

# New U.S. EPA Rules to Place Restrictions on Health Care Industry Wastes

*Jennifer Cave*

Medical facilities, including hospitals, pharmacies and dental offices, may soon be subject to new requirements under the Clean Water Act and the Resource Conservation and Recovery Act (RCRA). Until recently, the disposal of most medical wastes has been regulated by state and local law. However, the United States Environmental Protection Agency (U.S. EPA) has recently published regulations governing the disposal of dental amalgam and is expected to publish regulations governing the disposal of waste pharmaceuticals.

## ***New Effluent Limitations Guidelines to Affect Dental Offices***

The U.S. EPA recently finalized technology-based pretreatment standards under the Clean Water Act to reduce discharges of mercury and other metals from dental offices into municipal wastewater treatment plants, also known as publically owned treatment works (POTWs). Mercury-containing amalgam wastes enter the environment when new fillings are placed, old mercury-containing fillings are drilled out, or when waste amalgam materials are flushed into chair-side drains that are connected to the wastewater stream. The U.S. EPA has estimated that dental practices discharge over five tons of mercury every year into POTWs. When mercury enters a POTW, it can partition into sludge, which is ultimately incinerated, landfilled, applied to the land, or discharged to surface waters. The U.S. EPA estimates over 100,000 dental offices use or remove amalgam in the United States and almost all of these practices discharge wastewater to POTWs.

The new regulations generally require dental practices, dental schools and dental clinics that discharge wastewater to a POTW, and that regularly place or remove amalgam, to install an approved amalgam separator or other approved removal devices no later than July 14, 2020. An amalgam separator is a device designed to remove solids, including mercury and other metals, from dental office wastewater. Once captured by the separator, these metals can be recycled.

Newly established dental practices will be required to install ISO 11143 compliant amalgam separators prior to July 14, 2020. Currently operating dental practices with existing amalgam separators can continue to operate those separators for their lifetimes or for a period of 10 years, whichever comes first. When the

separator requires replacement or the 10-year period has ended, existing dental practices will need to replace their amalgam separators with one that is ISO 11143 compliant. All affected dental practices are also subject to amalgam separator inspection and reporting requirements.

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The regulations do not apply to mobile units or offices where the practice of dentistry consists only of oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics or prosthodontics. These specialty practices are not expected to engage in the practice of amalgam restorations or removals, and are thus not expected to have any wastewater discharges containing dental amalgam. In addition, dental dischargers that do not place dental amalgam, and do not remove dental amalgam except in limited emergency or unplanned, unanticipated circumstances are exempt from any further requirements as long as they certify such in their One-Time Compliance Report to U.S. EPA.

## ***New Rules for Pharmaceutical Wastes That Qualify as RCRA Hazardous Wastes***

The U.S. EPA has proposed regulations that would establish special management standards for pharmaceutical wastes that are classified as hazardous wastes under RCRA. The U.S. EPA estimates that more than 6,400 tons of hazardous waste pharmaceuticals are disposed of annually by health care facilities through public sewer systems. The proposed regulations would provide a tailored, sector-specific set of regulations for the management of hazardous waste pharmaceuticals by health care facilities (including pharmacies and retail stores with pharmacies) and reverse distributors (handlers of pharmaceuticals returned to the manufacturer for credit).

The U.S. EPA previously attempted to ease disposal of hazardous waste pharmaceuticals in 2008 when it proposed adding them to its Universal Waste Rule. However, states and industries raised numerous criticisms of the proposal, and the agency in 2012 announced it was withdrawing that proposal and working to develop a health care-specific proposal.

The proposed regulations are seen by the agency, and by many stakeholders, as an attempt to streamline the management of waste pharmaceuticals by eliminating many of the RCRA hazardous waste generator requirements currently applicable to pharmaceutical wastes. In developing the regulatory proposal, the U.S. EPA recognized the RCRA hazardous waste regulations were developed for industrial and manufacturing applications and are not well-suited to health care facilities and reverse distributors.

The U.S. EPA received nearly 200 comments on the proposed regulations and is working to address the policy implications raised in the comments before it publishes the finalized regulatory package, which is now expected in 2018. Until the proposed regulations are finalized, the generation, treatment, storage and disposal of hazardous waste pharmaceuticals will continue to be regulated under RCRA. RCRA subjects generators of hazardous waste pharmaceuticals to certain accumulation limits as well as manifesting and disposal requirements. The failure of hazardous waste generators to comply with these requirements can lead to legal and administrative actions, civil and criminal liability, fines and other costs.

Health care facilities should review the types and quantities of hazardous waste they generate, and ensure they are in compliance with the RCRA requirements—in particular, correctly identifying their RCRA generator status and reporting protocols. In addition, hospitals, pharmacies and other facilities should continue to stay abreast of impending changes to the hazardous waste regulatory landscape affecting health care facilities.

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