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Environmental and Utilities Legal Update

EPA Proposes to Add Pharmaceutical Wastes to the Universal Waste Rule

On December 2, 2008, the Environmental Protection Agency (EPA) published a proposed rule that would amend the Universal Waste Rule under the Resource Conservation and Recovery Act (RCRA) to include hazardous pharmaceutical waste. If finalized, this rule will streamline regulatory requirements for generators, collectors, and transporters of hazardous pharmaceutical wastes. The EPA anticipates that this rule will apply primarily to pharmacies, hospitals, health care facilities, veterinary clinics, and other entities that generate hazardous pharmaceutical wastes. Comments on the proposed rule must be submitted to the EPA on or before February 2, 2009.

The Universal Waste Rule was initially promulgated on May 11, 1995, to simplify the management, collection and disposal of certain widely generated hazardous wastes, including batteries, pesticides, thermostats, and fluorescent lights. Because pharmaceutical wastes, like other universal wastes, are generated by a variety of different sources at different quantities, the EPA is proposing to expand the Universal Waste Rule to include pharmaceutical wastes that are RCRA hazardous wastes.

Under the proposed rule, the EPA defines the term "pharmaceutical" broadly to include "any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or . . . that is intended to affect the structure or function of the body in man or other animals." The proposed rule is meant to include, among other things, pills, tablets, ointments, intravenous solutions, vaccines, and medicinal dermal patches. The definition does not include sharps or other infectious or biohazardous waste, dental amalgams, medical devices not used for dispensing purposes, equipment, contaminated personal protective equipment, or contaminated cleaning materials.

Under the proposed rule, generators of hazardous pharmaceutical wastes may choose whether to manage their waste under the current hazardous waste regulations (40 CFR Parts 260 to 268 and 270) or under the Universal Waste Rule (40 CFR Part 273). The proposed rule imposes storage, labeling, transportation, training, release response, and notification requirements on handlers of the waste, including generators. Generators are also encouraged, though not required, to treat nonhazardous drugs in the same manner.

According to EPA, the proposed rule will not affect current regulatory schemes or state programs. For example, the proposed rule does not apply to radioactive components of waste, which instead are regulated under the Atomic Energy Act by the Department of Energy or the Nuclear Regulatory Commission. Similarly, though the rule includes "controlled substances" regulated by the Drug Enforcement Administration (DEA), existing DEA regulations will not be affected. The proposal also emphasizes that RCRA-authorized states will not be required to modify their programs to adopt the proposed regulation. Currently, two states, Michigan and Florida, have already included pharmaceuticals in their universal waste regulations.

For More Information

The proposed rule may be accessed at 73 Fed. Reg. 73520-73544 (Dec. 2, 2008) or via the following link: http://edocket.access.gpo.gov/2008/pdf/E8-28161.pdf.

At Robinson & Cole, we have experienced environmental attorneys who understand that environmental compliance is but one aspect of the complex, multifaceted, and sometimes competing demands made on businesses.

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