Insights

Compliance Update: RCRA 'Subpart P' and the New Hazardous Waste Pharmaceutical Rules

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Health care facilities will need to comply with new regulations governing the management and disposal of Hazardous Waste Pharmaceuticals ("HWPs"). The Environmental Protection Agency ("EPA") has promulgated new rules to be codified at 40 C.F.R. Part 266, Subpart P of the implementing regulations of Resource Conservation Recovery Act ("RCRA") and commonly known as the new "Subpart P." These new rules modify, expand and/or clarify management, handling and disposal standards for HWPs. Health care facilities, including long-term care facilities and facilities that distribute, sell, or dispense pharmaceuticals, among others, will be subject to the 'sewer ban' component of Subpart P beginning on August 21, 2019. In Alaska and Iowa, the remainder of Subpart P goes into effect that same day. For other states, including Indiana, the remainder of Subpart P does not go into effect until adoption at the state level.

The EPA promulgated these new rules to promote more efficient management of HWPs by health care facilities and the pharmaceutical industry. The new Subpart P is designed to reduce overlapping regulations, brings a wider range of health care facilities handling HWPs within the rules and aims to regulate HWPs in a manner that is a better fit for the health care sector. The new Subpart P adds requirements to the existing regulatory framework, including among other things, training requirements for employees of health care facilities, standards for containing, labeling, and commingling waste pharmaceuticals, methods for shipment and disposal of HWPs, and notification/filing requirements. Subpart P also implements a broad "sewer ban"; amends and potentially eases regulations governing nicotine replacement therapies; and creates new incentives to "over-manage" pharmaceutical waste.

Subpart P and its new HWP rules present new compliance challenges for health care facilities and pharmaceutical companies. To ensure you are prepared to comply, join our podcast for a more in-depth review of the new rules. We will discuss the new regulations and Subpart P's impact on a variety of health care actors, and the steps that should be undertaken to achieve compliance. Tune in for a podcast on this compliance update on Friday, August 16, 2019 at 1 p.m. Eastern to learn more. Please contact Matthew D. Neumann with any questions.