives
- Pharmacy survey developed in preparation for meeting with DEQ

November 2009:

- Meeting request accepted by DEQ and scheduled for December 1, 2009
- Pharmacy survey sent to Michigan hospitals
- 60 + hospital representatives responded to attend meeting with DEQ



Preparation for Meeting with DEQ: Survey



- **Obtain data about common pharmaceutical waste accumulated in health care**
- **Identify various handling challenges in handling of chemotherapy and pharmaceutical waste**
- **Measure awareness of hazardous waste and liquid industrial waste regulations**



Survey Objectives



- **Identify other regulations conflicting or overlapping regulations**
- **Develop concerns and challenges in managing waste according to current regulations**
- **Determine interest in working as a focus group to address pharmaceutical waste concerns**



Survey Objectives



- **31 survey responses received**
- **Focus was on question #21 – disposal methodology for pharmaceutical waste (including chemo and investigational drugs)**
- **Question #21 represented the key challenges faced in applying overlapping and conflicting regulations**



Challenging Waste Decisions



- Nicotine gum (after patient use)
- Fentanyl patches
- Partially used epinephrine syringes
- Antivirals
- Hormones
- Medications left behind by inpatients
- Chemo
- Controlled substances left behind by inpatients
- Insulin
- Nitroglycerin
- Chemo spill residue
- Inhalers
- Injectables
- Hazardous drugs with needles
- Containers/wrappers that contained P listed waste



Challenging Disposal Options



- Sewer
- Solid trash
- Liquid industrial waste
- Universal waste
- Hazardous waste
- Regulated medical waste
- Reverse distributor
- Controlled substances



Results of Meeting



- **Support was given for the formation of a functioning advisory group to work with DEQ to address waste concerns**
- **Sheila Finch was MHA Pharmacy Sub-Committee chair**
- **Jack Schinderle was assigned as the DEQ lead person to work with the group**
- **One representative from each health system became members of the advisory group**



Health Care Perspectives



- **Small quantity of waste**
- **Regulations for larger quantity of waste**
- **Dual waste (medical and hazardous)**
- **Administrative devices**
- **Packaging of P-listed waste**
- **Lack of storage space for different waste containers**



DEQ Perspective



- **Appreciated the genuine interest of health care in being in compliance with the regulations.**
- **Recognized additional education tools would assist in understanding pharmaceutical handling and disposal options**
- **Gained an understanding of health care challenges in applying waste regulations atop of or with other industry pharmaceutical management standards**



Health Systems Represented



- **Beaumont**
- **Bostford**
- **Bronson**
- **Covenant Healthcare System**
- **Detroit Medical Center**
- **Henry Ford Health System**
- **Karmanos Cancer Center**
- **Michigan Health Association**
- **Mid Michigan**
- **McLaren**
- **Munson**
- **Northern Michigan Regional**
- **Promedica/Bixby**
- **St John Providence**
- **Sparrow**
- **University of Michigan**
- **VA Health System**



Regulatory Representatives



- **DEQ, Resource Management Division**
 - Jack Schinderle (DEQ Chair)
 - Jim Day
 - Andrew Shannon

- **DEQ, Office of Environmental Assistance**
 - Christine Grossman
 - Michael Young
 - Chad Rogers



Disposal Vendors & Others



- **Chemical Analytics**
- **IWRS**
- **Stericycle**
- **Clean Harbors**
- **Drug & Laboratory Disposal (DLD)**
- **MARSH, Inc. Healthcare Consultant**
- **Waste Management Health Care Solutions**
- **Heritage Environmental Service**
- **Veolia**



Pharmacy Group Objectives



- **Identify waste streams**
- **Identify waste streams that require additional research**
- **Identify applicable regulations**
- **Identify compliant waste disposal methods**
- **Develop waste disposal guide**
- **Review waste hauler/transportation requirements**
- **Discuss best management practices**



Committee Results



- **Very good participation from health system representatives, many drove to Lansing each month**
- **Additional health system representatives continued to join the group**
- **Conference call capability available for each meeting**
- **MHA perfect host for all the meetings**



Committee Results



- **Identified applicable regulations for trace chemo and bulk chemo**
- **Reviewed universal waste regulations**
- **Identified challenges and concerns with handling and disposal of controlled substances**



Initial Guide Timeline



January 2010

- First meeting with Health Systems & DEQ
- Meetings continued monthly hosted by MHA in Lansing

March 2011

- Final draft guide

August 2011

- First meeting with Disposal Vendors

January 2012

- Workshop Delivery of Initial MHA Guide (bulk chemo, trace chemo, & universal pharm)



DEA Rulemaking Status



- **Definitive answer to DEA issues cannot be provided yet since regulations are currently being written on the disposal issue as required under the Secure and Responsible Drug Disposal Act**
- **Notice of proposed DEA rulemaking is expected to be published in the Federal Registrar sometime in 2012**



EPA Rulemaking Status



- **December 2008 EPA proposed rules to make pharmaceuticals a federal universal waste type**
- **January 2009 EPA public comment period closed on proposed rules**
- **June 2012 EPA announced they are abandoning making pharmaceuticals a federal universal waste type based on public comment**



EPA Rulemaking Status



- **Proposed EPA rulemaking is to be available for public comment in Spring of 2013**
- **EPA proposal is to include health care facility specific regulations for managing hazardous pharmaceutical wastes**
- **EPA regulatory scheme is to address the unique issues faced by health care related facilities**
- *www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm*



Revised Guide Timeline



March 2012

- Guide revision meeting with Health Systems & DEQ

June 2012

- Guide revision meeting with Health Systems, DEQ, & Disposal Vendors

July 2012

- Revised Guide
- Webinar Delivery of Revised Guide



MHA Guide Overview



**Christine Grossman,
Office of Environmental Assistance, MDEQ**



MHA Guide Overview



Why the concern –

- Pharmaceuticals are an emerging contaminant
- Since 1999 USGS samples have detecting low levels of pharmaceuticals in the environment
- No know human health impacts
- Concern due to their presence in source waters used for our drinking water



MHA Guide Overview



Why was the guide developed –

- Provide a single resource to understand of Michigan's pharmaceutical waste regulations
- Highlight incineration as the preferred disposal option
- Streamline waste handling to help meet the many other requirements that apply to hazardous pharmaceuticals in health care (patient & worker protection, DEA requirements, etc.)



MHA Guide Overview



Why was the guide developed –

- Encourage the use of best management practices in handling hazardous pharmaceuticals
- Provide a collective understanding of practical approaches used in health care to handle common pharmaceutical wastes
- Increase awareness and education on the Michigan pharmaceutical waste requirements



MHA Guide Overview



The guide is a tool for . . .

- understanding target compliance options for common health care wastes
- selecting the best management option(s) for a site
- understanding best management practices for handling hazardous pharmaceuticals



MHA Guide Overview



The Guide...

- is completely optional
- does not constitute any new rulemaking or new requirements
- does not cover *waste characterization & generator status; recordkeeping; training & contingency planning; etc.*

Going “off-guide” is completely appropriate, acceptable, and anticipated; however, the waste must be managed to meet the statute and rules.



Guide Content/Format



Guide Background/Purpose

How to Use the Guide

Regulations Considered

Guide Glossary

Guide Sheets -

- Waste category defined
- Include/exclude tables
- Storage and labeling requirements
- Transport requirements
- Recordkeeping requirements
- Disposal requirements



General Guide Use Tips



- Review guide
- Determine your waste types
- Evaluate options (segregate vs commingle)
- Evaluate vendor costs
- Select compliance option(s)
- Implement compliance option(s)
- Perform self audits



Guide Sheets



Bulk Haz Pharm –

Includes hazardous waste (characteristic & listed) pharmaceuticals, NIOSH hazardous drugs, investigative chemo agents, hazardous pharmaceutical spill clean-up material, hazardous pharmaceutical contaminated PPE, and may include P-listed compounding sharps if vendor approved as non-infectious





Guide Sheets



Bulk Haz Pharm –

Outlines management standards for meeting the Rule 306, Part 111 generator exemption for (LQG 90 day and SQG 180 day)

Includes BMP to manage NIOSH hazardous drugs and investigational chemo as a hazardous waste



Trace Chemo –

Includes materials exposed during chemo administration but not known to be contaminated with chemo agents, may include medical waste if preferred

Guide Sheet outlines management standards for solid waste in Part 115 and medical waste generators per Part 138 of Public Health Code





Guide Sheets



Universal Waste Pharm –

includes all Bulk Haz Pharm wastes
except spill material and contaminated
PPE



may include non-haz pharm if desired

Guide sheet outlines management standards for meeting Part 111, Rule 228, universal waste standards, and meeting the liquid industrial waste generator standards found under Section 12103 of Part 121



Guide Sheets



Universal Waste Pharm –

Primary benefits of managing materials as universal waste include:

- Longer storage time (1 year)
- Weight of waste not counted in hazardous waste generator status
- Not subject to satellite accumulation requirements (can “double satellite”)
- Less labeling



Guide Sheets



Universal Waste Pharm –

Potential benefit in managing materials as universal waste include a reduction in the site's generator status and a reduction in the environmental compliance requirements

See Table 2.6 in Chapter 2 of the DEQ guidebook at www.michigan.gov/ehsguide to compare the compliance requirements for the different hazardous waste generator types



Guide Waste Categories



Non-Haz Pharm

Includes all non-hazardous pharmaceutical wastes, solid, liquid, paste or aerosol



BMP provisions exclude NIOSH haz drugs and investigative chemo agents from management under this Non-haz Pharm Guide Sheet and recommends they be managed under the Bulk Haz Pharm Guide Sheet as a hazardous waste



Guide Waste Categories



Non-Haz Pharm

Can include exempt hazardous waste from a Conditionally Exempt Small Quantity Generator (CESQG) waste - site maintains generation records proving exempt status and otherwise lawfully handles/disposes of waste

CESQG waste exempted from hazardous waste regulations still has unique handling requirements, so check your vendor on CESQG waste



Guide Waste Categories



Non-Haz Pharm

Guide sheet outlines management standards for meeting the liquid industrial waste generator requirements found under Section 12103 of Part 121

Mixed/Dual Pharm –

Includes vaccinations with a live or attenuated virus preserved with thimerosal, pharm waste inadvertently mixed with medical waste may include P-listed sharps from compounding and/or intracavity chemo and body fluids (check with disposal vendor)



Recommend establishing provisions to prevent mixing of medical waste and pharm waste to prevent unanticipated cost overruns!



Guide Waste Categories

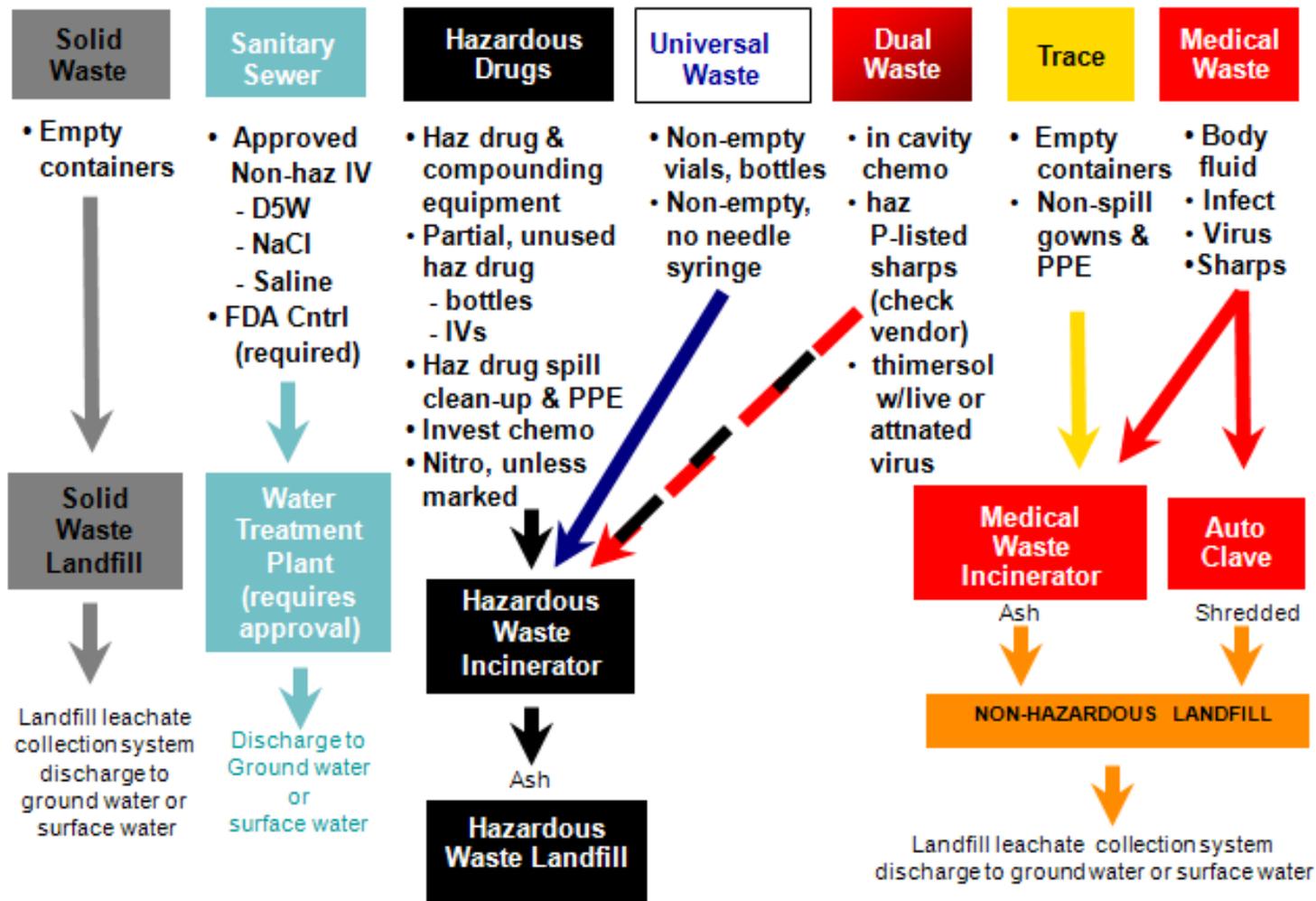


Mixed/Dual Pharm –

Guide sheet outlines management standards for both the hazardous waste regulations under Rule 306 of Part 111 and medical waste provisions under the public health code.

Intracavity chemo (after use/administration) is managed as a hazardous waste as a BMP

Example Pharmaceutical Chart





How to Use the Guide



Pick your compliance option (on or off guide) –

- **Segregate or commingling hazardous and non-hazardous pharmaceutical waste?**
- **Some sites segregate haz from non-haz, then manage segregated haz as Universal Waste for the greater flexibility in handling and reducing their generator status**



How to Use the Guide



- **Segregation –**
 - **Use Bulk Haz Pharm, Trace Chemo, Non-haz Pharm, and Mixed/Dual Pharm Guide Sheets**
- **Comminging –**
 - **Use Universal Waste Pharm, Trace Chemo, and Mixed Medical Waste Guide Sheets**



How to Use the Guide



How to use the guide –

- View the on-line, on-demand recorded webinars in the ***Introduction to Hazardous Waste Regulations Webinar Series*** at www.michigan.gov/deqworkshops to fill any knowledge gaps
- Drill down into more information in the guide at www.michigan.gov/deqhealthcare under “Waste Health Care Resources”

MHA Health Care
Pharmaceutical
Waste Management

Why be concerned about pharmaceuticals? Pharmaceuticals are drugs that are toxic (chemotherapy agents) to cause more limited physiological breakdown once released. As such, they generally remain absorbed by other plants, animals, and humans.

What is the environmentally friendly option for unused pharmaceutical disposal? Incineration. Incineration is performed at high burn temperatures and effluent systems, which prevent unused back into our water.

Incineration of pharmaceuticals

Why was the Michigan Health Waste Guide developed? The thousands of pharmaceuticals (U.S. EPA) and the Michigan Department of Environmental Quality (MDEQ) regulations, unused medication waste. Waste pharmaceuticals (liquid industrial waste, non-hazardous "dual" waste). The waste classification depends on what a common waste, the MDEQ has can be managed under stream classification determination (further regulation they must meet and) of management that must be characterized each of their waste and determine how much hazard information, they can determine be mixed with regulated medication highest disposal cost due to the evaluating a site's hazardous waste tests and services (e.g., xylene, from building maintenance (fluid from pharmaceutical preparation) inclusion in the monthly hazard to provide the management stance.

Bulk Hazardous Pharmaceutical Waste MHA Health Care Pharmaceutical Waste Management Guide Sheet

What is Bulk Hazardous Pharmaceutical Waste (Bulk Haz Pharm)?

Bulk hazardous pharmaceutical waste or Bulk Haz Pharm includes pharmaceuticals intended for discard that are a RCRA hazardous waste as defined in this guide, NIOSH hazardous drugs, and Investigative chemotherapy agents. Bulk Haz Pharm includes spill cleanup materials from hazardous pharmaceuticals; contaminated personal protective equipment used with hazardous pharmaceuticals; non-Empty containers used with hazardous pharmaceuticals (vials, ampules, IVs, bottles, tubing, and syringes with no sharps). Bulk Haz Pharm includes closed system drug transfer devices and sharps used for pharmacy compounding of hazardous pharmaceuticals (noninfectious) if approved by the disposal vendor. Bulk Haz Pharm does not include closed system drug transfer devices or sharps used to administer hazardous pharmaceuticals to patients. Bulk Haz Pharm is not to include fluids and/or devices removed from intracavity installations unless approved by the vendor as noninfectious. Bulk Haz Pharm does not include unused and intact pharmaceuticals in their original packaging directed for resale and reuse for its original intended purpose. Check with your disposal vendor to determine whether Mixed Medical/Dual Waste includes closed system drug transfer devices used in hazardous pharmaceutical compounding, sharps used in hazardous pharmaceutical compounding, and fluids and/or devices removed from intracavity hazardous pharmaceutical installations.



What is Included in Bulk Haz Pharm?

RCRA/Part 111 hazardous waste pharmaceuticals
NIOSH hazardous drugs
Investigative chemotherapy agents
Part 111 hazardous waste pharmaceuticals
Non-Empty containers, including vials, ampules, IVs, bottles, tubing, and syringes with no sharps
Materials used in hazardous pharmaceutical spill cleanup including PPE (gowns, gloves, shoe covers, absorbent pads, absorbent materials)
Contaminated items used in hazardous pharmaceutical compounding
Contaminated PPE used in hazardous pharmaceutical compounding and administration
Pharmacy containers that held hazardous pharmaceuticals
Closed system drug transfer devices and sharps used in pharmacy compounding of hazardous pharmaceuticals with approval as noninfectious by disposal vendor
Fluids and/or devices removed from intracavity hazardous pharmaceutical installations with approval as noninfectious by disposal vendor



MHA Guide Overview & Recap



Most of Michigan's pharmaceutical waste regs have been in place since 1980

EPA not updated the hazardous waste lists to include newly developed hazardous drugs since the 1980s

Managing OSHA haz drugs & investigative chemo as a haz waste will help achieve patient and worker protection standards and maintain licensing/accreditation



MHA Guide Overview & Recap



The MHA Pharm Guide advocates the use of **best management practices (BMPs)** in handling pharmaceutical waste and does *not establish any new regulations*

The MHA Pharm Guide is one of many health care tools that can be use to streamline waste management decisions and achieve compliance



MHA Guide Overview Recap



EPA intends to update the list of hazardous waste pharmaceuticals to include drugs developed since 1980s and known to be hazardous

The MHA Pharm Guide is intended to help Michigan health care providers achieve compliance with existing regulations and be ready to meet new regulations



MHA Guide Overview Recap



Once an established pharmaceutical waste management program is in place, consider self audits using DEQ inspection forms

Forms are on-line at www.michigan.gov/deqwaste after selecting “Hazardous and Liquid Industrial Waste Management” twice, lower right side

Look for new resources at
www.michigan.gov/deqhealthcare or
Call EAC at 1-800-662-9278

MHA

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Developing a Pharmaceutical Waste Program



Lisa Hardesty, Bronson Hospital

Developing a Pharmaceutical Waste Program

- **Guidance Document Implementation**
- **Waste Segregation**
- **Waste Container Management**
- **Conducting Audits**
- **Compliance Tips**

1. Getting Started

- **Treat as a multidisciplinary process**
- **Obtain support from senior management**
- **Establish a multidisciplinary committee and include pharmacy, environmental services, safety, nursing, education and infection control**
- **Secure budgetary needs**

2. Understand the Regulations

- **Locate regulatory standards (EPA, DOT, DEA, OSHA, DEQ, POTW, state pharmacy boards)**
- **Define waste categories (listed, characteristic, universal, controlled substances, medical waste, mixed/dual waste)**
- **Distinguish between trace and bulk chemotherapy waste, including spill clean up materials**
- **Understand hazardous waste management requirements (generator status, drain disposal, land disposal restrictions)**

3. Considering BMP for Non-regulated

- Formulations with a listed active ingredient that is not the “sole active ingredient”
- All chemotherapy agents
- Drugs meeting NIOSH hazardous drug criteria
- Drugs listed in Appendix IV of OSHA Technical Manual
- Drugs with low level lethal doses
- Carcinogenic drugs
- Drugs containing heavy metals
- Endocrine disruptors

4. Review Drug Inventory

- Review drug purchasing records for a complete list of pharmacy stock (national drug code, brand & generic names, manufacturer, strength, dosage, package size consider compounded items and reformulations).
- Make waste determination (hazardous, liquid industrial, universal, non-hazardous solid, controlled, etc.)
- Make best management practice decisions
- Document your waste decisions and keep the review current

5. Minimize Pharmaceutical Waste

- **Implement purchase policy that considers lifecycle**
- **Maximize use of multi-use chemotherapy vials**
- **Control physician samples (hold pharmaceutical reps accountable to maintain stock or use sample scripts)**
- **Label single patient items for home use**
- **Conduct routine survey examining container size/use**
- **Replace prepackaged unit dose with patient specific oral syringes, single dose syringes, insulin pens**
- **Monitor and date of emergency syringes three months prior to outdates to avoid waste**

6. Review Current Practices

- **Perform department reviews to estimate potential volumes and weights (helps with generator status and cost estimates)**
- **Analyze which drugs are dispensed to each unit and in what quantities over a specific time frame**
- **Confirm generator status**

7. Determine Communication/Labeling Needs

- Automate and incorporate waste collection/disposal data into pharmacy dispensing software (barcodes)
- Manually label in pharmacy
- Provide guidance on floor using stickers on containers
- Display guidance posters
- Select label message easy to understand that relays all pertinent information

8. Consider Management Options

- Segregate at point of generation (bed side)
- Collect all drugs and segregate at a central location
- Manage all drug waste as hazardous

9. Get Ready to Implement

- **Locate satellite accumulation areas**
- **Ensure storage area meets generator size requirements**
- **Select permitted/registered vendor to transport waste (hazardous, liquid industrial or universal)**
- **Understand reverse distributor handling & responsibility**
- **Conduct pilot program in high volume areas**
- **Develop pharmaceutical waste management policies and procedures, including ones for spills**

10. Launch the Program

- Educate and train staff on policies and procedures
- Stage roll-out and include input of all the parties
- Provide training prior to a “go-live” date
- Fill-out manifest and land restrictions understanding hazardous waste and DOT requirements
- Track, measure and record progress



Questions?

Type your question into the
chat/question bar



MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Compliance Resources



More Questions?

Go to www.michigan.gov/deqhealthcare

**Contact the Environmental Assistance Center at
1-800-662-9278 or deq-assist@michigan.gov**

Contact Christine Grossman at 517-373-0590



Upcoming Workshops

www.michigan.gov/deqworkshops



Michigan Green HEALTHCARE CONFERENCE



Who Should Attend

The Michigan Green Health Care Conference is intended for individuals and organizations interested in promoting sustainability practices within the health care industry. We encourage sustainability officers, dietitians, clinicians, engineers, architects, pharmacists, environmental services, food and nutrition, and maintenance managers, energy coordinators, business partners, governmental agencies, public health professionals, non-profits, and anyone else with a passion for reducing the ecological footprint of the health care industry to attend the conference.



St. Joseph Mercy Hospital

Information

The Michigan Green Health Care Conference is scheduled for Wednesday, September 12, 2012, at Washtenaw Community College in Ann Arbor. Hospital tours will take place at St. Joseph Mercy Hospital on September 11 with a reception to follow. More information, including sponsorship and exhibitor opportunities, and registration will be available this summer. For more information, please visit the Michigan Green Health Care Committee website

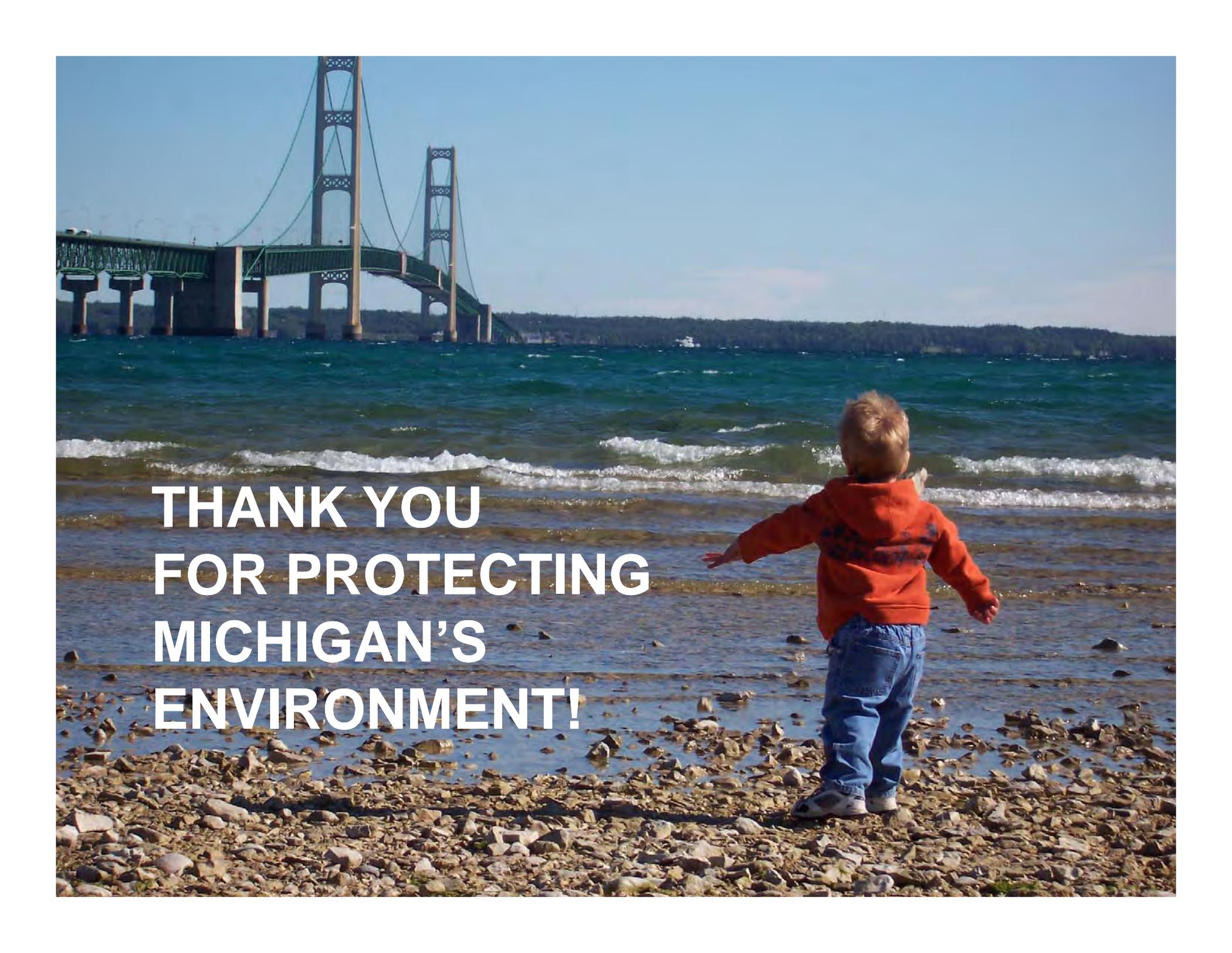
Tuesday, Sept. 11

Afternoon (optional)
Pre-Conference
Tours & Reception

Wednesday, Sept. 12

Conference
Washtenaw Community
College, Ann Arbor, Michigan



A young child with blonde hair, wearing an orange hoodie and blue jeans, stands on a rocky beach. The child is facing away from the camera, looking out at a large suspension bridge with two tall towers. The bridge spans across a body of water with white-capped waves. The sky is clear and blue. The text "THANK YOU FOR PROTECTING MICHIGAN'S ENVIRONMENT!" is overlaid in white, bold, sans-serif font on the left side of the image.

**THANK YOU
FOR PROTECTING
MICHIGAN'S
ENVIRONMENT!**