



A New Pill to Swallow: EPA's Hazardous Waste Pharmaceuticals Rule

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Certain pharmaceuticals are regulated under the Resource Conservation and Recovery Act (RCRA) as hazardous waste when they are discarded. EPA recently finalized new management standards for hazardous waste pharmaceuticals from health care facilities and reverse distributors handling those wastes.

The final rule applies to health care facilities and to reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. A health care facility is defined to include retail pharmacies, hospitals, primary care physicians, veterinary care operations, and any business providing health care or dispensing pharmaceuticals. Reverse distributors include facilities receiving or accumulating unused pharmaceuticals no longer needed, for which the manufacturer may provide a credit. Facilities not subject to the final rule include manufacturers of pharmaceuticals and production facilities. The final rule also exempts certain nicotine replacement therapies (NRT) from hazardous waste regulation.

Many health care facilities face a complex regulatory scenario when dealing with hazardous waste. For a large hospital, small quantities of various forms and types of hazardous waste may be generated at hundreds of points throughout the facility (e.g. patient rooms, operating rooms, nursing stations, emergency rooms). Under RCRA, hazardous waste determinations must be made by the generator at the point of generation. In part, the final rule is intended to relieve facilities employees, who are often undertrained in hazardous waste management, from some of the regulatory burdens of RCRA. The final rule sets sector-specific standards that apply to waste pharmaceuticals in lieu of existing hazardous waste generator requirements.

Health care facilities will no longer be deemed large quantity generators when generating more than 1 kg of acute hazardous waste pharmaceuticals in a calendar month. Covered facilities will no longer be responsible for meeting satellite accumulation area provisions of RCRA and may accumulate hazardous waste pharmaceuticals on site without a permit for up to one year. In addition, health care facilities will no longer be required to specify hazardous waste codes on manifests.

However, the final rule includes a number of new requirements for health care facilities, including new

reporting, notification, recordkeeping, labeling, and training requirements. In addition, the final rule prohibits health care facilities and reverse distributors from disposal of hazardous waste pharmaceuticals by flushing them down a drain or a toilet.

When health care facilities have unused pharmaceuticals, a reverse distributor assists the facility by returning them to the manufacturer. If the unused product still has a legitimate use, the facility may receive a credit. If not, the reverse distributor must dispose of the product. The final rule clarifies that, because prescription pharmaceuticals handled by reverse distributors are almost always unusable, prescription pharmaceuticals moving through the reverse distribution system are solid waste (and, therefore, potentially hazardous waste) at the health care facility. Therefore, the point of generation for these prescription pharmaceutical wastes will be at the health care facility. For nonprescription pharmaceuticals, as long as there is a reasonable expectation of legitimate reuse or reclamation, the products are not considered a solid waste at the healthcare facility. This is an important distinction because the point in time at which a given pharmaceutical is deemed to be a waste controls when management standards under the final rule apply.

The effective date of the final rule is August 21, 2019. However, with one important exception, it will not apply to health care facilities and reverse distributors in states authorized by EPA to operate their own hazardous waste management program. The final rule won't apply in those states until the state adopts the final rule and incorporates it into the state's regulations. The important exception? The ban on flushing hazardous waste pharmaceuticals down the drain becomes effective in all states on August 21st.

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 84 Fed. Reg. 5816 (February 22, 2019).

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