

Publications

Health Care Alert: Ohio EPA Undertakes Rulemaking to Adopt New Federal Standards for Management of Hazardous Pharmaceutical Waste by Ohio's Health Care Industry

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Ohio's health care industry will soon take on significant new obligations with respect to the management of hazardous pharmaceutical waste, pursuant to a federal rule being implemented by Ohio Environmental Protection Agency (EPA).

The new federal rule establishes a set of industry-specific requirements for the management of pharmaceutical wastes that constitute "hazardous waste," meaning those that either (1) are specifically listed as hazardous pursuant to regulation or (2) exhibit certain designated hazardous characteristics (e.g., ignitability, corrosivity, reactivity, and/or toxicity). Because the new federal rule is more stringent than Ohio's existing regulatory scheme – under which most pharmaceuticals have historically *not* been subject to full hazardous waste regulation – the state must adopt updated requirements by **August 21, 2019** (six months from publication of the federal rule).

The new rules will apply to any Ohio "healthcare facility," which is broadly defined to mean any person¹ lawfully authorized to (1) provide 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) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition of a "healthcare facility" is not intended to include pharmaceutical manufacturers; it does, however, include "long term care facilities," which will no longer be eligible for the "household waste" exclusion under the Resource Conservation and Recovery Act (RCRA).²

To comply with the federal rule's requirements for the storage, labeling, transportation, and disposal of hazardous waste pharmaceuticals, subject facilities will be responsible for identifying and segregating hazardous waste materials at potentially numerous collection points, marking a significant departure from current processes.

Ohio EPA expects to make draft versions of its implementing regulations available for comment in late summer 2019.³ However, given the limited time allowed for the state to adopt its final regulations, health care providers and industry businesses would be prudent to begin familiarizing themselves with the provisions of the federal rule. The full text of the federal rule can be found [here](#).

If you have questions about the new regulatory scheme for the management of hazardous waste pharmaceuticals and its impact on your organization, please contact [Jolie Havens](#), [Kristin Watt](#), [David Edelstein](#), [Mairi Mull](#), or your Vorys attorney. To receive updates about additional developments and educational opportunities related to these rules, please contact Andy Laux at adlaux@vorys.com.

¹ For purposes of this rule, “person” means “an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.” 40 C.F.R. §260.10.

² Entities that are not included within the federal rule’s definition of “long term care facility” (e.g., group homes and independent living communities, and the independent living portions of continuing care retirement communities) may continue to qualify for the “household waste” exclusion.

³ See Ohio Environmental Protection Agency, *Early Stakeholder Outreach – Hazardous Waste Pharmaceuticals and Airbag Modules and Airbag Inflators*, May 6, 2019. Available at: <https://epa.ohio.gov/Portals/30/rules/HazWaste/2019/ESO%20pharms%20and%20airbags%204.25.19%20js%2003.pdf>