



Hazardous waste pharmaceuticals rulemaking

September 12, 2019

The U.S. Environmental Protection Agency's final rule governing management of hazardous waste pharmaceuticals became effective August 21, 2019. The new regulations apply to the management of hazardous waste pharmaceuticals by health care facilities and reverse distributors.

Notable changes include:

- **Sewer Ban:** The dumping of hazardous waste pharmaceuticals down the drain is now banned (effective immediately); this broadly applies to all hazardous waste pharmaceuticals, with no exceptions.
- **Nicotine Replacement Therapies Exemption:** FDA-approved over-the-counter nicotine replacement therapies (*i.e.*, nicotine patches, gums and lozenges) will no longer be considered hazardous waste when discarded.
- **Health Care Facilities and Reverse Distributors:** New management standards are imposed for hazardous waste pharmaceuticals moving through the reverse distribution process (*i.e.*, health care facilities sending unused or expired prescription pharmaceuticals to distributors).
- **Other:** Also addressed are employee training requirements, container storage and labeling requirements, and reporting and recordkeeping standards.

In states with delegated authority to administer hazardous waste programs, many of the new regulations must be adopted at the state level. Ohio has already begun this process. On May 6, 2019, Ohio EPA issued an early stakeholder outreach public notice, through which it sought input on Ohio EPA's intent to incorporate federal rulemaking into Ohio rules. This public notice allowed for early feedback from interested parties before proceeding with developing rule language.

Although Ohio EPA has yet to determine which provisions of the federal rule it will propose for adoption, Ohio entities will be required to adopt those provisions that are more stringent than Ohio's current rules.

These regulations are intended to establish cost savings and to streamline the handling of hazardous waste pharmaceuticals. Anyone currently regulated by Ohio's hazardous waste management rules will likely be affected by these new rules, and health care providers are encouraged to provide feedback to Ohio EPA during the next comment stage of rulemaking, expected later this year.

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