
Retail Environmental Workgroup

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Michigan Pharmaceutical Environmental Disposal Regulations Webinar

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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**
- **Notes page**

Environmental Assistance Center (EAC)

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

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

Technical Assistance Services Include:

Air
Waste
Water

Environmental Audit Privilege
Site Remediation
Permit Coordination

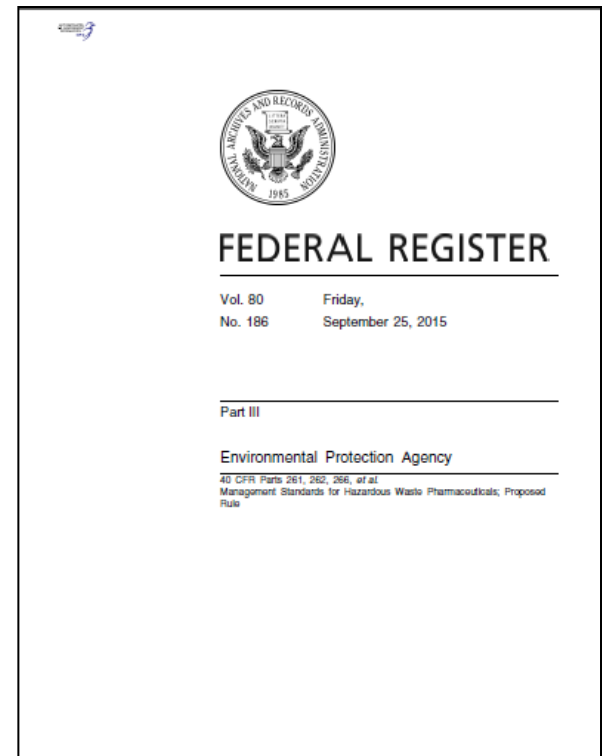
Today's Goals

- ✓ 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 sewerage - all HW pharmaceuticals
- Proposed to require MI abandon current regulations



Environmental & Public Health Issues



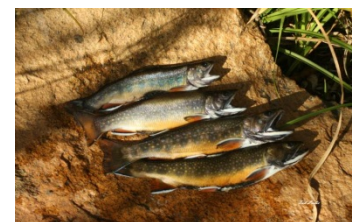
Pharmaceuticals

An Emerging Contaminant

First detected at low levels in Dead Sea
in 1970's

Studies continue to show they are
ubiquitous globally and persistent - see
<http://toxics.usgs.gov>

They 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 are known 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

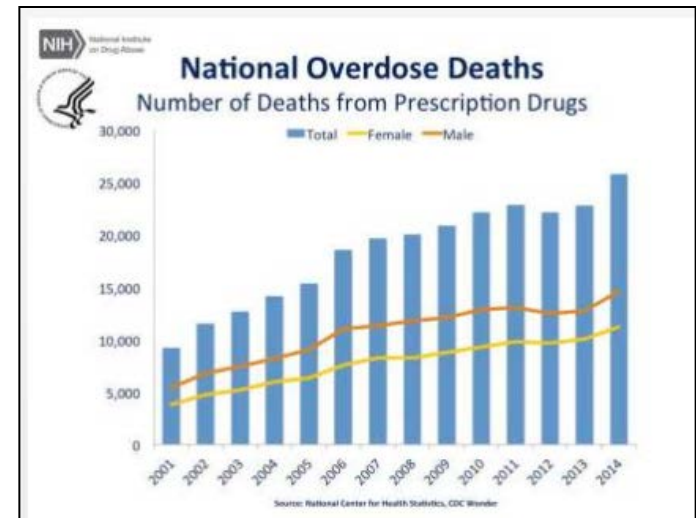


Pharmaceuticals

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



Above -Graph shows a 2.8 fold increase in accidental deaths from overdose between 2004 to 2014

What We Can Do Now

- ✓ Manage inventories
- ✓ Incinerate - preferred disposal option

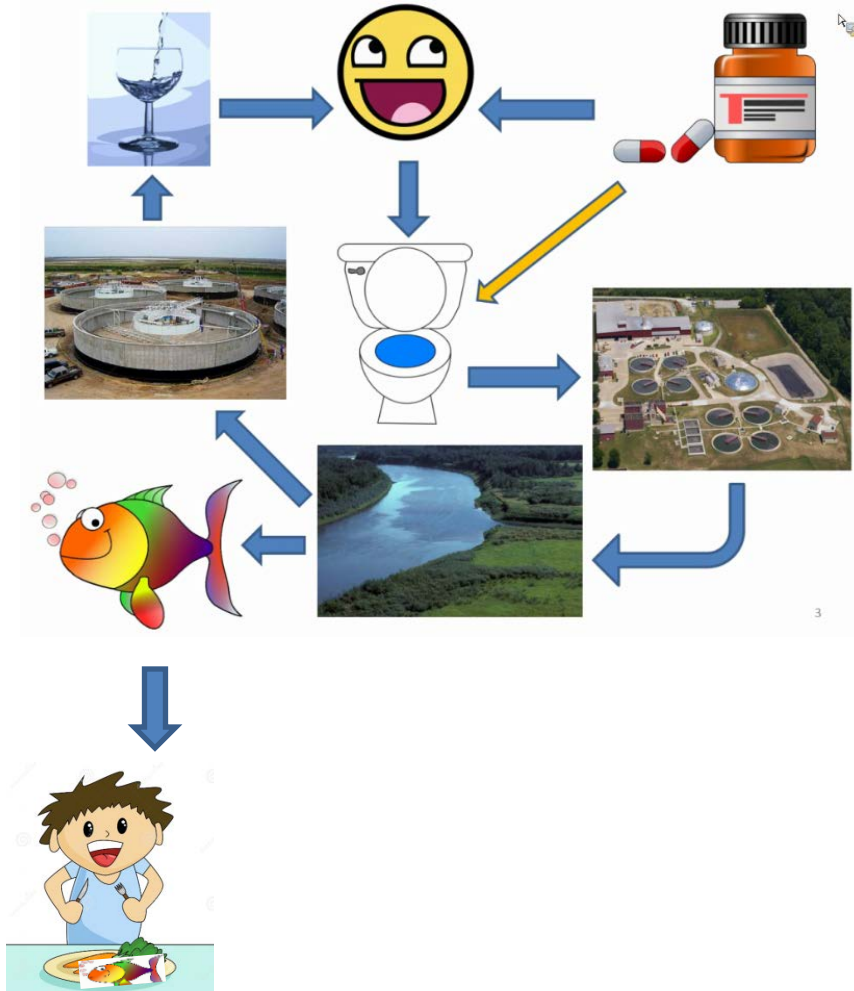


It destroys the chemicals and prevents them from cycling in our environment

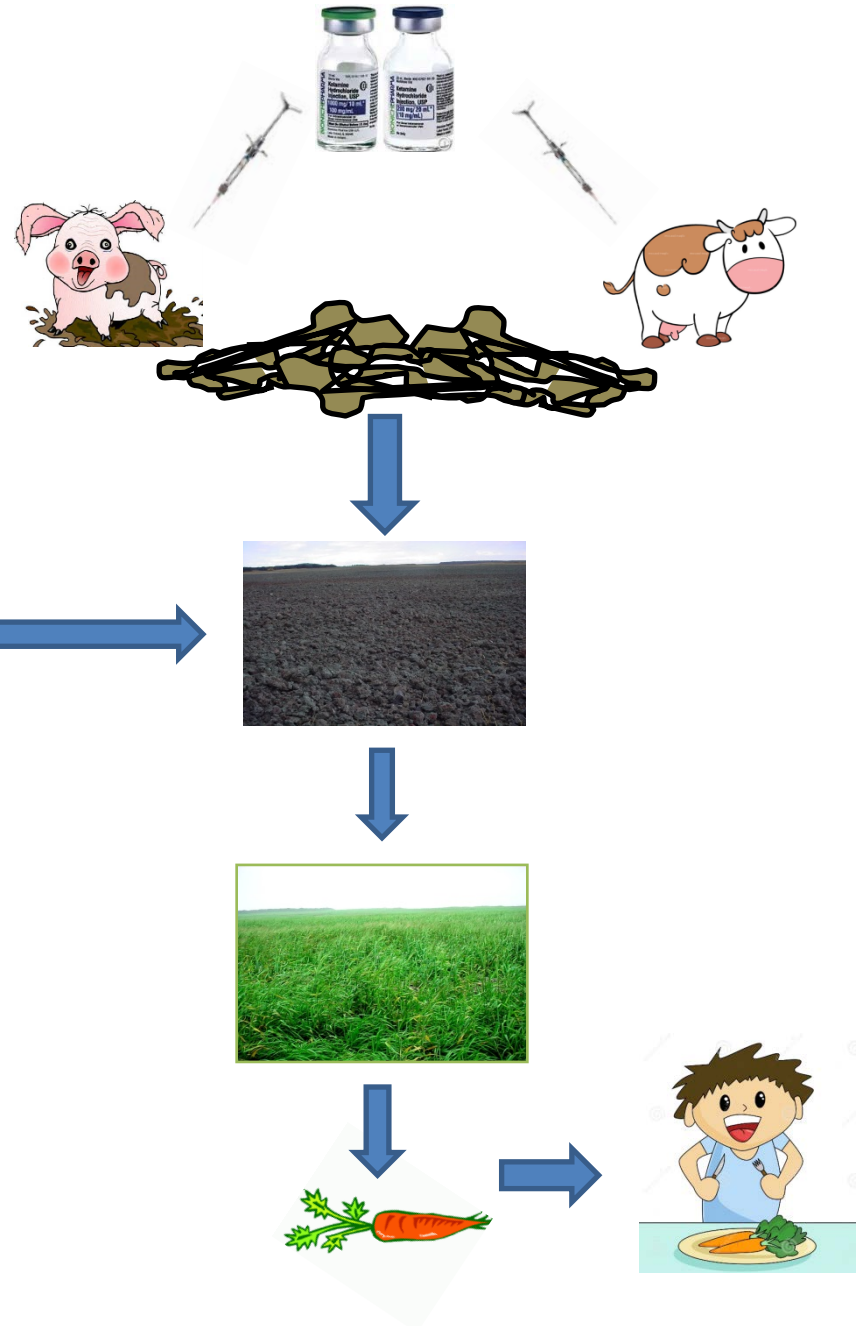
What We Can Do Now

Establish Waste Minimization Policies

- ✓ 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

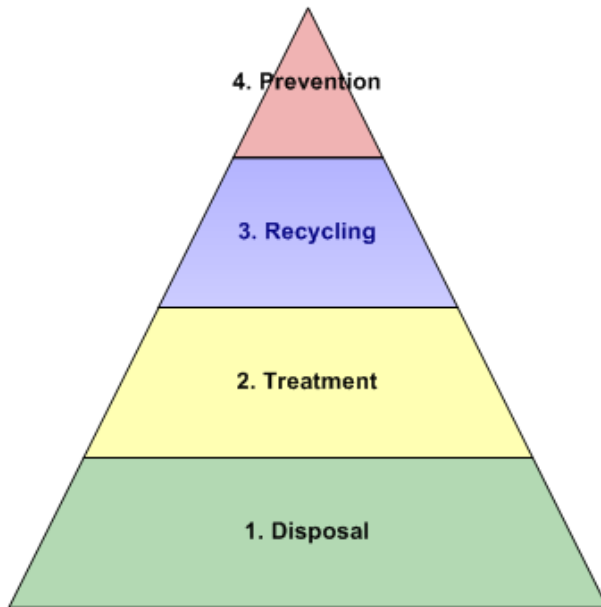


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Paradigm Switch

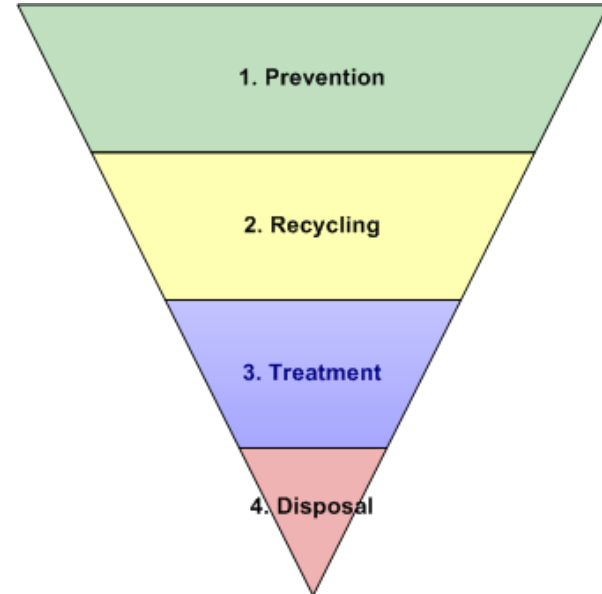
Reactionary



SHIFT



Anticipatory



Existing Environmental Pharmaceutical Disposal Regulations



Existing Waste Regulation

National HW Pharmaceuticals

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

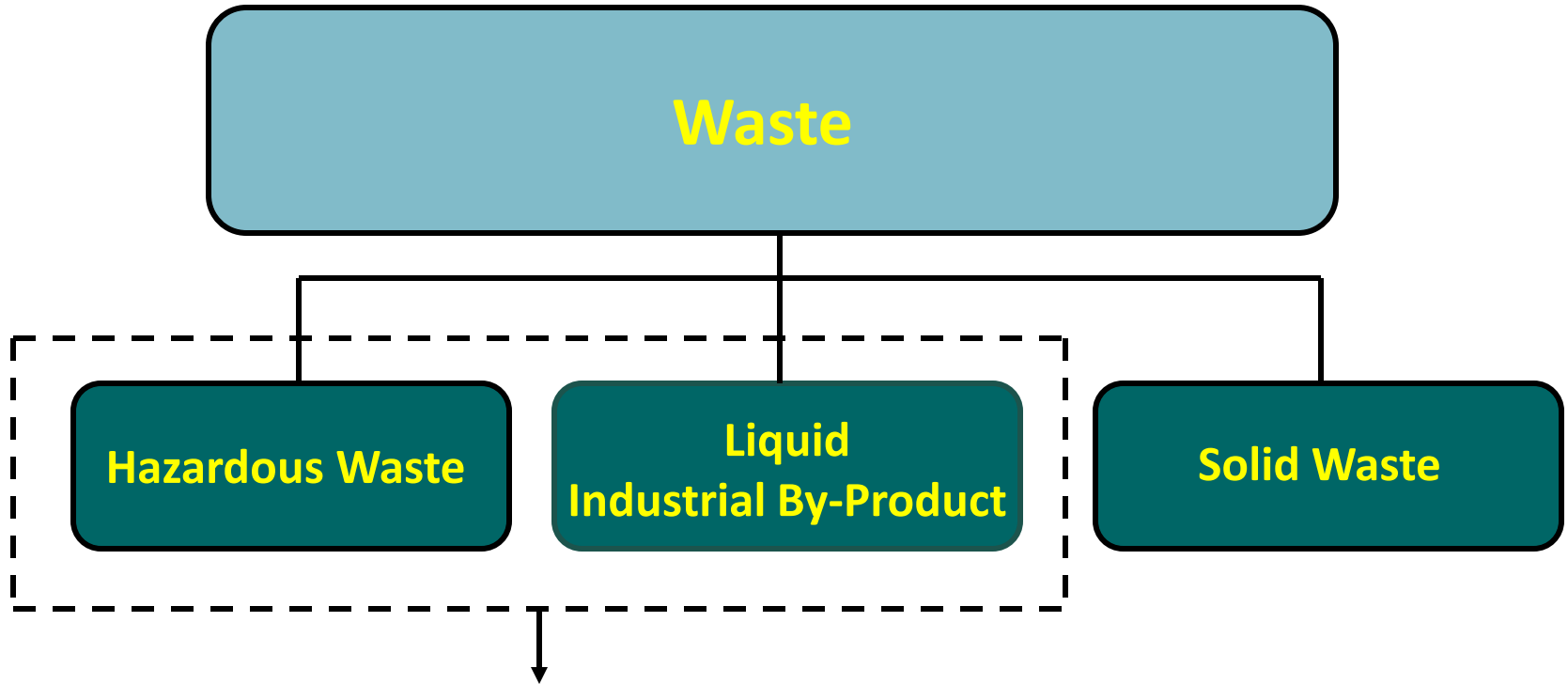
Michigan HW Pharmaceuticals

Drugs are generally a ...

- ✓ Hazardous Waste
(Part 111 of Act 451) - listed or characteristic
- ✓ Liquid Industrial Waste
(Part 121 of Act 451) - hazardous & liquid
- ✓ Non-Hazardous solid waste
(Part 115 of Act 451) - not hazardous & solid



Waste Characterization



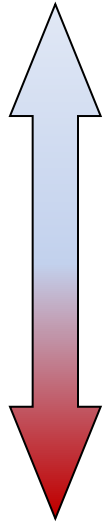
Non-household waste subject unless excluded:

- **Hazardous if listed or characteristic**
- **Liquid industrial by-product if free liquids**

Existing Waste Regulation

National HW Pharmaceuticals

Less
Regulation



More
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!

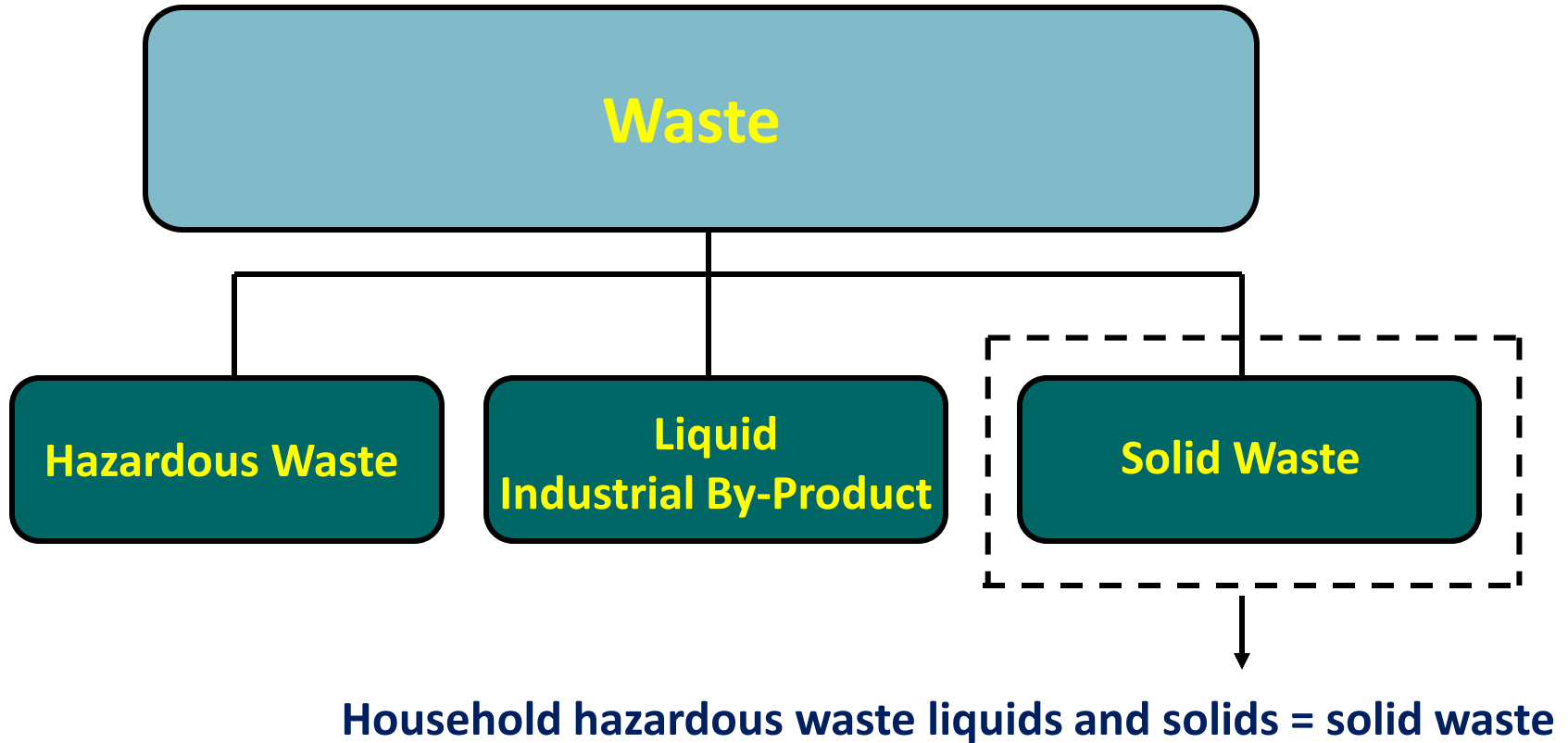
Hazardous Waste Generator Status

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

Household Pharmaceuticals



Household Takebacks

Diverted Waste Part 115 Section 11521b

- ✓ Household or non-household waste lawfully to landfill or incinerate
- ✓ Separated from other waste
- ✓ Collected at HHW collections
- ✓ Diverted to environmental preferred management option



Household Takebacks

Management Requirements

Diverted waste must be:

- 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

Household Takebacks

Management Requirements

Diverted waste must be:

- Managed to prevent release
- Stored < 1 year
- Documented (types, volumes, and disposition)
- If non-household, handled to meet additional CESQG and liquid industrial by-product collection requirements

Existing Waste Regulation

Non-Household Pharmaceuticals

Estimate between 5% to 10% pharmaceuticals are HW:

- ✓ Listed
- ✓ Characteristic
 - Ignitable
 - Corrosive
 - Toxic
 - Reactive

See limited data provided by EPA at <http://hwpharms.wikispaces.com/>

HW Code	Chemical Name as it appears on P-List	Common Name	Brand Name & Manufacturer	Medical Use	Form	Dosage	CAS#	NDC Code	Reference	Contributor
P000	Maceupum	Fiction	Brand Name Manufacturer	Anticoagulant	Capsule	10mg	123-45-67	1234-5678-90	Reference 2	John Doe, USEPA
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	1mg	81-81-2	00056-0169-75 100/btl	Reference 1	
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	2mg	81-81-2	00056-0170-75 100/boc		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	2.5mg	81-81-2	00056-0176-75 100/btl		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	tablet	3mg	81-81-2	00056-0188-75 100/btl		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	4mg	81-81-2	00056-0168-75 100/btl		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	5mg	81-81-2	00056-0172-75 100 individually sealed		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	6mg	81-81-2	00056-0189-75 100/btl		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	7.5mg	81-81-2	00056-0173-75 100/btl		
P001	Warfarin	Warfarin	Coumadin Bristol-Myers Squibb Pharmaceutical	Anticoagulant	Tablet	10mg	81-81-2	00056-0174-75 100 individually sealed		
P012	arsenic trioxide	Tisanesox	Cephalon, Inc.	Chemotherapy	intravenous injection	10mg/10ml	1327-53-3	63403-006-10		
P030	Nitroglycerin	Hospira Inc.		Antihypertensive	Powder for Injection	50mg	14462-89-200409-3024-01			
P046	Phentermine hydrochloride	Profast SA American Pharmaceuticals		CNS Stimulant	Tablet	8mg	1191-21-3			
P075	Nicotine	Habitol Ciba Pharmaceuticals		Smoking Detent	Transdermal Film	7mg/24hr	54-11-6	58887-0810-26		
P075	Nicotine	Habitol Ciba Pharmaceuticals		Smoking Detent	Transdermal Film	14mg/24hr	54-11-6	58887-0820-26		
P075	Nicotine	Habitol Ciba Pharmaceuticals		Smoking Detent	Transdermal Film	21mg/24hr	54-11-6	58887-0830-26		
P084	Physostigmine Salicylate	Antilium Forest Pharmaceuticals Inc.		Detoxification Agent	Solution	1mg/ml	57-64-7	00456-1037-12		

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
- Carboic 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



A purple rectangular label with the words "universal waste" in white, bold, lowercase letters. Below the text are four white lines for information, each with a label to its left: "contents", "accumulation start date", "shipper", and "address". The bottom line is labeled "city, state, zip".



Existing Regulation

Universal Waste Pharmaceuticals

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

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” 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 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:

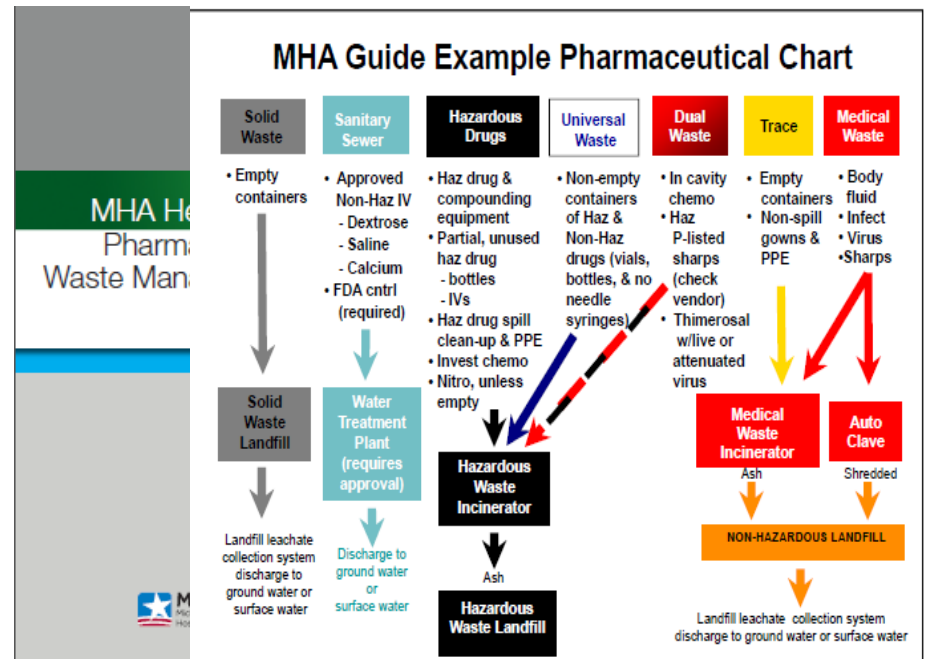
MHA Pharmaceutical
Waste Management Guide

MHA Guide Example Posting

Pharmaceutical Tutorial

Universal Waste Guidance

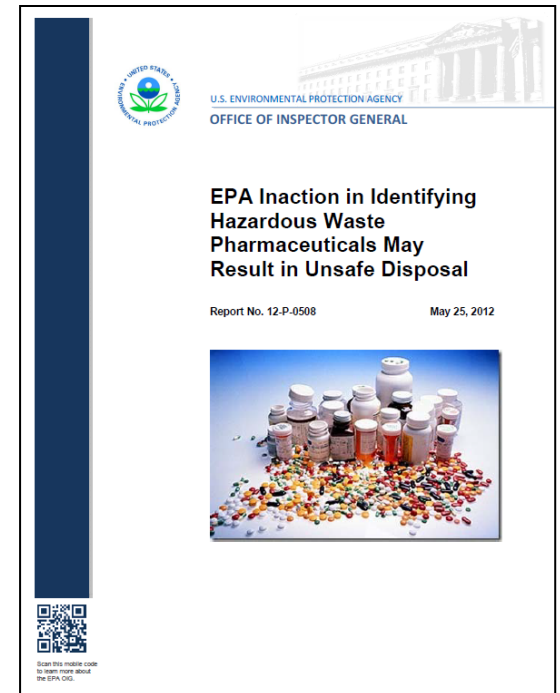
www.michigan.gov/deqdrugdisposal



What is Federal HW Pharmaceutical Proposal?

Initial Federal Proposed Rules

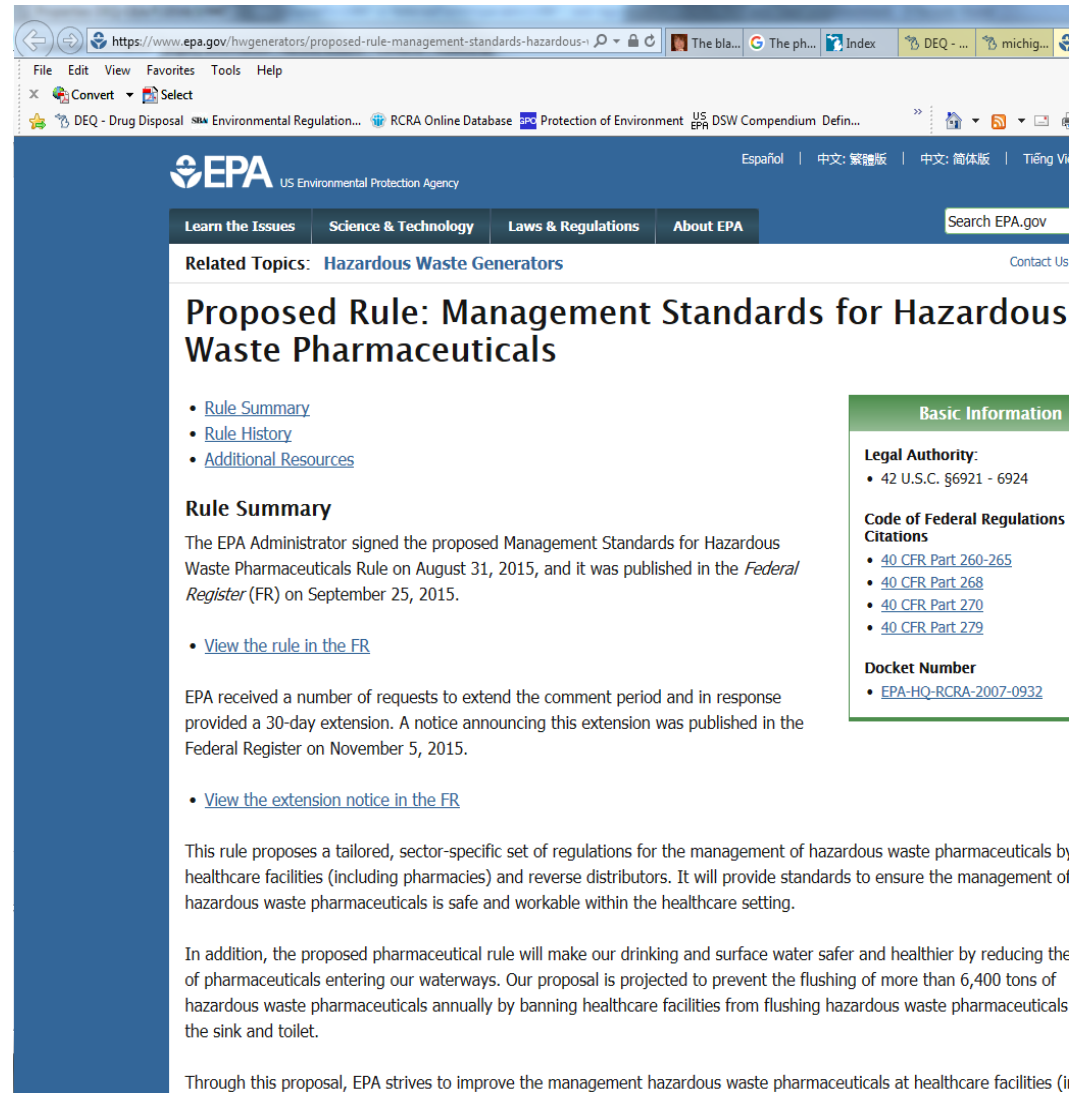
- 2008 - EPA proposes to establish pharmaceuticals as a federal universal waste type
- 2013 - EPA identifies intent to develop a completely different proposal for HW pharmaceuticals “due to substantial negative public comments”



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, 2016 - EPA
closed public comment



The screenshot shows the EPA website page for the proposed rule: "Proposed Rule: Management Standards for Hazardous Waste Pharmaceuticals". The page includes a navigation menu with "Learn the Issues", "Science & Technology", "Laws & Regulations", and "About EPA". A search bar is located in the top right corner. The main content area features a "Related Topics" section with "Hazardous Waste Generators". The title of the rule is prominently displayed. Below the title, there are links for "Rule Summary", "Rule History", and "Additional Resources". A "Rule Summary" section follows, detailing the EPA Administrator's signing of the rule on August 31, 2015, and its publication in the Federal Register on September 25, 2015. A "View the rule in the FR" link is provided. A "Basic Information" sidebar on the right lists the "Legal Authority" (42 U.S.C. §6921 - 6924), "Code of Federal Regulations Citations" (40 CFR Part 260-265, 40 CFR Part 268, 40 CFR Part 270, 40 CFR Part 279), and "Docket Number" (EPA-HQ-RCRA-2007-0932). The text below the summary explains that the rule proposes a tailored set of regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors, aiming to ensure safe and workable management within the healthcare setting. It also mentions that the rule will make drinking and surface water safer by reducing pharmaceuticals entering waterways, preventing the flushing of more than 6,400 tons of hazardous waste pharmaceuticals annually by banning healthcare facilities from flushing them down the sink and toilet. Finally, it states that through this proposal, EPA strives to improve the management of hazardous waste pharmaceuticals at healthcare facilities.

Status of Federal Proposed Rules

EPA received over 175 diverse comments from:

Reverse Distributors

States/Government

Retail

Pharmacists

Hospitals

Associations



EPA projects issuance of final rules in Fall 2016

Status of Federal Proposal

When final rulemaking is issued it becomes effective:

- Immediately in all states and territories for sewer ban
- Upon state adoption for all other provisions



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 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

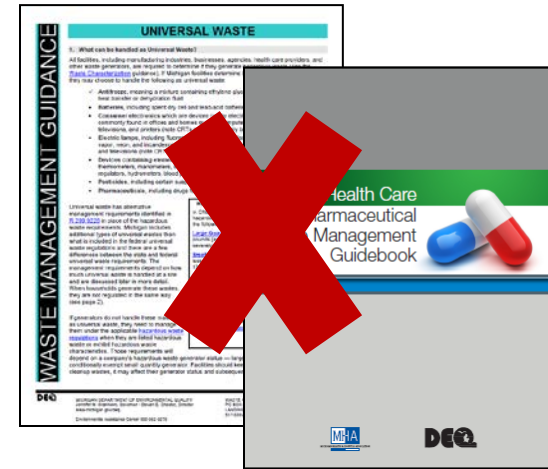
- ✓ 40 CFR Part 266, Subpart P for HW Pharmaceuticals
- ✓ Mandatory for SQGs/LQGS
- ✓ Optional for CESQGs

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 Defined

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**



Pharmaceutical Defined

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



Empty

Current federal rules

- Container residues are acute 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

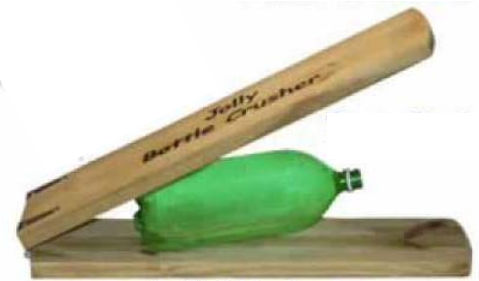


Clarify Empty

Proposed federal rules:

Unit-dose containers/devices (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**



Clarify Empty

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

Clarify Empty

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

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



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 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

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

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

Maximum Transfers Allowed



HCF/Pharmacy

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



1st RD
can be a
manufacturer



2nd RD
can be a
manufacturer



3rd RD
must be a
manufacturer



HW
TSD

Reverse Distributor Accumulation

Potentially Creditable HW Pharmaceutical

Each Reverse Distributor must have:

- Inventory of HW pharmaceuticals
- Facility security

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

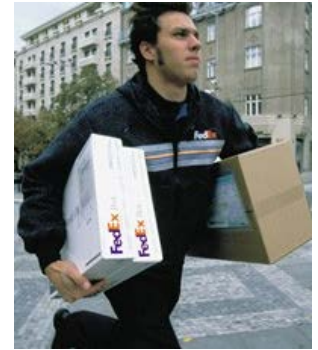
Evaluated HW Pharmaceuticals

- 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



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 sewerage of HW Pharmaceuticals from all of healthcare and reverse distribution

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

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!



Thank you for your continued commitment to protecting our shared resources!