Pharmaceutical Waste Regulations: Existing *Michigan Regulations*, *Final Federal* Regulations & Strategies for Minimizing Pharm Waste in Healthcare

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The webinar notes below are updated to reflect changes in the final federal rulemaking. All updates, since the initial webinar, are shown in italics OR included in a text box that is noted as being an update since the webinar.

Today's Goals

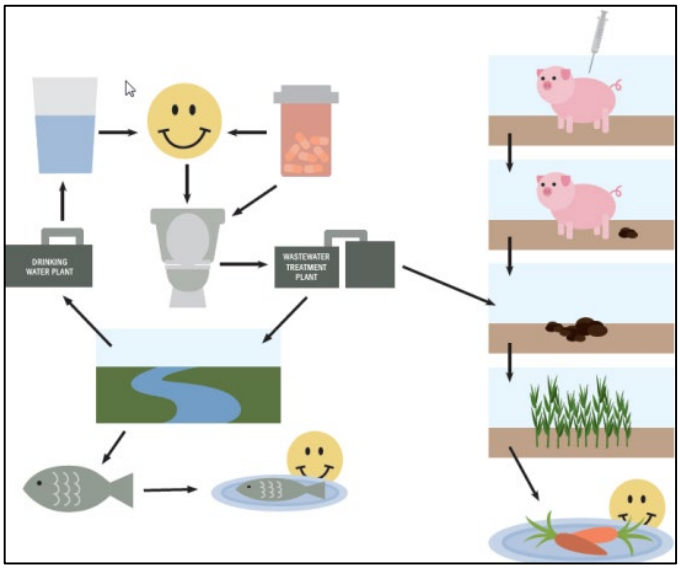
- Identify environmental and public health concerns related to pharmaceuticals
- Provide an overview of Michigan's existing environmental pharmaceutical waste regulations
- Provide overview of the *proposed* ***(Now Final)*** *federal environmental hazardous waste (HW) pharmaceutical rules*
- Identify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

Why Cover a Proposed Rule?

- Changes are Extensive:
  - Proposes to establish entirely new management standard for pharmaceuticals from healthcare
  - Proposes to prohibit 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
  - 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 that was reauthorized last on August 28, 2015.

UPDATE SINCE WEBINAR:

Last reauthorization occurred on **June 6, 2019**

Hazardous Waste (HW) Pharmaceutical Regulations

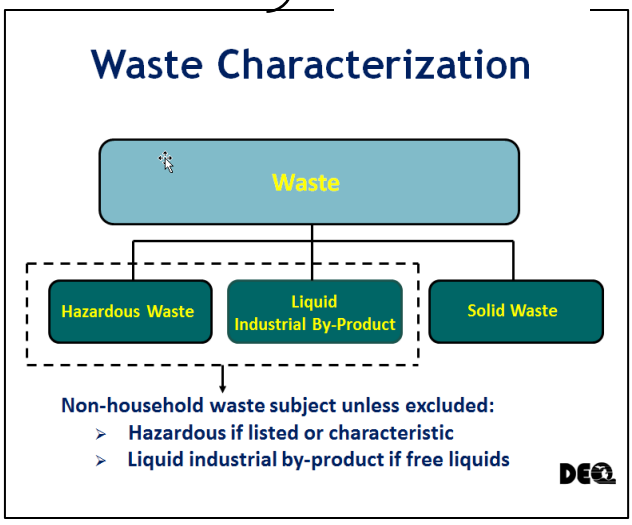
- Require each non-household site generating waste to:
  - characterize each waste stream (each pharmaceutical at each dose)
  - determine the total weight of all hazardous generated site-wide monthly (all hazardous waste types)
  - determine their legal disposal options
- Drugs are generally a …
  - 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

Implemented in Michigan instead of the federal RCRA per EPA's authorization

Regulations unique to Michigan

Hazardous Waste (HW) Generator Status

- Conditionally Exempt Small Quantity Generator (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
- Small Quantity Generators and Large Quantity Generators of HW
  - Generate ≥ 220 lbs. non-acute HW monthly
  - Generate ≥ 2.2 lbs. acute HW monthly
  - Accumulate ≥ 2200 pounds non-acute HW
  - Accumulate ≥ 2.2 lbs. acute HW

Pharmaceutical Waste Characterization

- Between 5% to 15% pharmaceuticals are HW:
  - Listed
  - Characteristic
    - Ignitable - Corrosive
    - Toxic - Reactive
- 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)

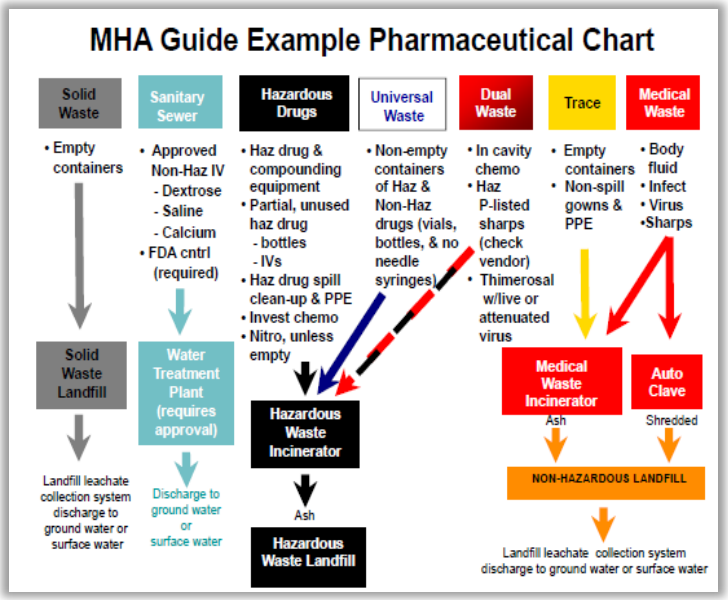
Examples of Reactive D003 HW Pharmaceuticals

- 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 ***(Now EGLE)*** 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
- Universal Waste Guidance

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

UPDATE SINCE WEBINAR:

Final Rulemaking:

- 2/22/19 EPA issued final rules
- 8/21/19 the sewer ban becomes effective nationally
- All other provisions in the final rules do not become effective in other states until they are adopted, except in Alaska and Iowa

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

Who is impacted by Proposed *(Now Final)* Rules?

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

Purpose of Proposed *(Now Final)* 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 *(Now Final)* Rules

- Manage all pharmaceuticals, both HW and non-HW pharmaceutical under the proposed ***(Now Final)*** rules
- Exempted CESQGs should opt-in to simplify management standard and maintain compliance
- Incineration of pharmaceuticals at licensed hazardous waste incinerator unless otherwise prohibited under the land disposal restrictions

EPA Primary Goal under Proposed *(Now Final)* Rules

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

Key General Benefits of Proposed *(Now Final)* Rules

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

Novel Provisions of Proposed *(Now Final)* Rules

- Establishes completely new regulatory scheme nationally for HW pharmaceuticals
- 40 CFR Part 266, Subpart P for HW Pharmaceuticals
- Mandatory for Small Quantity Generators (SQGs) and Large Quantity Generators (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 *(Now Final)* 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 *(Now Final)* 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 *(Now Final)* 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

UPDATE SINCE WEBINAR:

Healthcare includes:

- Long term care facilities
- It does NOT include adult care facilities unless they have **on-site nursing facilities**

UPDATE SINCE WEBINAR:

- Long term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility.
- Long term care facility includes, but is not limited to:
  - hospice facilities
  - nursing facilities
  - skilled nursing facilities and
  - the nursing and skilled nursing care portions of continuing care retirement communities.
- Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

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 *(Now Final)* Rules

- Generally includes any chemical formulation intended to:
  - diagnosis, cure, mitigate, care for, treat, or prevent disease or injury or
  - formulated to affect 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

UPDATE SINCE WEBINAR:

Contaminated PPE and pharmaceutical spill clean-up materials are not "pharmaceuticals" as defined under the universal waste regulations. Therefore, they cannot be managed as a universal waste under Michigan's existing hazardous waste regulations. They must be managed as a hazardous waste by SQGs and LQGs of hazardous waste. generators.

Hazardous Waste Pharmaceutical Defined - Existing & Proposed *(Now Final)* 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 *(Now Final)* 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")
- 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

UPDATE SINCE WEBINAR:

Empty containers do not need to be destroyed or crushed under final rulemaking.

UPDATE SINCE WEBINAR:

- **All other containers,** including delivery devices , IV bags and tubing, nebulizers and ointments that once held non-acute hazardous waste pharmaceuticals are empty and not subject to hazardous waste regulation if the container or the inner lining that held non-acute hazardous waste has had as much material removed as possible using practices commonly used to remove that material (e.g. pouring, pumping, and aspirating)
- Empty containers and devices should be accumulated in a secured area with limited access (BMP)

Eliminate DEA Overlap – Proposed *(Now Final)* 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 *(Now Final)*** – Exempt controlled substances that are also a hazardous waste pharmaceutical if managed to meet DEA regulations and incinerate at:
  - a licensed municipal solid waste incinerator or
  - a licensed hazardous waste incinerator

UPDATE SINCE WEBINAR:
How to manage controlled substances in Michigan

Wastage – The DEA does not approve products for rendering controlled substances non-retrievable. Consequently, the wasting of leftover, unadministered partial doses of controlled substances, like a dose that remains in a vial, tube, transdermal patch, or syringe should be:

- witnessed and documented,
- wasted into containers that include absorbents or chemical reactants that bind or chemically alter the contents to prevent diversion and illicit use, and
- the containers should be secured.

The collected wastage is no longer regulated by DEA if the controlled substances were administered to patients and the leftover pharmaceutical wasting was witnessed and documented. As a result, the wasting containers remain subject to hazardous waste regulation and should be managed as a universal waste.

Controlled Substances Inventories Sent for Reverse Distribution – Inventories of controlled substances that can no longer be administered to a patient and are sent for manufacturer credit through reverse distribution remain subject to both DEA regulations and the hazardous waste regulations. They can be managed to meet the universal waste regulations in Michigan. The transfer to the reverse distributor is considered a distribution under the DEA regulations and requires recordkeeping.

Controlled Substances Sent for Hazardous Waste Disposal – Controlled substances that are a hazardous waste being disposed remain subject to both the DEA regulations and the hazardous waste regulations. They can be managed to meet the universal waste regulations in Michigan. The transfer to the reverse distributor is considered a distribution under the DEA regulations and requires recordkeeping.

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
  To be potentially creditable HW pharmaceuticals, the pharmaceuticals must:
  - Be unused/un-administered
  - <1 year of expiration
  - In original packaging

- 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 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

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

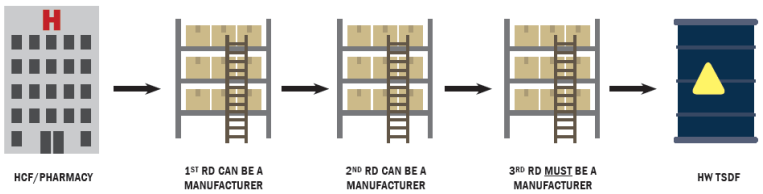
- Only authorized to accept potentially creditable HW pharmaceuticals
- Must have contingency plan
- Must documented staff training
- One-time notification as RD
- Maximum of 3 reverse distributors can be used to establish credit before disposal is required
- Notification required if reverse distributor 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 universal waste handler locations that accumulate larger shipment volumes for hazardous waste incineration
- Secondary locations accepting non-creditable pharmaceuticals must be:
  - transfer facility (10 day storage) or
  - License hazardous waste TSD

Wrap Up

- **Proposed (*Now Final*)** Federal HW Pharmaceutical Rule:
  - Establishes new regulatory framework for HW Pharmaceuticals under 40 CFR, Part 266, Subpart P
  - Prohibits sewering of HW Pharmaceuticals from all of healthcare and reverse distribution, including CESQGs!

    UPDATE SINCE WEBINAR:
    Sewering of HW Pharmaceuticals from all of healthcare and reverse distribution, including CESQGs, is prohibited on and after **August 21, 2019**

  - Authorizes reverse distribution HW pharmaceuticals storage without a license by establishing:
    - Potential Creditable HW Pharmaceuticals
    - Non-Creditable HW Pharmaceuticals
    - Evaluated HW Pharmaceuticals
  - Requires Michigan & Florida to abandon their universal waste designation for national consistency
  - Provides mandatory management standards HW pharmaceuticals from SQG and LQGs
- Federal Proposed *(Now Final)* HW pharmaceutical rule encourages CESQGs "opt in" to standards
- Federal Proposed *(Now Final)* HW pharmaceutical rule encourages management of all pharmaceuticals under new standards

Federal Proposed *(Now Final)* Rules Effective Date

- 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 *(UPATE: sewer ban becomes effective on 8/21/19)*
  - Other provisions become effective upon adoption into state rules *(UPDATE: The other provisions become effective upon adoption into states rules in all states, except on Alaska and Iowa)*
  - Final rules may be *(are)* different than proposed rules *(see UPDATE boxes)*

> **UPDATE SINCE WEBINAR:**
> Final federal rules were published on 2/22/19 and become effective on 8/21/19

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

> **UPDATE SINCE WEBINAR:**
> Michigan promulgation of the rules to adopt the final rules will likely start in Fall 2019 and take about a year to complete

  - Call with questions!!!