

Publications

Health Care Alert: ICF/IIDs will be Exempt From New Standards for the Management of Hazardous Waste Pharmaceuticals in Ohio

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On December 2, 2019, the Vorys health care team received confirmation from the Ohio Environmental Protection Agency (Ohio EPA) that it plans to adopt our proposed interpretation of new federal standards for the management of hazardous waste pharmaceuticals, effectively exempting Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) from compliance with the new standards.

By way of background, in February 2019, the federal Environmental Protection Agency (U.S. EPA) published a final rule under the authority of the Resource Conservation and Recovery Act (RCRA). This rule established new standards for the management of hazardous waste pharmaceuticals by any “health care facility,” defined broadly to mean any person 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. (To read the Vorys client alert discussing the February 2019 rule, click [here](#).)

Per EPA regulations, “household wastes” are excluded from the definition of “hazardous waste” subject to regulation under RCRA. Specifically, the “household waste exclusion” applies to wastes that are (1) generated by individuals on the premise of a temporary or permanent residence, and (2) composed primarily of materials found in wastes generated by consumers in their homes.¹ Historically, most long-term care facilities have been exempt from hazardous waste management standards under this exemption.

In the 2019 rule, however, U.S. EPA created a new definition of “long-term care facility” (LTCF), indicating that health care facilities falling within such definition would no longer qualify for the household waste exclusion. Although U.S. EPA expressly excluded certain types of facilities from the LTCF definition (e.g., group homes and assisted living

facilities), it did not provide any comment on its characterization of Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs). Further, due to certain unique characteristics of ICF/IIDs, the criteria on which U.S. EPA based its other exceptions did not allow these providers to assess their own status under the rule.

With the support of the Ohio Provider Resource Association, the Vorys Health Care team reached out to U.S. EPA to request guidance on this issue and to advocate for the exclusion of ICF/IIDs from the LTCF definition. In October, we received a response indicating that the U.S. EPA agreed with our interpretation of the rule's applicability; however, the States are generally authorized to impose requirements under RCRA that are more stringent than the federal standards. Accordingly, the December 2nd confirmation for the first time conclusively resolved that **Ohio ICF/IIDs will not be considered LTCFs for purposes of RCRA and may continue to rely on the household waste exclusion.**

If you have questions about the new standards or the impact of the agencies' determination, please contact Robin Amicon, Mairi Mull, or your regular Vorys attorney.

¹ For more information, visit <https://www.epa.gov/hw/household-hazardous-waste-hhw#Regs>.