



EPA's New Hazardous Waste Pharmaceuticals Rule: Top Ten Take-Aways

EPA's Final Rule, *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, is quite a mouthful to say and the new regulations provide a great deal of information to digest. So here are PharmEcology's Top Ten Take-aways:

1. **What is 40 CFR 266 subpart P and why is it important?** It is one of the few times that EPA has carved out an industry-specific regulation. Due to the very different nature of healthcare, EPA has created a specific subpart to address healthcare facilities and reverse distributors, specifically.
2. **Who does the rule apply to?** Healthcare facilities that are large (LQG) or small (SQG) hazardous waste generators, including retail pharmacies and many other related practices in addition to hospitals. Very small quantity generators (VSQG, fka Conditionally Exempt Small Quantity) may participate but are not obligated to. If they do not participate, however, they must follow all current RCRA regulations. The rule also applies to reverse distributors who manage outdated Rx drugs.
3. **When does the sewer prohibition take effect?** The prohibition against sewerage hazardous waste pharmaceuticals will take effect six months after publication in the Federal Register throughout the country for all healthcare facilities.
4. **When does the rest of the rule apply?** The rule will be in force federally six months after it is published in the Federal Register which means only the states of Iowa and Alaska will be impacted at that time. All other states must adopt the rule which can take one to two years.
5. **Will hazardous waste pharmaceuticals still need to be counted towards generator status under subpart P?** No, this is one of the major benefits of the new rule. They only need to be counted the first time to determine if the facility must comply with subpart P.
6. **Are any new drugs being listed as hazardous waste?** No, EPA mentions it is interested in doing so, however, this will be a separate rulemaking in the future.
7. **Will nicotine and warfarin wrappers be exempt from disposal as a hazardous waste?** Yes, but for different reasons. Warfarin wrappers will be exempt due to changes in the status of residues. Nicotine wrappers will be exempt because nicotine in certain dosage forms will be excluded as a hazardous waste. (See next question.)
8. **Are all nicotine dosage forms exempted?** No, only FDA-approved OTC lozenges, gums, and patches.
9. **What about controlled substances?** Controlled substances that are also a hazardous waste will be exempted from the RCRA hazardous waste regulations under subpart P assuming all DEA requirements for disposal are met.
10. **What about outdated Rx drugs sent to a reverse distributor?** An Rx drug will be considered a waste when it outdates at the pharmacy. If it is potentially creditable, as defined in the regulation, it can be sent to a reverse distributor for evaluation, following certain additional requirements. OTCs are managed differently under the regulations.

For more information regarding the new rule, compliance assistance regarding EPA hazardous waste regulations, or assistance developing your USP <800> Hazardous Drug Assessment of Risk, contact us at 877-247-7430 or info@pharmecology.com



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