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Healthcare Providers Face New Rules Governing the Disposal of Pharmaceuticals

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On September 25, 2015, the United States Environmental Protection Agency published a proposed rule concerning "Management Standards for Hazardous Waste Pharmaceuticals". Under the proposed rule, the term "healthcare facilities" is defined broadly and includes: any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. Therefore, this rule has the potential to impact (i) nearly all healthcare facilities including pharmacies, veterinary clinics, physicians' offices (including ophthalmologists), dentists' offices, other health practitioners (e.g., chiropractors), outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities (e.g., assisted living facilities, nursing homes, U.S. veterans domiciliary centers), continuing care retirement communities (e.g., assisted living facilities with on-site nursing facilities), medical examiners and coroners' offices, and (ii) Pharmaceutical Reverse Distributors.

EPA has proposed this rule to address concerns regarding the difficulty in implementing the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations for the management of hazardous waste pharmaceuticals and to prevent pharmaceuticals from entering the environment, through flushing or other means.

Certain pharmaceuticals are regulated as hazardous waste under RCRA when discarded. EPA's proposed rule would require healthcare facilities and all pharmaceutical reverse distributors to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR 266. Under the Proposed Rule a "pharmaceutical reverse distributor'' would be defined as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor. EPA's definition is much broader than the existing DEA definition of a "reverse distributor".

Non-creditable hazardous waste pharmaceuticals (i.e., those that are not expected to be eligible to receive "manufacturer's credit") may be managed on-site similar to how they would have been under a previous proposal for managing these wastes (2008 Universal Waste proposal for pharmaceutical wastes). When shipped off-site, they must be transported as hazardous wastes and sent to a RCRA interim status or permitted facility. Healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers' credit. EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

EPA is also proposing the following: (1) to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (i.e, flushed or sewered); (2) that hazardous waste pharmaceuticals managed under Subpart P will not be counted toward calculating the site's generator category (i.e. as a large quantity generator, small quantity generator of conditionally exempt small quantity generator); (3) a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances, and; (4) management standards for hazardous waste pharmaceutical residues remaining in containers.

Comments on this Proposed Rule will be accepted until November 24, 2015.