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Are You Ready for the New EPA Rule on Hazardous Waste Pharmaceuticals?

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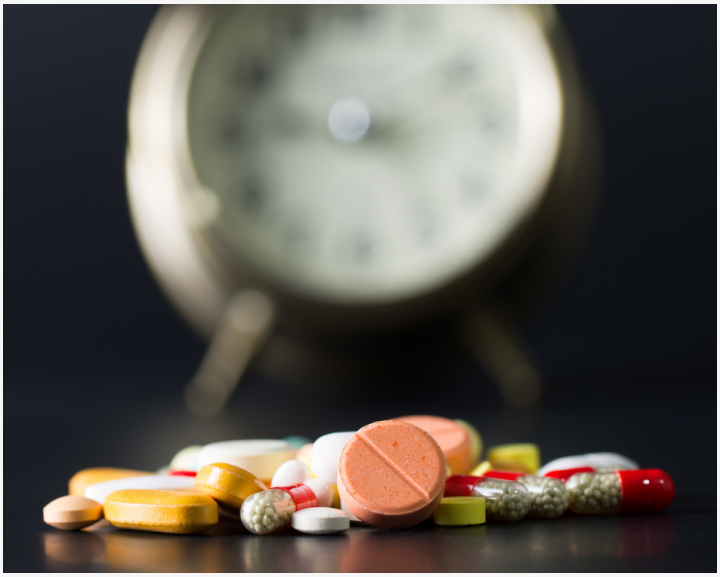
The United States Environmental Protection Agency (EPA) has created 40 CFR Part 266, Subpart P to define hazardous waste management requirements for approximately 600,000 hospitals, outpatient care centers, ambulatory healthcare services, physician, dentist and other health provider offices and veterinary services, and approximately 148,000 "reverse distributors" that send or receive unused or expired prescription pharmaceuticals to be evaluated for potential manufacturer credit. Reverse Distributors include many retailers, larger healthcare facilities, pharma manufacturers and third-party evaluators.

The new rule seeks to reduce the volume of pharmaceuticals disposed down the drain (aka "sewering"), address overlap between EPA and Drug Enforcement Agency (DEA) requirements and clarify the regulatory status of reverse distributors that were often avoiding, intentionally or not, EPA requirements that apply to handlers and transporters of hazardous waste.



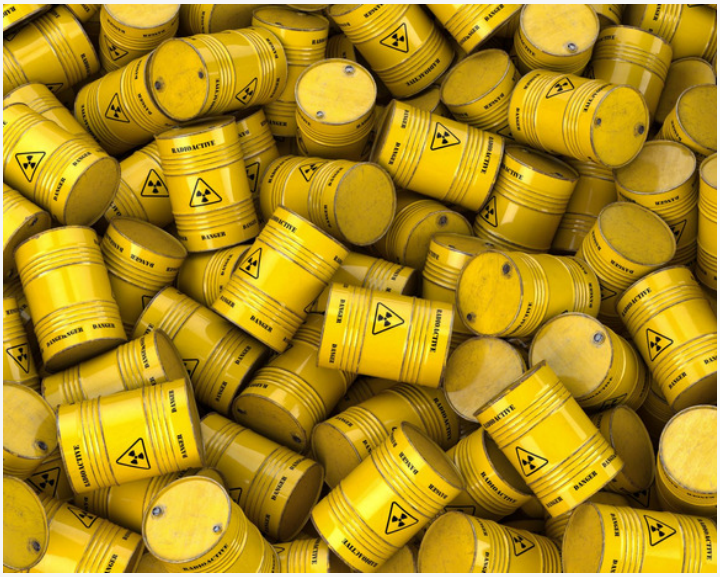
The object of all this attention is prescription pharmaceuticals that are hazardous wastes under the Resource Conservation and Recovery Act (RCRA) when disposed. Many are listed, such as Warfarin and salts at greater than 0.3% (P001) and Mitomycin (U010), while others, such as those containing mercury, may be characteristically hazardous (D009) when tested using the Toxicity Characteristic Leaching Procedure (TCLP).

Streamlined requirements for healthcare facilities include simpler manifesting (e.g., no waste codes required, use "PHARMS" for everything), training (e.g., any form that is "effective" and no requirement to document) and accumulation times of up to one year. Hazardous meds not being returned for potential credit must go to a permitted disposal facility, usually for incineration, except for those containing hazardous levels of metals, which are not to be combusted and must be containerized separately.

Reverse distributors, considered by EPA to be more sophisticated in their knowledge and capabilities to manage these wastes, face numerous additional requirements. For example, they must inventory and evaluate received materials within 30 calendar days of receipt, accumulate for no more than 180 days and develop and maintain procedures for security, personnel training (formal and documented), contingency planning, site closure and reporting.

Two issues not contemplated by the new Rule relate to transporters and Superfund liability under CERCLA. First, even a fully licensed medical waste transporter or processer is not able to legally transport or manage hazardous waste pharmaceuticals without additional registrations with their state, EPA and DOT as well as meeting numerous training, insurance, recordkeeping, security and other requirements, so that industry has a great deal of preparation to make. The second is "cradle-to-grave" liability for your waste.

In very simple terms, as a generator you are responsible forever for what happens to your waste -- period. If it ends up somewhere it should not be, you are subject to EPA enforcement (i.e., you owe us money) to resolve the site. It matters not whether you did everything right. Because of that, it is imperative that all generators understand that deciding where to send hazardous waste meds and containers involves much more than simply having it gone. You need to understand the rules of engagement, vet the transporter and the treatment and disposal company, obtain insurance coverage for hazardous waste activity etc., all routine in the mainstream hazardous waste universe but much less so in healthcare and retail pharma.



The same vetting recommendation goes for reverse distributors, as they will eventually dispose of your non-creditable (no reuse potential) materials. Where they choose to send it attaches liability to you, the original generator. Expect to receive an invoice for that service since the reverse distributors are no longer able to sewer or otherwise quietly put this material to rest.

The sewering prohibition went into effect on August 21, 2019. However, healthcare facilities and reverse distributors have 60 days after the implementation date in their respective states to register with the EPA as hazardous waste generators. That will be August 21, 2021 in states with an authorized hazardous waste program (most), although several (AK, FL, IA, KY, NJ and PA) reportedly implemented the Rule in its entirety on August 21, 2019. Facilities already registered as generators must update their notification to indicate that they will operate under the new Rule.

Choose your partners carefully in this process. There are many moving parts, new requirements and additional liabilities for everyone involved. If there is only one takeaway from this article, it should be: *Do not let a transporter, reverse distributor or disposal company touch your hazardous waste pharma until validated by someone you trust to do that.*

Review the Rule at the EPA website or contact a trusted advisor for additional information.

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