

PUBLICATION

EPA Issues New Hazardous Waste Pharmaceuticals Rule

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The United States Environmental Protection Agency (EPA) recently issued its Final Rule imposing new requirements for hazardous waste pharmaceuticals. The Hazardous Waste Pharmaceuticals Rule, issued February 22, 2019, modifies 40 C.F.R. Parts 261, 262, 264, et al., relating to management standards for hazardous waste pharmaceuticals. 84 Fed. Reg. 5816. It is effective nationwide on August 21, 2019.

The goals of the Hazardous Waste Pharmaceuticals Rule are to strengthen the health care sector; provide for the management of hazardous waste pharmaceuticals by health care facilities; eliminate the disposal of hazardous waste pharmaceuticals in sewers; reduce overlapping regulations; provide national consistency on how federal hazardous waste laws apply to reverse distribution and reverse logistics of hazardous waste pharmaceuticals; and provide new requirements for health care facilities which generate small amounts of nicotine replacement therapies.

With respect to nicotine, certain over-the-counter nicotine replacement therapies that have been approved by the Food and Drug Administration are no longer included in the federal acute hazardous waste listing. The EPA concluded that nicotine patches, gums, and lozenges are not acute hazardous waste, and can be discarded as non-hazardous waste. Other forms of nicotine are still listed as acute hazardous waste.

The Hazardous Waste Pharmaceuticals Rule also addresses reverse distribution and reverse logistics of hazardous waste pharmaceuticals. The rule codifies the EPA's policy that non-prescription pharmaceuticals such as over-the-counter drugs that are sent through reverse logistics are not waste if they have a reasonable expectation of being lawfully used or reused for their intended purpose, or reclaimed. The Hazardous Waste Pharmaceuticals Rule also establishes that prescription pharmaceuticals moving through reverse distribution are waste at the health care facility. Reverse distributors typically receive shipments of unused or expired prescription pharmaceuticals from health care facilities and facilitates the process of crediting health care facilities for these unused pharmaceuticals. Prescription pharmaceuticals at reverse distribution are not reused nor resold and are discarded. The EPA has developed a system designed with existing business practices in mind for unused or expired prescription pharmaceuticals sent through reverse distribution.

The Hazardous Waste Pharmaceuticals Rule also provides definitions for key terms. A *hazardous waste pharmaceutical* is a pharmaceutical that is a solid waste, as defined in federal regulations by virtue of it exhibiting one or more hazardous characteristics or being listed. A pharmaceutical is not a solid waste and therefore not a hazardous waste pharmaceutical if it is used, reused, or reclaimed. In addition, an over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being used, reused, lawfully redistributed, or reclaimed.

The Hazardous Waste Pharmaceuticals Rule applies to all health care facilities, including hospitals, health clinics, physician offices, long term care facilities, pharmacies, and other facilities, but does not include pharmaceutical manufacturers, reverse distributors, or reverse logistic centers. A long term care facility includes hospices, nursing facilities, skilled nursing facilities, and nursing and skilled nursing care portions of

continuing care retirement communities. It does not include group homes, independent living communities, assisted living facilities, or independent and assisted living portions of continuing care retirement communities.

The Hazardous Waste Pharmaceuticals Rule specifically provides new health care facility standards, including notification, training, hazardous waste determinations, commingling, labeling, container standards, accumulation times, and other new requirements for health care facilities subject to the new rule. One of the specific prohibitions in the new rule is that hazardous waste pharmaceuticals may not be disposed of down the drain or flushed in a toilet. In addition, there are new empty container standards applicable to hazardous waste pharmaceuticals.

Health care facilities impacted by the Hazardous Waste Pharmaceuticals Rule are urged to become familiar with these new requirements and to contact their qualified attorneys for more information.