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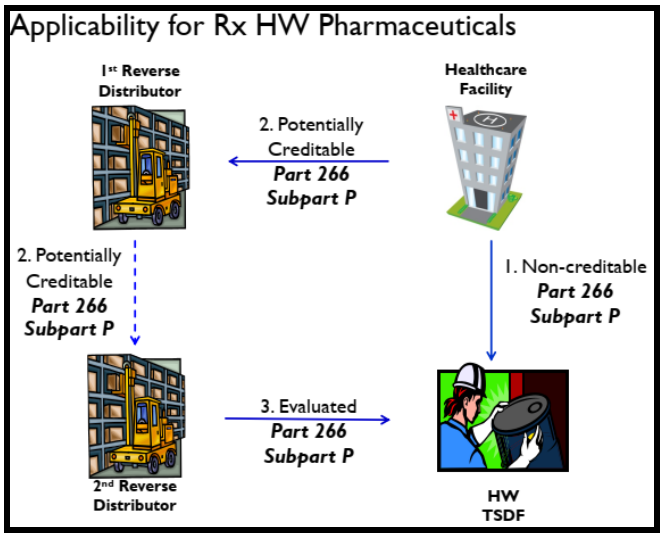
Hospital Waste

More on EPA's Final Hazardous Pharmaceutical Waste Rule: 40 CFR §266, Subpart P

The U. S. Environmental Protection Agency (EPA) presented a series of webinars in February and March 2019 to introduce its final Hazardous Pharmaceutical Waste Rule, 40 CFR §266, Subpart P.

The goals of the rule are to:

- Create regulations that are a better fit for the healthcare sector,
- Eliminate the intentional sewering of hazardous waste pharmaceuticals
- Reduce overlapping regulations (DEA, FDA),
- Provide regulatory clarity and national consistency on how RCRA applies to reverse distribution and reverse logistics, and
- Provide regulatory relief to healthcare facilities that are strictly regulated as large quantity generators even when generating small amounts of nicotine replacement therapies [Note: nicotine designates as a RCRA acutely hazardous waste, P075].



The change to the federal nicotine rule is considered **less** stringent and need not be adopted by Washington. The federal rule change allows Over-The-Counter Nicotine Replacement Therapy waste (OTC NRT waste) an exemption from the P075 listing for hazardous waste. This includes patches, gums, and lozenges that will no longer meet the regulatory criteria for acutely hazardous waste. Nicotine solutions—such as in e-cigarettes—will still carry the AHW listing of P075.

The 40 CFR § 266, Subpart P rule is considered **more** stringent and, therefore, must be adopted by Washington. For example, by August 2019 the ban on sewering hazardous pharmaceutical waste will be effective across the U.S.

Much of the text of the Subpart P rule applies to reverse distributors of unwanted pharmaceuticals. One important distinction that was made is between prescription and nonprescription pharmaceuticals:

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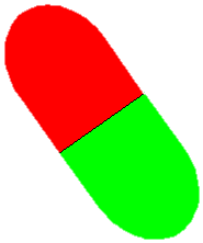

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- **Reverse Distribution**—of prescription (Rx) pharmaceuticals, and
- **Reverse Logistics**—of nonprescription pharmaceuticals (e.g., OTC, supplements, etc) and all other unsold retail items.

Subpart P also distinguishes among several types of hazardous waste pharmaceuticals:

- Non-creditable hazardous waste pharmaceutical,
- Potentially creditable hazardous waste pharmaceutical, and
- Evaluated hazardous waste pharmaceutical.

Non-creditable waste is broken, leaking, repackaged, dispensed, expired (> 1 yr), contaminated, investigational, floor sweepings or clean-up materials. Potentially creditable wastes are unwanted pharmaceuticals that may be sent to a reverse distributor for evaluation. Evaluated waste is material that has been deemed waste by the reverse distributor and has no economic value.

One important note is that *there are no generator categories under Part 266 Subpart P.*

All personnel managing non-creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

Healthcare facilities are re-

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How EPA and DEA Have Chosen to Regulate Controlled Substance Waste

With the pre-publication of EPA's final *Management Standards for Hazardous Pharmaceutical Waste* rule (40 CFR §266, Subpart P), we now have guidance from the U. S. Environmental Protection Agency (EPA) and the U. S. Drug Enforcement Agency (DEA) as to how these agencies will oversee management of controlled substance waste.

The Washington Department of Ecology, which has final jurisdiction over this waste in our state, is expected to issue its own final rule later in 2019.

While some controlled substances also designate as RCRA hazardous waste (when unwanted, outdated or left over) and were thus subject to management by conflicting rules of both the EPA and DEA, most controlled substances do not designate as hazardous pharmaceutical waste.

Non-hazardous controlled substance waste will continue to be regulated solely by DEA rules. The EPA has chosen to delegate the management of all hazardous (RCRA) controlled substance waste to the DEA. Across the U. S., hazardous controlled substance waste is now exempt from 40 CFR §266, Subpart P regulations.

It is extremely likely that the same will be true in Washington after Ecology issues its final pharmaceutical waste management rule.

Which controlled substances will be exempt from EPA's *Hazardous Pharmaceutical Waste* rule? They are:

- Chloral hydrate
- Paraldehyde
- Phenobarbital
- Phentermine
- Codeine
- Diazepam
- Terpin hydrate/codeine
- Fentanyl sublingual spray
- Testosterone gel
- Valium injectable

Any controlled substance waste, whether hazardous or non-hazardous, will be exempt from EPA regulations and subject only to DEA regulations except for the EPA stipulation that controlled substance waste may not be disposed of via a sewer.

This clarification of conflicting federal agency rules should make compliance much easier for both waste generators and those who treat and manage pharmaceutical waste. It is expected that Washington Ecology will adopt the same rules for controlled substance waste. Ecology's final rule is expected to be published in mid– to late–2019.

Ecology and Peace-Health St. Joseph's Hospital Settle $16,000 Penalty for Dangerous Waste Management Violations

In May 2018 Washington's Dept. of Ecology and Peacehealth St. Joseph's Hospital (Bellingham) settled several violations to the Dangerous Waste Regulations for a fine of $16,000. The violations were identified during a 2017 inspection.

The violations cited by Ecology included:

- Inappropriate disposal of dangerous waste by shipping it to a facility not licensed to handle that type of waste;
- Staff were not properly trained to handle dangerous waste;
- The hospital failed to submit a dangerous waste report to Ecology; and
- Staff failed to conduct or document weekly accumulation area inspections.

These violations could potentially happen at any Washington healthcare facility. Most facilities are properly managing their pharmaceutical waste according to Ecology's *Interim Pharmaceutical Waste Policy*, but staff need to regularly monitor how their vendors are disposing of this waste stream.

P. W. Grosser Consulting performs mock dangerous waste surveys and can assist you in preparing your facility for its next Ecology inspection.

High-Level, Cold Disinfectants: What You Need to Know About Them

Cold, high-level sterilants have been evolving quickly over the past decade. These products are used extensively to disinfect scopes between use in patients. There are new active ingredients in these products—weak acids and hydrogen peroxide—that you need to know about.

Once, glutaraldehyde was the active ingredient of choice. Unfortunately, it's odors made it difficult for care givers to use without excellent ventilation. It was also very toxic, although it was easily decomposed in wastewater treatment plants and can be discharged in many municipalities without pretreatment.

Then came OPA, or *ortho*-phthalaldehyde. Because it is more toxic than glutaraldehyde it can be used as a cold, high-level sterilant in lower concentrations. This means that it releases a lower amount of irritating fumes. However, it's toxicity to aquatic flora requires it to be neutralized before discharge to the sewer.

Lately, many of the cold, high-level sterilants used in healthcare to disinfect scopes contain a mixture of a weak acid and hydrogen peroxide. These weak acids give off very irritating fumes and the machines that use these products to disinfect scopes can hold up to 5 liters of solution. If this solution leaks out, the size of the spill can generate debilitating fumes for anyone in the area. The acidic fumes can cause irritation of the eyes, throat, mouth and nose.

Code Orange hazmat emergency response team members should be prepared to use a PAPR with air purifying cartridges to deal with acid fumes from spills of these materials.

Products which contain these weak acids and hydrogen peroxide include:

- Resert™ XL HLD (2-Furoic Acid)
- Rapicide PA® (Peroxyacetic Acid)
- Revital-Ox Resert™ (2-Furancarboxylic Acid)

These products, because they are effective due to their acidity and oxidative power and not their toxicity, often can be discharged without pretreatment [**Important**: In many western Washington wastewater treatment districts the waste from these products has a pH *below* wastewater pretreatment discharge standards and should be treated to raise the pH before discharge to the sewer].

The primary goal of emergency response is safety and a chemical-resistant PAPR is essential PPE.

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sponsible for determining if a waste pharmaceutical is hazardous, whether creditable or non-creditable.

Facilities may comingle non-hazardous and hazardous pharmaceutical waste. The only labeling requirement is "Hazardous Waste Pharmaceuticals." There is no requirement for waste codes or other information on the label. However, the facility must be able to show that non-creditable pharmaceutical waste has not been accumulated onsite for more than one year. There is no accumulation time limit for potentially creditable pharmaceutical waste.

Pharmaceutical containers (bottles, vials, syringes) are considered empty when their contents have been removed by normal means. There is no requirement to triple rinse containers that held acutely hazardous waste.

Potentially creditable waste can be shipped by common carrier without a manifest. Non-creditable and evaluated waste must be shipped with a uniform hazardous waste manifest to a treatment, storage, disposal & recycling (TSDR) facility using a licensed hazardous waste vendor. The manifest waste code for non-creditable and evaluated pharmaceutical waste should be PHARMS (in manifest box #13).

It is very important to note that these federal regulations may be made more stringent or applied to a wider range of waste streams by Ecology for Washington healthcare facilities. Ecology's final pharmaceutical waste rule should be published later in 2019.