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ADVISORY

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EPA FINALIZES NEW REQUIREMENTS FOR HAZARDOUS WASTE PHARMACEUTICALS

The U.S. Environmental Protection Agency (EPA) has finalized regulations, effective August 21, 2019, applicable to the generation, management, storage, treatment, and disposal of hazardous waste pharmaceuticals under the Resource Conservation and Recovery Act (RCRA). The long-awaited regulations will affect what EPA defines as a "healthcare facility," which term includes, among other facilities, hospitals, nursing and hospice facilities, medical clinics, physicians' offices, retail pharmacies, and reverse distributors. Compliance with current RCRA regulations by the healthcare industry, including the retail pharmacy sector, has presented unique challenges. Prior to the final rule, facilities generating hazardous waste pharmaceuticals were required to follow RCRA regulations applicable to generators of other hazardous wastes. These requirements have been particularly onerous for healthcare facilities that, unlike industrial generators of hazardous waste, may generate a wide variety of different types of waste at multiple locations within the same facility, without consistency or predictability. For instance, due to the generation of even small quantities of certain hazardous waste pharmaceuticals, most notably nicotine products, healthcare facilities could have previously experienced an unanticipated change in hazardous waste generator status and become subject to complicated and onerous requirements. Despite these challenges, healthcare facilities have been expected to comply with RCRA requirements. Failure to do so in connection with the generation of hazardous waste pharmaceuticals can subject healthcare facilities to civil penalties of up to $72,718 per violation per day.

The new regulations exclude the generation of hazardous waste pharmaceuticals from the RCRA regulations applicable to generators of other hazardous waste and instead add requirements tailored specifically to the generation, management and disposal of hazardous waste pharmaceuticals. Similar to existing RCRA regulations, the applicability of the new hazardous waste pharmaceutical

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regulations, now set forth in new Subpart P of 40 CFR Part 266, is determined by the amounts of hazardous waste pharmaceuticals generated by a particular facility in a given month. More specifically, healthcare facilities that generate more than 100 kilograms of hazardous waste pharmaceuticals or more than 1 kilogram of acute hazardous waste pharmaceuticals per month are subject to the new regulations. Healthcare facilities that generate hazardous waste pharmaceuticals below these thresholds are largely exempt from the RCRA-related provisions of the new regulations.

The new regulations also address reverse distribution—that is, the accumulation of pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The new regulations exempt from the definition of "solid waste" non-prescription pharmaceuticals (e.g., over-the-counter drugs and supplements) that have a "reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed" when sent through reverse distribution. Healthcare facilities should be wary about the potential overuse of this exemption, however, because broken, damaged or leaking items might be considered "solid waste" (and, where appropriate, hazardous waste pharmaceuticals) at the point of generation, or the healthcare facility, under certain circumstances, which would subject that facility to regulatory requirements.

The new regulations also exempt Food and Drug Administration approved over-the-counter nicotine patches, gums and lozenges from RCRA requirements. Notably, however, the exemption does not cover prescription nicotine replacement therapies, nicotine-containing e-liquids or e-cigarettes. The new regulations include a prohibition on "sewering" or flushing hazardous waste pharmaceuticals, which goes into effect without further state action on August 21, 2019.

Authorized RCRA state programs will be required to take regulatory action to adopt the new provisions (other than the sewering prohibition) that are more stringent than currently applicable RCRA requirements. Because the new rules ease the requirements for management and disposal of certain over-the-counter nicotine products, authorized states may, but are not required to, adopt the exemption. We will continue to monitor the status of state implementation of the new regulations.

Should you have any questions about how the new regulations might affect your business, please contact Michael Miller.