



Client Alert

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EPA Issues Proposed Rule Streamlining Disposal of Hazardous Pharmaceutical Waste

On December 2, 2008, the U.S. Environmental Protection Agency issued a proposed rule designed to make it easier for generators of hazardous pharmaceutical waste to collect, store and dispose of those wastes. The rule also encourages generators to dispose of this waste as a “universal waste”, which would remove it from the municipal solid waste system. The rule, which potentially affects over 600,000 entities, covers waste from pharmacies, hospitals, physicians’ offices, dentists’ offices, outpatient care centers, ambulatory health care services, residential care facilities and veterinary clinics, among others. The proposed rule is published at 73 Fed. Reg. 73519 (Dec. 2, 2008).

Under the proposed rule, hazardous pharmaceutical waste generators may elect to have their waste remain regulated under the federal rules governing hazardous waste (the Resource Conservation and Recovery Act), or they would be able to manage their wastes under the Universal Waste Rule (UWR). The UWR is a set of streamlined requirements for the collection of widely dispersed hazardous wastes, such as batteries, mercury thermostats, certain pesticides and fluorescent bulbs. These types of wastes are generally considered lower risk than other types of hazardous wastes, and are therefore not regulated as strictly. EPA has stated that opting to handle the wastes under the UWR will be easier and more cost-effective, predicting that the rule could result in a savings of \$35.2 million per year for the regulated entities.

Significantly, if the rule is finalized, generators of hazardous pharmaceutical wastes will not be required to use a hazardous waste carrier to transport those wastes. Instead, a generator may use a common carrier that is abiding by the UWR. Unlike hazardous waste transporters, common carriers transporting hazardous pharmaceutical wastes will not be required to use manifests for the waste. Further, RCRA’s rules for accumulation and storage times of pharmaceutical hazardous waste would be relaxed under the proposed rule. This would allow facilities additional time to collect hazardous pharmaceutical waste, thereby making it more cost-effective to ship it offsite with an appropriate hauler. However, the proposed rule continues to require that the wastes be disposed of at a hazardous waste management facility.

According to EPA, the rule will also make it easier for facilities to start “take-back” programs, whereby the manufacturers collect unused pharmaceuticals from health care facilities and retail customers.

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