

The Latest on EPA Regulations for Hazardous Waste Pharmaceuticals And RCRA Problem-Solving Guidance for the Retail Sector

Greenbaum, Rowe, Smith & Davis LLP Client Alert

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At the beginning of 2016, the Environmental Protection Agency (EPA) appeared on track to accomplish three tasks intended to address problems faced by the retail sector in complying with hazardous waste regulations under the Resource, Conservation and Recovery Act (RCRA). But as a new year and a new administration settle into place, only one of those tasks has actually been finalized.

First promulgated in 1980, the RCRA regulations were admittedly designed with the industrial sector in mind. For the retail sector, they presented a classic “square peg in a round hole” predicament.

EPA’s efforts to address the retail sector problem began back in 2011 with an Executive Order requiring all federal agencies to develop plans to “determine whether any [of their] regulations should be modified, streamlined, expanded, or repealed so as to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.”

In 2014, EPA collected comments from the public regarding difficulties encountered by the retail sector in complying with RCRA. In August 2015, EPA addressed some of these concerns by proposing two regulatory amendments, the Hazardous Waste Generator Improvements Rule and the Management Standards for Hazardous Waste Pharmaceuticals Rule. The public comment period on the two proposed amendments ended in December 2015, presumably clearing the way for their promulgation in 2016.

In addition, it was expected that EPA would issue a new guidance document explaining, in general, how the retail sector could reasonably work within the amended RCRA program to minimize the problems experienced in the past.

The final Generator Improvements Rule was published in the Federal Register on November 28, 2016. As outlined in our recent Client Alert, the regulation is a mixed bag that provides a modest increase in flexibility in some areas, but notably increases potential penalty exposure, regulatory burdens, and restrictions in others, and should be carefully considered by all hazardous waste generators.

The Waste Pharmaceuticals Rule has been stalled as of this writing due to EPA’s review of comments. Unlike the Generator Improvements Rule, the Waste Pharmaceuticals Rule would apply only to a newly defined category of generators, “healthcare facilities,” handling a newly defined category of hazardous waste, “hazardous waste pharmaceuticals.” Having narrowly limited the proposed amendment’s applicability, the proposed Waste Pharmaceuticals Rule is more innovative in deviating from the

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industrial-oriented regulatory scheme than the Generator Improvements Rule. Once finalized, the amendment has the potential to provide welcome relief to that portion of the retail sector affected by it.

Instead of publishing a RCRA guidance document comprehensively addressing the most significant problems identified by the retail sector, EPA published in September 2016 a “Strategy for Addressing the Retail Sector under RCRA’s Regulatory Framework.” In its strategy document, EPA summarizes the comments received from the retail sector, and suggests that the retail sector has been helped by EPA’s 2015 modification of the RCRA regulations affecting the recycling of waste materials, as well as some aspects of the Generator Improvements Rule. EPA also touts the proposed Waste Pharmaceuticals Rule as part of its ultimate solution for the retail sector.

Beyond these pending and finalized regulatory amendments, EPA is pursuing a more narrow issue-by-issue problem solving strategy. It released guidance letters clarifying when nicotine products are considered hazardous wastes and when pharmaceutical controlled substances can be accepted at Drug Enforcement Agency-authorized collection receptacles. EPA is still working on solutions for retail sector management of waste aerosol cans and consumer goods, including the potential for allowing reverse distribution or management as universal waste.

Please contact the author of this Alert, **Daniel Flynn**, for any questions regarding the issues discussed in this Alert or compliance with RCRA in general.