Pharmaceutical Waste Regulations
Existing and Proposed
&
Strategies for Minimizing Pharmaceutical Waste in Healthcare
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Housekeeping

- All lines will be muted
- Questions can be sent to us via the question/chat box
- We will record webinar and post online at www.michigan.gov/deqdrugdisposal
- Notes page

Pharmaceutical Waste Regulations: Existing and Proposed Regulations & Strategies for Minimizing Pharm Waste in Healthcare

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Today's Goals
- Identify environmental and public health concerns related to pharmaceuticals
- Provide an overview of Michigan's existing environmental pharmaceutical waste regulations
- Provide overview of the proposed federal environmental hazardous waste (HW) pharmaceutical rules
- Identify what to expect next

Why Cover a Proposed Rule
- Changes are extensive:
  - Proposed to establish entirely new management standard for pharmaceuticals from healthcare
  - Proposes to prohibit sewer - all HW pharmaceuticals
  - Proposes to commence MI abandon current regulations
  - Proposal is expected to go to final rule making next

Pharmaceuticals - Emerging Contaminants of Concern
- First detected at low levels in Europe in 1970's
- Studies continue to show they are ubiquitous globally and persistent - see http://toxics.usgs.gov and search for pharmaceuticals
- Many are persistent because they are manufactured to be resistant to transformation in water
- Most medications are excreted intact and end up in our WWTPs
- WWTPs don't remove drugs
- Annually people continue to take more and more drugs
- Without change levels will continue to increase
- Pharmaceuticals in environment have been shown to cause adverse impacts to amphibians, fish, and bacteria
- Proposed rules memorialize EPA expects pharmaceuticals may cause adverse human health impacts
  - EPA notes that pharmaceuticals are:
    - Inherently bioactive compounds able to impact living systems
    - Known to have adverse side effects that are exacerbated when combined
    - Once released to the environment, there is little ability to prevent co-administration

Pharmaceutical Diversion - A Human Health Crisis
- Pharmaceuticals are also:
  - Diverted and abused
  - Known to result in accidental poisoning
  - Presently the leading cause of accidental death in the US
  - 2004 to 2014 statistics show a three-fold increase in the accidental death rate from prescription drug overdose

What We Can Do Now
- Manage inventories
- Establish policies that minimize pharmaceutical waste
- Incur pharmaceuticals where possible to destroy the chemicals in the drugs, preventing them from entering our water
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Waste
Water
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Today’s Goals

- Environmental & Public Health Issues
- Existing Michigan HW Pharmaceutical Rules
- EPA Proposed Federal HW Pharmaceutical Rule
- What To Expect
Why Cover Proposed Rule

Changes are Extensive:

• Establishes entirely new management standard

• Prohibits sewering - all HW pharmaceuticals

• Proposed to require MI abandon current regulations
Environmental & Public Health Issues
Pharmaceuticals
An Emerging Contaminant

First detected at low levels in Europe in 1970’s

Studies continue to show they are ubiquitous globally and persistent - see http://toxics.usgs.gov & search for pharmaceuticals

Many are persistent because they are manufactured to be resistant to transformation in water
Pharmaceuticals
An Emerging Contaminant

Most medications are excreted intact and end up in our WWTPs

WWTPs don’t remove drugs

Annually people continue to take more and more drugs

Above - Aerial of a Waste Water Treatment Plant (WWTP)

Left - WWTP Clarification Tank
Pharmaceuticals
An Emerging Contaminant

Without change levels will continue to increase

Pharmaceuticals in environment have been shown to cause adverse impacts to amphibians, fish, and bacteria

Proposed rules memorialize EPA expects pharmaceuticals may cause adverse human health impacts
Pharmaceuticals
An Emerging Contaminant

EPA’s cites that pharmaceuticals . . .

are intrinsically bioactive compounds able to impact living systems

are known to have adverse side effects that are exacerbated when combined

once released to the environment, there is little ability to prevent co-administration

See Federal Register, Volume 80 Page 58046
Pharmaceuticals are also:

- diverted and abused
- known to result in accidental poisoning
- presently the leading cause of accidental death in the US

Above graph shows a near three fold increase in accidental deaths from prescription drug overdose from 2004 to 2014.
What We Can Do Now

- Manage inventories
- Incinerate - preferred disposal option

It destroys the chemicals and prevents them from cycling in our environment.
What We Can Do Now

- Manage only what you need
- Prescribe least eco-toxic drugs
- Minimize sample inventories
- Issue sample scripts where possible
- Issue shorter initial scripts for new prescriptions with undesirable side effects
Paradigm Switch

Reactionary

1. Disposal
2. Treatment
3. Recycling
4. Prevention

Anticipatory

1. Prevention
2. Recycling
3. Treatment
4. Disposal

SHIFT
Existing Environmental Pharmaceutical Disposal Regulations
Hazardous waste regulations require each non-household site generating waste to:

- characterize their wastes
- determine the total weight of all hazardous generated monthly
- determine their legal disposal options
Existing Waste Regulation

Drugs are generally a ...

- Hazardous Waste
  (Part 111 of Act 451 in lieu of RCRA) - listed or characteristic hazardous waste

- Liquid Industrial By-Product
  (Part 121 of Act 451) - not hazardous & liquid

- Non-Hazardous Solid Waste
  (Part 115 of Act 451) - not hazardous & solid
Waste Characterization

Non-household waste subject unless excluded:
- Hazardous if listed or characteristic
- Liquid industrial by-product if free liquids
Existing Waste Regulation

Hazardous Waste Generator Status:

- Conditionally Exempt Small Quantity Generator (CESQG)
- Small Quantity Generator (SQG)
- Large Quantity Generator (LQG)
Hazardous Waste Generator Status

CESQG

- Generates < 220 lbs. non-acute HW monthly
- Generates < 2.2 lbs. acute HW monthly
- Never accumulates > 2200 pounds non-acute HW
- Never accumulates > 2.2 lbs. acute HW
Hazardous Waste Generator Status

CESQG exempted HW must be properly disposed under other regulations:

- Liquid industrial by-product or
- Solid waste regulations

Need receiving facility that wants it!
Hazardous Waste Generator Status

CESQG required records include:

- Waste characterization
- Generator status verification
- Special waste approval
- Disposal records/receipts (solids)
- Shipping records/manifests (liquids)

3 years of records must be maintained
Existing Waste Regulation

Estimates identify between 5% to 15% pharmaceuticals are hazardous waste (HW):

- Listed
- Characteristic
  - Ignitable
  - Toxic
  - Corrosive
  - Reactive
Ignitable
D001 HW Pharmaceuticals Examples

Disinfectant hand washes
Etoposide (chemotherapy)
Faslodex (chemotherapy)
Paregoric (controlled substance)
Paclitaxel (chemotherapy)
Rubbing alcohol
Nyquil
Toxic & Acutely Toxic
D004 to D043 HW Pharmaceuticals Examples

Afrin - toxic (D009)
Arsenic Trioxide - acutely toxic (P012)
Barium Hydroxide Crystals - toxic (D005)
Coumadin (Warfarin < .3%) - toxic (U248)
Coumadin (Warfarin > .3%) - acutely toxic (P001)
Epinephrine (P188)
Nicotine & salts - acutely toxic (P075)
Phentermine HCL (P046)
Corrosive
D002 HW Pharmaceuticals Examples

Wart removers - trichloroacetic acid

Eye medications - acetic and phosphoric acids

Glycopyrrolate

Compounding chemicals like

• Glacial Acetic Acid
• Sodium Hydroxide
• Carbolic acid (liquid phenols)
Reactive
D003 HW Pharmaceuticals

Nitroglycerin - acutely toxic (P081) and reactive (D003)

Clinatest - reactive (D003)

Dry Picric Acid - reactive (D003)
Existing Regulation
Universal Waste Pharmaceuticals

HW pharmaceuticals can be managed as Universal Waste (MI & FL only)

Universal Waste standards are streamlined HW standards

Dual Waste - Pharmaceutical waste mixed with medical waste
  - Most expensive
  - Only 90 day storage
  - HW and medical waste regulations apply
2004 MI established pharmaceuticals as a universal waste type

EPA reauthorized MI program August 28, 2015

Encourage all pharmaceuticals

- managed as UW (BMP)
- incinerated (BMP)
Existing Regulation
Universal Waste Pharmaceuticals

Benefits:
- No counting
- No proving CESQG exempt status
- Less characterization, presume hazardous waste
- Longer storage time
- One set of container standards
- Less training
- Less containers
- Ultimate disposal is the same, licensed HW disposal facility
Existing Regulation
Universal Waste Pharmaceuticals

Container and Labeling

- Compatible with waste
- Closed except to add/remove
- Labeled “Universal Waste Pharmaceutical”
- Date container when waste first added
Existing Regulation
Universal Waste Pharmaceuticals

Storage/Accumulation

- Secured from weather, fire, physical damage, and vandals
- Separate incompatible materials
- Prevent releases
- Inspected weekly (BMP)
- Secondary containment (BMP)
Existing Regulation
Universal Waste Pharmaceuticals

Transportation & Disposal

- Occur within one year of accumulation
- Be in compliance with the DOT requirements
- Accompanied by a “Shipping Document” or manifest if liquids
- May be shipped to universal waste handler
- Ultimate disposal is licensed HW disposal facility
Existing Regulation
Universal Waste Pharmaceuticals

Shipping document must include:

- Generator name and address of
- Transporter name
- Waste type and volume shipment
- Date of generator shipment
- Designated facility name, address, and Site ID number
Existing Regulation
Universal Waste Pharmaceuticals

Shipping document or manifest must be:
- Certified by generator
- Certified by transporter
- Kept at least 3 years

Receiving facility must:
- verify they’re the listed designated facility
- notify generator of receipt of shipment
Universal Waste
Pharmaceuticals

Additional Resources include:

- MHA Pharmaceutical Waste Management Guide
- MHA Guide Example Posting
- Pharmaceutical Tutorial
- Universal Waste Guidance

www.michigan.gov/deqdrugdisposal
What is Federal HW Pharmaceutical Proposal?
Initial Federal Proposed Rules

2008 - EPA proposes to establish pharmaceuticals as a federal universal waste type

2013 - EPA identifies intent to develop a completely different proposal for HW pharmaceuticals due to substantial negative public comments
Current Federal Proposed Rules

September 25, 2015 - EPA issued proposed rules requiring Michigan abandon its universal waste designation and establish new healthcare/RD standards

December 24, 2015 - Public comment closed
Status of Federal Proposed Rules

EPA received over 175 diverse comments from:

- Reverse Distributors
- States/Government
- Retail
- Pharmacists
- Hospitals
- Associations

EPA projected issuance of final rules in Fall 2016

Final rules now projected sometime in 2017
Overview

Who is impacted?

1,624 hospitals

142,400 non-hospital healthcare facilities

28 reverse distributors
Purpose

Protect water resources

Provide regulatory relief to healthcare and pharmacies

Authorize reverse distribution practices

Eliminate DEA controlled substance overlap

Formalize adhoc interpretations
EPA Recommendations

Manage all pharmaceuticals, both HW and non-HW pharmaceutical under proposal

Exempted CESQGs opt-in

Incineration of pharmaceuticals at licensed hazardous waste incinerator unless otherwise prohibited under the land disposal restrictions

Above - Aerial Photo of a Hazardous Waste Incinerator
EPA Primary Goal

Protect water resources by sending most unwanted post manufacture pharmaceuticals for disposals via incineration
Key General Benefits

Divert 6,400 tons of hazardous waste (HW) pharmaceuticals from potentially reaching our water resources to incineration
Novel Provisions

Establishes completely new regulatory scheme nationally for HW pharmaceuticals

- 40 CFR Part 266, Subpart P for HW Pharmaceuticals
- Mandatory for SQGs/LQGS
- Optional for CESQGs
Novel Provisions

Prohibits wasting HW pharmaceutical to sewer

Mandates Michigan abandon pharmaceuticals as a universal waste
Novel Provisions

Concludes that pharmaceutical sent for reverse distribution are waste

Authorizes HW pharmaceutical storage at RD without HW storage license, financial assurance, or corrective action
Key General Provisions

Establishes separate management requirements for

• Potentially Creditable HW Pharmaceuticals” in RD

• “Non-Creditable HW Pharmaceuticals” being disposed by Healthcare

• Evaluated HW Pharmaceuticals being disposed by RD
Key Reverse Distributor
Benefits

Assigns value to RD pharmaceuticals for

- manufacture assigned credit
- street value for non-controlled pharmaceuticals

Authorizes HW pharmaceutical storage at RD without HW storage license, financial assurance, or corrective action obligation
Healthcare Defined

Healthcare is specifically defined as any person that

- provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and **counseling**, service, assessment or procedure with respect to the **physical or mental** condition, or functional status, of a **human or animal** or that affects the structure or function of the human or animal body

- sells or dispenses over-the-counter or prescription pharmaceuticals.
Healthcare Defined

Healthcare includes:

- Independent dental, veterinary, and medical offices
- Hospitals, medical and veterinary
- Health clinics
- Surgical clinics
- Chemotherapy clinics
- Coroners offices - NEW
- Adult care facilities - NEW
Healthcare is defined to include all pharmacies, including:

- Retail brick and mortar pharmacies
- Mail order pharmacies
- Compounding pharmacies
- Long term care pharmacies
Reverse Distributor (RD) Defined

Any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit
Pharmaceutical Defined

Generally includes any chemical formulation intended to:

- diagnosis, cure, mitigate, care for, treat, or prevent disease or injury or

- formulated to effect the structure or function of the body of a human or other animal
Pharmaceutical Defined

Pharmaceuticals includes:

• Prescription & OTC drugs
• Dietary supplements
• DEA controlled substances unless managed to meet exemption
• Contaminated PPE - NEW
• Pharmaceutical spill clean-up NEW
Pharmaceuticals do not include:

- Medical waste
- R & D pharmaceuticals
- Pharmaceutical manufacture waste
- Exempt DEA pharmaceuticals - NEW
- Exempt “empty” containers and syringes - NEW

Rule of Thumb: Includes any formulation with a Drug Fact label
Hazardous Waste Pharmaceutical Defined

Ignitables
D001 HW Pharmaceuticals Examples

Corrosive
D002 HW Pharmaceuticals Examples

Reactive
D003 HW Pharmaceuticals

Wart removers
Eye medicine
Glycopyrrolate

Compounding
- Glacial Acetic Acid
- Sodium hydroxide
- Carbolic acid

Nitroglycerin - acutely toxic (P081) and reactive (D003)

Clinatest - reactive (D003)

Dry Picric Acid - reactive (D003)
Current federal rules:

- Container residues are acute P-listed HW, unless triple-rinsed or cleaned by an equivalent method.
- Long standing EPA policy that vials, dixie cups, soufflé cups, blister packs are not empty once dose is administered.

### Table 205a

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<th>EPA Hazardous Waste Number</th>
<th>Chemical Abstract Services Number</th>
<th>Substance</th>
<th>Hazard Code</th>
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<td>1314-63-1</td>
<td>Vanadium(V) oxide or vanadium pentoxide</td>
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<td>P084</td>
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<td>Vinylamine, N-methyl-N-nitrosocyanate</td>
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### Table 205b

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<td>U005</td>
<td>53-96-3</td>
<td>Acetamide, N-(9H-fluoren-2-yl)-</td>
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Clarify Empty

Proposed federal rules:

Unit-dose containers (packets, cups, blister packs) and dispensing bottles (vials up to 1 liter or 1000 pills) are empty and exempt if:

- All content is fully dispensed (rendering the container “RCRA empty”) AND
- Container is destroyed to prevent divers (e.g., crushed) - NEW
Proposed federal rules

Dispensed syringes are RCRA empty and exempt if:

- The syringe has been used to administer the pharmaceutical to a patient, AND
- The syringe is placed in a sharps containers that is managed appropriately
All other containers, including delivery devices, that once held listed P or U or exhibit a characteristic, must be managed as hazardous waste, including:

- IV bags and tubing
- Nebulizers
- Ointment tubes
Examples of current dually regulated pharmaceuticals by EPA and DEA include:

- Chloral hydrate (U034)
- Fentanyl sublingual spray (D001)
- Phenobarbital (D001)
- Valium injectable (D001)
- Testosterone gels (D001)
Eliminate DEA Overlap

Current - Meet both DEA and HW

Proposed - Exempt controlled if managed to meet DEA regulations and incinerate at:

- a licensed municipal solid waste incinerator or
- a licensed hazardous waste incinerator

Above: Municipal solid waste incinerator
Clarifies HW Status of Specific Pharmaceuticals

Epinephrine salts are not P-listed wastes

Phentermine salts are not P-listed wastes

Federal register sought comment on HW status of nicotine patches, gum, lozenges as acutely hazardous
Potentially Creditable HW Pharmaceutical Defined

Includes HW pharmaceuticals that have the potential to receive manufacturer credit

Must:
  • Be unused/un-administered
  • <1 year of expiration
  • In original packaging
Potentially Creditable HW Pharmaceutical Defined

Does not include:

- Samples
- > 1 year expired
- Removed from their original container
- Re-packaged for dispensing
- Generated during patient care
- Refused by a patient
Potentially Creditable HW
Pharmaceutical Defined

Potentially creditable HW pharmaceuticals do not include:

- Evaluated hazardous waste pharmaceuticals
- Non-empty container residues
- Contaminated PPE
- Spill clean-up
Potentially Creditable HW Pharmaceutical Defined

If there is no reasonable expectation of credit, the HW pharmaceutical cannot go to an RD

If an RD receives non-creditable HW pharmaceuticals, it must:

• Prepare an “unauthorized waste report” and send it to the Healthcare facility and to EPA

• Manage the waste appropriately
Non-creditable HW pharmaceuticals includes HW pharmaceuticals that are not eligible for manufacturers credit.
Evaluated HW Pharmaceutical

A hazardous waste pharmaceutical that was potentially creditable but has been evaluated by a RD to establish manufacturer credit eligibility and will not be sent to another pharmaceutical reverse distributor for further evaluation.
Healthcare
General Requirements

One-time notification as Healthcare Facility

Performance-based training for healthcare workers

CESQGs can opt in with notification
Healthcare Accumulation
Potentially Creditable Pharmaceuticals

No specific labeling

No specific accumulation requirements

No specific time limits
Healthcare Shipping
Potentially Creditable Pharmaceuticals

- Written, advance notice of shipments to RD
- Confirmation of receipt of shipment by RD
- Recordkeeping of shipments/confirmation to/from RD
- Allows common carrier
- HW codes not required for shipment
Healthcare Accumulation
Non-Creditable Pharmaceuticals

- Closed containers secured to prevent access
- Label as “Hazardous Waste Pharmaceuticals”
- One year accumulation limit
- Segregate wastes that can’t be incinerated per land disposal restrictions (e.g., arsenic trioxide)
- HW codes not required on accumulation containers
Healthcare Shipping
Non-Creditable HW Pharmaceuticals

- HW transporter required
- Manifesting required
- Must meet U.S. DOT requirements
- HW codes not required on manifest
- “Hazardous waste pharmaceuticals” must be noted in Box 14 of manifest
- Land disposal notice not required but TSD must know codes to treat to LDRs
Key Healthcare Benefits

Extends 90/180 day accumulation to 1 year
Eliminates pharmaceutical waste counting
Eliminates satellite/accumulation area requirements
Reduces training and documentation requirements
Eliminates LQG biennial reporting
Clarifies ambiguous and overlapping requirements
Healthcare CESQG Allowances

A CESQG healthcare facility may:

• send potentially creditable hazardous waste pharmaceuticals to a pharmaceuticals reverse distributor

• send potentially creditable and non-creditable hazardous waste pharmaceuticals to their owner or a site contracted to supply their pharmaceuticals for disposal under subpart P by receiving facility
Healthcare Facilities Receiving CESQG HW Pharmaceuticals

Receiving healthcare facility must:

• own or supply via contract pharmaceuticals to CESQG

• operate under Subpart P

• manages non-creditable pharmaceuticals from the CESQG under subpart P

• keep records of the creditable and non-creditable pharmaceuticals received from off-site for 3 years
LTC Allowance

Long-term care CESQGs can dispose their non-creditable hazardous waste pharmaceuticals in a DEA registered collection receptacle managed to meet the DEA controlled substance regulations.
Reverse Distributor
General Requirements

• Only authorized to accept potentially creditable HW pharmaceuticals

• Must have contingency plan

• Must documented staff training
Reverse Distributor (RD)
General Requirements

- One-time notification as RD
- Maximum of 3 RDs before disposal
- Notification if receive shipment of non-creditable HW pharmaceuticals
- Biennial reporting
Reverse Distributor Accumulation
Potentially Creditable HW Pharmaceuticals

No specific labeling or container standards

Each Reverse Distributor:

• Must evaluate whether “creditable” under manufacture contract within 21 days or receipt

• Is allowed maximum of 90 day storage
Reverse Distributor Accumulation
Potentially Creditable HW Pharmaceuticals

Within 90 days of receipt the RD must:

- Assign credit to healthcare facility AND send to a licensed HW TSDF for treatment or disposal in accordance with “Evaluated HW Pharmaceutical” requirements OR

- Send to another RD to evaluate credit
Reverse Distributor Accumulation
Potentially Creditable HW Pharmaceutical

Each Reverse Distributor must have:

• Inventory of HW pharmaceuticals

• Facility security
Reverse Distributor
Maximum Transfers Allowed

Maximum additional storage duration is 270 days until TSD disposal is required.
Reverse Distributor Accumulation
Evaluated HW Pharmaceutical

- Must designate an on-site accumulation area
- Must conduct and keep a log of weekly inspections
- LQG training for personnel handling evaluated HW pharmaceuticals
Reverse Distributor Accumulation
Evaluated HW Pharmaceuticals

• Closed containers for liquids or gels
• Wastes that can’t be incinerated must be accumulated separately (e.g., arsenic trioxide P012)
• HW codes required prior to transport off-site
• Label as “Hazardous Waste Pharmaceuticals”
Reverse Distributor Shipping
Potentially Creditable HW Pharmaceuticals

- Written, advance notice of shipments to next RD
- Confirmation of receipt of shipment from receiving RD
- Recordkeeping of shipments to RD
- Common carrier allowed
- HW codes not required during shipment
Reverse Distributor Shipping
Evaluated HW Pharmaceuticals

- HW transporter required
- Manifesting required
- Must meet U.S. DOT requirements
- HW codes not required on manifest
- “Hazardous waste pharmaceuticals” must be noted in Box 14 of manifest
- Land disposal notice not required but TSD must know and treat to LDRs
Key Changes for Michigan

Proposal eliminates current universal waste handlers locations that accumulate larger shipment volumes for HW incineration

Secondary locations accepting non-creditable pharmaceuticals must be:
  • transfer facility (10 day storage) or
  • License hazardous waste TSD
Federal HW Pharmaceutical Rule proposes to:

• Establish new regulatory framework for HW Pharmaceuticals under 40 CFR, Part 266, Subpart P

• Prohibit sewering of HW Pharmaceuticals from all of healthcare and reverse distribution, including CESQGs!
Wrap Up

Federal HW Pharmaceutical Rule proposes to:

• Authorize reverse distribution HW pharmaceuticals storage without a license by establishing:
  • Potential Creditable HW Pharmaceuticals
  • Non-Creditable HW Pharmaceuticals
  • Evaluated HW Pharmaceuticals

• Would require Michigan & Florida to abandon their universal waste designation for national consistency
Wrap Up

Provides mandatory management standards
HW pharmaceuticals from SQG and LQGs

Encourages CESQGs “opt in” to standards

Encourages management of all pharmaceuticals under new standards
Federal Proposed Rules

Effective Date

When final rulemaking is issued it becomes effective:

• Immediately in all states and territories for sewer ban
• Upon state adoption for all other provisions
• Final rules may be different than proposed rules
Glimpse of What to Expect

Sites relying on Michigan’s universal waste rule can continue to do so until:

- the federal rules final
- Michigan promulgates rules to adopt the final rules into the state program under Part 111
Bottom Line

Managing all pharmaceuticals as a universal waste in Michigan, regardless of generator status, will establish procedures that make compliance with the new subpart for healthcare easy!
To establish a pharmaceutical waste program or refine an existing program:

- See MHA Guide Universal Waste Guide Sheet
- See Pharmaceutical Waste Disposal Vendor List
- Consider 10 Step Process
- Call with questions!!!
Questions?
Thank you for your continued commitment to protecting our shared resources!
Questions?