STAY ENGAGED. STAY INFORMED.

TUESDAY, FEBRUARY 12:
IMPACT OF NEW EPA RULES ON YOUR PRACTICE
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Iowa Pharmacy Association
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Management Standards for Hazardous Waste Pharmaceuticals
EPA Subpart P

Iowa Pharmacy Association

February 12th, 2019
Jeff Hollar - PharmWaste Technologies, Inc.
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Snapshot In Time
Presentation views expressed represent information from EPA's pre-publication version as of the date of the presentation. Any subsequent changes or written clarifications made public by the EPA are not taken into account.

State specific - IA
Presentation views expressed represent information as they pertain to federal EPA, which Iowa follows. Some states may choose to impose stricter regulations.
Presentation Goals

By the end of this presentation, the viewer should be able to:

- identify a public health benefit of the EPA Subpart P
- determine if your facility impacted by EPA Subpart P
- identify which popular drug is no longer considered acutely hazardous by the EPA
EPA Subpart P Overview

- EPA’s core mission: Protect human health and the environment (air, water, land)
- Current RCRA regulations do not adequately take into effect the management complexities of hazardous waste pharmaceuticals (HWP’s) generated in healthcare facilities (HCF’s)
- EPA has create: 40 CFR part 266 Subpart P to address those complexities
- Important - New regulations pertain to HWP’s (5% of average formulary)
EPA Subpart P Overview

- Well documented - Pharmaceuticals in our water supply have negative impacts on aquatic ecosystems

- Significant Change 1: EPA bans HCF’s from drain disposing HWP’s
  - Major public health benefit:
    - will make drinking and surface water safer by reducing the amount of hazardous waste entering the waterways *
    - estimated up to 2,300 tons/year will now bypass our waterways *

EPA Subpart P Overview

**Significant change 2** - All prescription pharmaceuticals moving through a Reverse Distributor (RD) are solid wastes at the healthcare facility (HCF). Therefore, the HCF is actually the generator of these wastes. Previously, waste determination, other than obvious waste, was typically made by the RD. Subpart P addresses the management of the solid waste pharmaceuticals that are hazardous.

**Significant change 3** - All non-prescription pharmaceuticals may or may not be solid waste. They are not solid waste if they are returned through a Reverse Logistics Center for use/reuse or reclamation.
EPA Subpart P Overview - continued

- Regulations go into effect 6 months after they are published in the Federal Register
- Mandatory for LQG’s and SQG’s, but optional for VSQG’s
- New definitions have been created pertaining to these new regulations
- Overall impact is stricter both for HCF’s and RD’s
- Regulatory relief in some instances
- There are many facets to the new regulations
- This presentation covers some of the basics from the HCF’s point of view
Hazardous Waste Pharmaceutical

- **P-Listed**
  - Acutely hazardous
  - Sole active ingredient
  - EPA waste code starting with P

- **U-Listed**
  - Non-acutely hazardous
  - Sole active ingredient
  - EPA waste code starts with U

- **Characteristic Waste**
  - Ignitable, Corrosive, Toxic, Reactive
  - EPA waste code starts with D
Ignitability - 40 CFR 261.21

- Aqueous solution containing at least 24% alcohol by volume and a flash point of <140°F (<60°C)
- Includes flammable aerosols
- EPA waste code is D001

Corrosivity - 40 CFR 261.22

- Aqueous solution whose pH is ≤ 2 or ≥ 12.5
- Acid if ≤ 2, Base if ≥ 12.5
- EPA waste code is D002
Reactivity - 40 CFR 261.23

- Wastes that are not stable under normal conditions
- Nitroglycerin was exempted August 14th, 2001 under Federal Register: May 16th 2001
- EPA waste code is D003

Toxicity - 40 CFR 261.24

- 40 chemicals and heavy metals that meet certain leaching concentrations as determined by a TCLP (Toxicity Characteristic Leaching Procedure)
- Regulatory concentrations are measured in mg/L
  - m-cresol 200mg/L - some insulins contain m-cresol - D024
New Subpart P - Added to 40 CFR

- 266.500 - Definitions
- 266.501 - Impacted HCF’s
- 266.502 - Standards - Non-creditable HWP
- 266.503 - Standards - Potentially creditable HWP
- 266.504 - VSQG’s
- 266.505 - Sewer ban of HWP
- 266.506 - DEA/HWP exemption
- 266.507 - Empty container exemption of HWP
- 266.508 - Shipping - Non-creditable HWP
- 266.509 - Shipping - Potentially creditable HWP
- 266.510 - Standards - RD’s
Definitions - Pay close attention

- Potentially creditable vs. Non-creditable
- Hazardous waste vs. Non-hazardous waste
- Pharmaceutical vs. Non-pharmaceutical
- Prescription vs. Non-prescription
- Solid waste vs. Not solid waste
- VSQG vs. SQG vs. LQG
- Generation vs. Accumulation
- Reverse Distributor vs. Reverse Logistics Center
Key Definitions Simplified - 40 CFR 266.500

- Pharmaceuticals
  - Any drug for use by humans or animals
  - Rx, OTC, dietary supplements, homeopathic drugs, compounded drugs, investigational drugs, residues in non-empty containers, PPE contaminated with HWP, cleanup material from HWP spills

- Hazardous Waste Pharmaceuticals (HWP)
  - Solid waste pharmaceuticals that are considered RCRA hazardous by the EPA. Excluded are non-prescription pharmaceuticals that have a reasonable expectation of being used/reused or reclaimed (rare).

- Reverse Distributor/Reverse Logistics Center
  - RD - Reverse flow of prescription and non-prescription for potential credit
  - RLC - Reverse flow of non-prescription and other unsold retail items
Key Definition Simplified - 40 CFR 266.500

- Potentially Creditable Hazardous Waste Pharmaceutical
  - HWP that has a reasonable expectation for manufacturer credit
  - OK to send Potentially Creditable HWP back to RD if:
    - Undispensed (and)
    - Prescription (and)
    - In original manufacturer container (and)
    - Less than 1 year past expiration date
Key Definition Simplified - 40 CFR 266.500

Non-Creditable Hazardous Waste Pharmaceutical

- HWP that has NO reasonable expectation for manufacturer credit
- DO NOT send back to a reverse distributor
- A HWP that fails at least one of the Potentially Creditable HWP criteria
  - Undispensed, Rx, original packaging, < 1 year expired
- Also includes non-prescription HWP’s that do not have a reasonable expectation of legitimately being used/reused or reclaimed
- Examples of non-creditable pharmaceuticals:
  - Samples, investigational drugs, compounding chemicals, compounded drugs
**Key Definition Simplified - 40 CFR 266.500**

- **Healthcare facility (HCF)**
  - Any person that is lawfully authorized to provide patient care to humans or animals. Or, a facility that sells or dispenses OTC or prescription drugs.
# Impacted Healthcare Facilities

- 40 CFR 266.501

<table>
<thead>
<tr>
<th>NAICS</th>
<th>Facility Type</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>4242</td>
<td>Drug Wholesalers</td>
<td>12,962</td>
</tr>
<tr>
<td>44511</td>
<td>Supermarkets &amp; Other Grocery (not convenience) Stores</td>
<td>94,915</td>
</tr>
<tr>
<td>44611</td>
<td>Pharmacies and Drug Stores</td>
<td>53,256</td>
</tr>
<tr>
<td>452311</td>
<td>Warehouse Clubs and Supercenters</td>
<td>1,790</td>
</tr>
<tr>
<td>54194</td>
<td>Veterinary Services</td>
<td>43,681</td>
</tr>
<tr>
<td>6211</td>
<td>Physicians’ Offices</td>
<td>445,363</td>
</tr>
<tr>
<td>6212</td>
<td>Dentists’ Offices</td>
<td>193,685</td>
</tr>
<tr>
<td>6213</td>
<td>Other Health Practitioners (e.g., chiropractors)</td>
<td>264,274</td>
</tr>
<tr>
<td>6214</td>
<td>Outpatient Care Centers</td>
<td>64,236</td>
</tr>
<tr>
<td>6219</td>
<td>Other Ambulatory Health Care Services</td>
<td>140,505</td>
</tr>
<tr>
<td>6221</td>
<td>General Medical and Surgical Hospitals</td>
<td>24,973</td>
</tr>
<tr>
<td>6222</td>
<td>Psychiatric and Substance Abuse Hospitals</td>
<td>4,078</td>
</tr>
<tr>
<td>6223</td>
<td>Specialty Hospitals</td>
<td>2,728</td>
</tr>
<tr>
<td>6231</td>
<td>Nursing Care Facilities</td>
<td>32,548</td>
</tr>
<tr>
<td>Various</td>
<td>Reverse Distributors</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>1,379,044</strong></td>
</tr>
</tbody>
</table>

* #'s taken from www.naics.com at time of presentation - Some agencies allow for more than one NAICS code per establishment.

* In Federal Register /Vol. 80, No. 186 / Friday, September 25, 2015 / Proposed Rules - EPA estimated 174,000 facilities affected
Facility Examples

- **Includes**
  - Retail pharmacies, acute care pharmacies, hospitals, pharmaceutical wholesaler distributors, drug compounding facilities, LTC pharmacies, LTC hospice facilities, LTC nursing facilities, LTC skilled nursing facilities, 3rd party logistics providers that serve as forward distributors, psychiatric hospitals, ambulatory surgical centers, health clinics, optical providers, dental providers, chiropractors, mail order pharmacies, veterinary clinics, veterinary hospitals, veterinary pharmacies and locations that sell pharmaceuticals over the internet, mail or other distribution systems.

- **DOES NOT Include**
  - Pharmaceutical manufacturers (most), coroners or medical examiners unless in a healthcare facility
  - LTCF’s:
    - Assisted living facilities, group homes, independent living communities
Non-creditable HWP Standards - 40 CFR 266.502

- A prescription HWP that does not have a reasonable expectation to receive credit or - A non-prescription HWP that does not have a reasonable expectation to be legitimately used/reused or reclaimed.

- One time facility notification - 8700-12 - EPA Region VII

- Generator to identify HW Drugs (§ 266.502(c))

- Container & Storage requirements (structurally sound, compatible contents, secure)
  - Unsuitable for incineration (P012 - Arsenic Trioxide)

- Labeling requirements (Hazardous Waste Pharmaceuticals)

- Accumulation time limit (1 year - no extensions)
Non-creditable HWP Standards - continued

- Training requirements (performance based - waste handling and emergency procedures)
- Land disposal restrictions (LDR) apply
- Recordkeeping requirements (3 years with exceptions, readily available)
- Shipping requirements (UHWM - Uniform HW Manifest required)
- Reporting requirements (UHWM within 60 days, rejected shipments)
- Spill response requirements (immediate containment and management)
Potentially Creditable HWP Standards - 266.503

- A prescription HWP that does have a reasonable expectation to receive credit
  - Undispensed, Rx, original packaging, < 1 year expired
- OK to send back to Reverse Distributor
- One time facility notification - 8700-12 - EPA Region VII
- Generator to identify HWP’s (§ 266.503(a))
- No requirements for: container, storage, accumulation time, labeling
- Spill response requirements (immediate containment and management)
- Shipping to Reverse Distributor (no HW manifest, common carrier, receipt confirmed by RD)
- Recordkeeping requirements (3 years with exceptions)
Potentially Creditable HWP Standards - 266.503

- Option to manage all as hazardous waste pharmaceuticals
  - Do not need to figure out which pharmaceuticals are HW
  - You are making the assumption that every drug being returned is a HWP
  - Further limits what can go back to the RD
  - Must meet Potentially Creditable HWP Criteria for entire shipment
    - Undispensed, Rx, original packaging, < 1 year expired
  - Cannot send any non-creditable HWP to RD
    - OTC, samples, blister cards, etc.
VSQG’s - 40 CFR 266.504

- VSQG - Very Small Quantity Generator
- Lowest generator category offers relief from stricter regulations (SQG, LQG)
- Subpart P is optional for VSQG’s
- Most healthcare facilities are VSQG’s
- LTCF’s with 20 or less beds are VSQG’s
- IMPORTANT - HCF’s not participating in Subpart P need to prove their VSQG status if audited
  - Determine amount of HW generated on monthly basis
  - Don’t forget to include any HWP sent to RD
  - Still need to follow 40 CFR 262.14 (VSQG’s)
Determine your generator status

- Three different levels of regulations based on the amount of hazardous waste generated in a month
  - VSQG - Very Small Quantity Generators
  - SQG - Small Quantity Generators
  - LQG - Large Quantity Generators
- To determine generator status, calculate all the HW generated at your facility, including outside of the pharmacy on a monthly basis
- Under Subpart P, a HCF no longer has to include HWP’s when calculating their generator status.
- Generation versus accumulation - difference
# Generator Status Chart

<table>
<thead>
<tr>
<th>Generator Status</th>
<th>Acute HW Generated Monthly</th>
<th>Non-Acute HW Generated Monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSQG</td>
<td>≤ 1 kg (and)</td>
<td>≤ 100 kg</td>
</tr>
<tr>
<td>SQG</td>
<td>&lt; 1 kg (and)</td>
<td>&gt; 100 kg and &lt; 1000 kg</td>
</tr>
<tr>
<td>LQG</td>
<td>&gt; 1 kg (or)</td>
<td>≥ 1000 kg</td>
</tr>
</tbody>
</table>

- 1 kg = 2.2 lbs, 100 kg = 220 lbs, 1,000 kg = 2,200 lbs
- Acute HW = P-Listed Waste,
- Non-Acute HW = U-Listed or Characteristic D Codes
VSQG Option - Subpart P or not?

- Facilities may find more advantages by NOT operating under Subpart P

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Subpart P</th>
<th>Not Subpart P</th>
<th>RED Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA notification</td>
<td>YES</td>
<td>NO</td>
<td>EPA audit increase</td>
</tr>
<tr>
<td>Accumulation time limits</td>
<td>YES</td>
<td>NO</td>
<td>1 year - No extension</td>
</tr>
<tr>
<td>Training (NC)</td>
<td>YES</td>
<td>NO</td>
<td>Audit issue</td>
</tr>
<tr>
<td>Containers (NC)</td>
<td>YES</td>
<td>NO</td>
<td>Audit issue</td>
</tr>
<tr>
<td>Labeling (NC)</td>
<td>YES</td>
<td>NO</td>
<td>Audit issue</td>
</tr>
<tr>
<td>Unsuitable for incineration</td>
<td>YES</td>
<td>NO</td>
<td>Audit issue</td>
</tr>
<tr>
<td>No SAA or CAA</td>
<td>YES</td>
<td>YES</td>
<td>No difference</td>
</tr>
<tr>
<td>Nicotine relief</td>
<td>YES</td>
<td>YES</td>
<td>No difference</td>
</tr>
<tr>
<td>Empty containers</td>
<td>YES</td>
<td>YES</td>
<td>No difference</td>
</tr>
<tr>
<td>Potentially creditable to RD</td>
<td>YES</td>
<td>YES</td>
<td>No difference</td>
</tr>
<tr>
<td>Sewer ban</td>
<td>YES</td>
<td>YES</td>
<td>No difference</td>
</tr>
<tr>
<td>DEA/HWP exemption</td>
<td>YES</td>
<td>NO</td>
<td>No difference likely</td>
</tr>
<tr>
<td>Document generator status</td>
<td>NO</td>
<td>YES</td>
<td>Takes time</td>
</tr>
</tbody>
</table>

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Sewer Ban - Subpart P - 40 CFR 266.505

- All HCF’s are prohibited from sewering hazardous waste pharmaceuticals
- A formulary review will indicate which drugs this pertains to
- DEA/HWP Exemption does not apply.
DEA/HWP Exemption - 40 CFR 266.506

- Some pharmaceuticals are both DEA controlled and EPA hazardous
  - Chloral hydrate, Paregoric, Testosterone gels, Diazepam solutions, plus more…

- DEA controlled substances are not HW if:
  - DEA regulations are followed when disposing;
  - DEA controls are disposed of through incineration at a permitted combustor (5 types allowed) or other DEA publicly approved method

- IMPORTANT - HWP sewer ban trumps this DEA/HWP exemption.
  - If a pharmaceutical is both DEA controlled and hazardous waste, the waste left over after administration (Pharmaceutical Wastage*) is prohibited from being drain disposed.
  - HCF’s can no longer drain dispose any medications left over after administration if they are HWP’s.

* DEA - letter to practitioners 10/17/2014
Conditional exemption for containers (including residue) that once contained HWP’s may now be considered RCRA empty.

Containers include: stock and dispensing bottles, vials or ampules and unit dose containers.

- Unit dose container examples: unit dose packet, cup, wrapper, blister pack, or delivery device.

Empty if all contents of the container are removed by practices commonly employed (normal means).

This applies to drug containers up to 10,000 tabs or 1 liter if a liquid.

Regulatory relief on containers and residue does not apply to: aerosols, tubes, gels, creams, ointments and nebulizers.
Empty Syringes - 40 CFR 266.507(b)

- A syringe (including residue) that contained a HWP is considered RCRA empty when the contents have been removed by "fully depressing the plunger" of the syringe.

- HWP’s in used syringes without fully depressed plungers need to be treated as non-creditable HWP’s. In addition, sharps and medical waste regulations may apply.
Empty IV Bags - 40 CFR 266.507(c)

- Intravenous bags (including residue) that contained a HWP are considered RCRA empty when the contents have been fully administered to the patient.

- HWP’s in used IV bags that have not been fully administered are to be treated as non-creditable hazardous waste pharmaceuticals, unless they are non-acute and RCRA empty under § 261.7(b)(1).
Reverse Distributor Standards - 40 CFR 266.510

- Overall stricter regulations pertaining to RD’s
- RD’s are limited on that they can take back
  - Can accept potentially creditable HWP
  - Cannot accept non-creditable HWP
  - No restrictions on non-hazardous waste pharmaceuticals
- Service and procedures will vary depending upon the RD
- Contact your RD to see what changes have been implemented and how this will affect your return
MAIN POINT - Reverse Distributors

- RD’s can accept Potentially Creditable HWP’s (and non-hazardous pharmaceuticals)

- RD’s cannot accept Non-creditable HWP’s (or other HW for disposal).
Reverse Distributor - Unauthorized Wastes

- Waste received by the RD that it is not authorized to receive or manage

Examples

- Non-creditable HWP’s
- Non-pharmaceutical HW
- Medical or infectious waste
- Patient care waste (IV bags, tubing)
- Contaminated PPE
- Contaminated sharps
Reverse Distributor – Unauthorized Wastes

- RD reporting requirements
  - RD to send report to healthcare facility
  - RD to send report to regional EPA Administrator

- What happens to senders of unauthorized waste?
  - EPA can investigate likely based on:
    - Type
    - Frequency
    - Quantity
FDA approved Over-The-Counter (OTC) Nicotine Replacement Therapies (NTR’s) are exempted from the P075 listing

- The exemption only applies to patches, gums and lozenges
- The exemption does not apply to nicotine containing e-cigarettes (e.g., electronic cigarettes and vaping pens), e-liquids (packaged for retail sale) or prescription NRT’s even though the EPA considers them to be pharmaceuticals

Previously, NTR’s were considered an acute hazardous waste by the EPA

This is good!
DEA Onsite Collection Receptacles

- These are the DEA authorized collection containers that consumers can place their household drug waste into.
- HWP’s that are also DEA controls are not considered hazardous waste.
- Per DEA regulation, only household (Ultimate User) pharmaceuticals can be placed in container.
- A healthcare facility that is a DEA registrant, CANNOT put their HWP’s in the receptacle as this would be a violation of DEA regulations.
- Does not apply to contaminated PPE or clean up residues.
- DOT regulations apply when in transport.
EPA overhauled the hazardous waste generator regulations under RCRA (Resource Conservation and Recovery Act of 1976).


Emphasis on the importance of accurate HW determinations - 40 CFR 262.11

GOOD NEWS! - Allows for episodic generation - Part 262 subpart L (§§ 262.230-262.233)

VSQG can go over VSQG generated limits in certain limited circumstances without it affecting their generator status.

EPA Generator Improvement Rule Workshop - March 2017

PPT presentation available for viewing - www.pwaste.com - Resources - Publications
DOT Implications - 49 CFR

- Potentially Creditable HWP’s
  - You are shipping hazardous materials!
  - Different DOT shipping classes (2.1, 2.2, 3, 5.1, 6.1, 8, 9)
  - 49 CFR parts 171 through 180
  - RD should advise on proper procedure as this may vary between RD’s

- Non-Creditable Hazardous Waste
  - 49 CFR Parts 172(E), 172(D), 173, 178, 180
  - Packaging, labeling, marking, manifesting
  - Disposal transporter should be well versed in this area and can advise
Formulary Review - Importance

- A formulary review is a waste characterization of which pharmaceuticals are considered hazardous by EPA and therefore fall under Subpart P (5%)

- A formulary review:
  - is needed to determine your facility’s generator status (if applicable)
  - will indicate which drugs are EPA hazardous and therefore cannot be sewered
  - will indicate which drugs are DOT hazardous materials when shipping

- A hazardous waste vendor will need the EPA waste codes generated at your facility in order to set up disposal profiles for non-creditable HWP’s

- An ongoing formulary review is needed
  - to account for new drugs received by the HCF;
  - and demonstrate to regulators waste characterizations are current

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Quiz Time - Question 1

EPA’s Subpart P will have the following effect on our waterways?

a) Increase the amount of HWP’s entering our waterways
b) Decrease the amount of HWP’s entering our waterways
c) Have no effect on the amount of HWP’s entering our waterways
Quiz Time - Question 2

Which facilities are potentially impacted by EPA’s Subpart P?

a) Pharmacies
b) Dentist offices
c) Hospitals
d) All of the above

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Quiz Time - Question 3

EPA’s Subpart P is optional for?

a) VSQG’s (Very Small Quantity Generators)
b) SQG’s (Small Quantity Generators)
c) LQG’s (Large Quantity Generators)
d) All of the above
Nicotine Replacement Therapies in the form of gum, patches and lozenges are no longer considered hazardous waste by the EPA.

a) True
b) False
Quiz Time - Question 5

Subpart P allows for all expired pharmaceuticals to be sent back to a RD for credit and or disposal.

a) True
b) False
Questions?

Additional information on EPA’s Subpart P

www.PWaste.com/EPA-Subpart-P

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QUESTIONS?
JOIN US TUESDAY, MARCH 12:

STATEWIDE PROTOCOLS: NEXT STEPS

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713