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

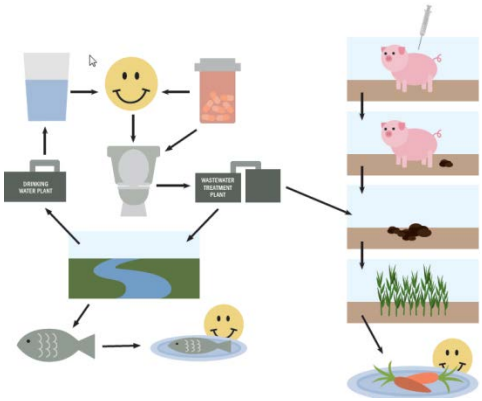
- Changes are Extensive:
  - Proposes to establishes entirely new management standard for pharmaceuticals from healthcare
  - Proposes to prohibits sewering - all HW pharmaceuticals
  - Proposes to require MI abandon current regulations
  - Proposal is expected to go to final rulemaking next

Pharmaceuticals - Emerging Contaminants of Concern

- First detected at low levels in Europe in1970'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'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

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
- Incinerate pharmaceuticals where possible to destroy the chemicals in the drugs, preventing them from entering our water

- 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
- Be proactive focusing on prevention first, not reactive since pharmaceuticals cannot generally be recycled and must be disposed when over-inventoried

> In Michigan the hazardous waste regulations are found under Part 111 and the Part 111 rules. The Michigan hazardous waste program is implemented under the state regulations instead of the federal Resource Conservation and Recovery Act and its rules as part of the Michigan's authorization which was reauthorized last on August 28, 2015.

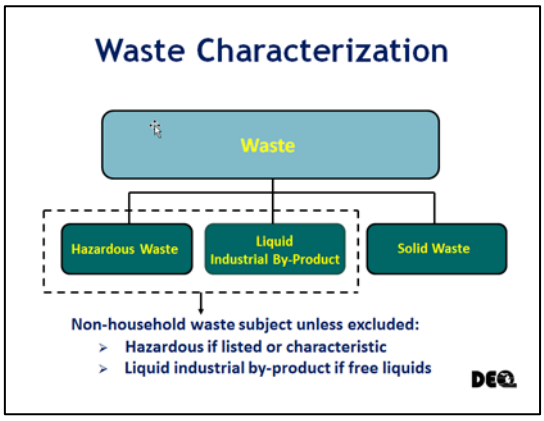
Hazardous Waste (HW) Pharmaceutical Regulations

- Require each non-household site generating waste to:
  - characterize each waste stream (each pharmaceutical at each dose)
  - determine the total weight of all hazardous generated site-wide monthly (all hazardous waste types)
  - determine their legal disposal options
- Drugs are generally a …
  - Hazardous Waste under Part 111 of Act 451and the Part 111 rules
    - listed or characteristic hazardous waste
  - Liquid Industrial By-Product under Part 121 of Act 451
    - not hazardous & liquid
  - Non-Hazardous Solid Waste under Part 115 of Act 451 and the Part 115 rules
    - not hazardous & solid

Regulations unique to Michigan

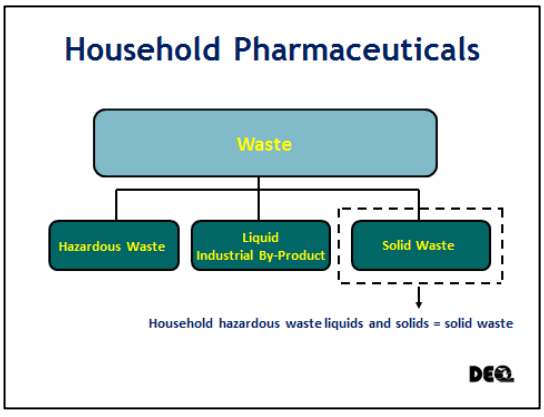
Hazardous Waste (HW) Generator Status

- 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
- CESQG exempted HW must be properly disposed under:
  - Liquid industrial by-product regulations or
  - Solid waste regulations
- CESQGs need receiving facility that wants exempted hazardous waste!
- 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



Household & CESQG Pharmaceutical Collections

- Diverted waste provisions are found in Part 115, Section 11521b
- Diverted waste includes household or non-household waste that can be lawfully landfill or incinerated
- Diverted waste must be
  - Separated from other waste



- Diverted to environmental preferred management option
- Collected safely, lawfully & by knowledgeable staff
- Collected at a secure location protected from weather, fire, physical damage, and vandals
- Not processed except to ensure safe and efficient transport
- Managed to prevent release
- Stored < 1 year
- Documented (types, volumes, and disposition)
- If non-household, must also be handled to meet:
  - CESQG requirements under Part 111, Rule 205(4)
  - Liquid industrial by-product designated facility requirements under Part 121

Pharmaceutical Waste Characterization

- Between 5% to 15% pharmaceuticals are HW:
  - Listed
  - Characteristic
    - Ignitable - Corrosive
    - Toxic - Reactive
- See EPA wiki data at http://hwpharms.wikispaces.com/
- Expect more as EPA reviews pharmaceuticals for listings, like NIOSH hazardous drugs
- Must characterize each pharmaceutical at each dose

Examples of Ignitable D001 HW Pharmaceuticals

- Disinfectant hand washes
- Etoposide (chemotherapy)
- Faslodex (chemotherapy)
- Paregoric (controlled substance)
- Paclitaxel (chemotherapy)
- Rubbing alcohol
- Nyquil

Examples of Toxic & Acutely Toxic D004 to D043 HW Pharmaceuticals

- 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)

Examples of Corrosive D002 HW Pharmaceuticals

- Wart removers - trichloroacetic acid
- Eye medications - acetic and phosphoric acids
- Glycopyrrolate
- Compounding chemicals like
  - Glacial Acetic Acid
  - Sodium Hydroxide
  - Carbolic acid (liquid phenols)

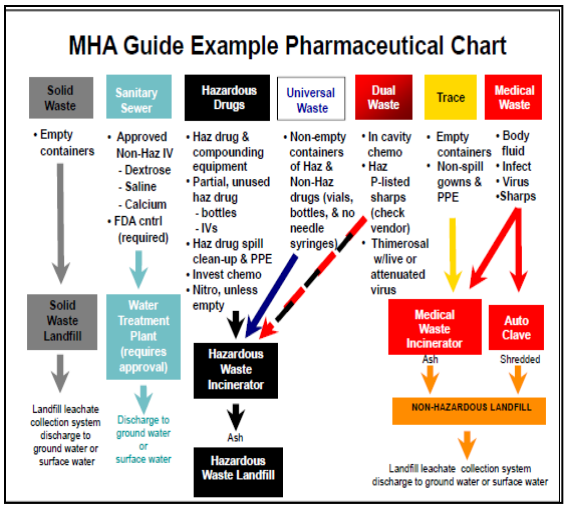
Examples of Reactive D003 HW Pharmaceuticals

- Nitroglycerin – acutely toxic (P081) and reactive (D003)
- Clinatest – reactive (D003)
- Dry Picric Acid – reactive (D003)

Michigan Universal Waste Pharmaceuticals

- HW pharmaceuticals can be managed as Universal Waste, but only in MI & FL

- Universal waste standards are streamlined HW standards in the state regulations
- Don't mix pharmaceutical waste with medical waste, as it's dually regulated (thus called "Dual Waste")
  - Most expensive
  - Only allowed 90 day storage
  - Both HW and medical waste regulations apply
- 2004 MI established pharmaceuticals as a universal waste type
- EPA reauthorized MI program August 28, 2015
- DEQ encourages all pharmaceuticals be
  - managed as universal waste (BMP)
  - incinerated (BMP)
- Universal Waste 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, preferably incineration
- Universal Waste Container and Labeling
  - Compatible with waste
  - Closed except to add/remove waste
  - Labeled "Universal Waste Pharmaceutical"
  - Date container when waste first added
- Universal Waste Storage/Accumulation
  - Secured from weather, fire, physical damage, and vandals
  - Separate incompatible materials
  - Managed to prevent releases
  - Inspected weekly (BMP)
  - Secondary containment (BMP)
- Universal Waste 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
- 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
- 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



Current Michigan Compliance Resources

- MHA Pharmaceutical Waste Management Guide

- MHA Guide Example Posting
- Pharmaceutical Tutorial
- Universal Waste Guidance
- All are found online at www.michigan.gov/deqdrugdisposal

What is Federal HW Pharmaceutical Proposal?

- Initial Federal Proposed Rules
  - 2008 EPA proposed to establish pharmaceuticals as a federal universal waste type
  - 2013 EPA identified intent to develop a completely different proposal for HW pharmaceuticals due to substantial negative public comments
  - 9/25/15 EPA proposed rules requiring Michigan abandon its universal waste designation and establish new healthcare and reverse distribution standards
  - 12/24/15 public comment closed

Status of Federal Proposed Rules

- EPA received over 175 diverse comments from:
  - Reverse Distributors
  - States/Government
  - Retail
  - Pharmacists
  - Hospitals
  - Associations
- EPA initially projected issuing final rules in Fall 2016
- Final rules now projected sometime in 2017
- When final rules are published, and become effective (typically 180 days after publication):
  - Proposed sewer ban of HW pharmaceuticals becomes immediately effective in all states
  - Other provisions become effective upon adoption

Who is impacted by Proposed Rules?

- 1,624 hospitals
- 142,400 non-hospital healthcare facilities
- 28 reverse distributors

Purpose of Proposed Rules

- Protect water resources
- Provide regulatory relief to healthcare and pharmacies
- Authorize reverse distribution practices
- Eliminate DEA controlled substance overlap
- Formalize adhoc interpretations

EPA Recommendations under Proposed Rules

- 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

EPA Primary Goal under Proposed Rules

- Protect water resources by sending most unwanted post manufacture pharmaceuticals for disposals via incineration

Key General Benefits of Proposed Rules

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

Novel Provisions of Proposed Rules

- 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
- Prohibits wasting HW pharmaceutical to sewer
- Mandates Michigan abandon pharmaceuticals as a universal waste
- 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 of Proposed Rules

- 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 of Proposed Rules

- 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 - Proposed Rules

- 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 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 - Proposed Rules

- 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
- 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 - Existing & Proposed Rules

- Unchanged by proposed rules
- EPA issuing separating rulemaking to expand the list of HW pharmaceuticals
- Includes listed and characteristic HW pharmaceutical

Empty Defined - Existing Rules

- 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

Empty Defined - Proposed 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 diversion (e.g., crushed) - NEW
- 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

Eliminate DEA Overlap – Proposed Rules

- 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)
- 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

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
- Does not include:
  - Samples
  - > 1 year expired
  - Removed from their original container

    - Re-packaged for dispensing
    - Generated during patient care
    - Refused by a patient
    - Evaluated hazardous waste pharmaceuticals
    - Non-empty container residues
    - Contaminated PPE
    - Spill clean-up
- 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 Pharmaceutical

- Non-creditable HW pharmaceuticals includes HW pharmaceuticals that are not eligible for manufacturers credit

Evaluated HW Pharmaceutical

- A hazardous HW 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

Long Term Care Facility 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
- One-time notification as RD
- Maximum of 3 reverse distributors can be used to establish credit before disposal is required
- Notification required if reverse distributor receives 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
- 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
- Inventory of HW pharmaceuticals
- Facility security

Reverse Distributor Maximum Transfers Allowed

- 3 allowed before disposal is required
- Maximum additional storage duration is 270 days until TSD disposal in accordance with Land Disposal Restrictions is required.

Reverse Distributor Accumulation Evaluated HW Pharmaceuticals

- Must designate an on-site accumulation area
- Must conduct and keep a log of weekly inspections
- Have LQG equivalent training for personnel handling 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 handlers locations that accumulate larger shipment volumes over a year
- Secondary locations accepting non-creditable pharmaceuticals must be:
- transfer facility (10 day storage) or
- License hazardous waste TSD

Wrap Up

- 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!
  - Authorize reverse distribution HW pharmaceuticals storage without a license by establishing:
    - Potential Creditable HW Pharmaceuticals
    - Non-Creditable HW Pharmaceuticals
    - Evaluated HW Pharmaceuticals
  - Require Michigan & Florida to abandon their universal waste designation for national consistency
  - Provides mandatory management standards HW pharmaceuticals from SQG and LQGs
- Federal proposed HW pharmaceutical rule encourages CESQGs “opt in” to standards
- Federal proposed HW pharmaceutical rule encourages management of all pharmaceuticals under new standards

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!!!