EPA Promulgates Long-Awaited Standard for Management of Hazardous Waste Pharmaceuticals and Provides Other RCRA Relief for Retailers

Daniel Flynn
Greenbaum, Rowe, Smith & Davis LLP

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After considerable deliberation and delay, the Environmental Protection Agency (EPA) has amended its hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) to provide a more practical way for pharmacies, hospitals, clinics, physicians, and many retailers to manage pharmaceutical waste classified as hazardous under RCRA. The amendment, entitled "Management Standards for Hazardous Waste Pharmaceuticals Rule" (Hazardous Waste Pharmaceutical Rule), will become effective six months after its publication in the Federal Register.

Entities impacted by the new rule will need to carefully assess how it affects the way pharmaceutical wastes are to be managed, and will need to arrange for training and process changes necessary to ensure compliance. As discussed below, retailers not affected by the Hazardous Waste Pharmaceutical Rule should nonetheless review the portion of the preamble announcing a broader EPA policy covering the use of reverse logistics to deal with any unsold retail item no longer wanted by the retailer in situations not covered by the new rule.

EPA's Search for a Solution

Initially, EPA's scheme for the management of hazardous waste under RCRA was designed primarily with industry-generated waste in mind, and became a trap for the unwary when applied to the health and retail business sectors. Over the past ten years, large retailers of pharmaceuticals and other consumer products, including Walmart, CVS, Walgreens, Rite-Aid, Target, and Home Depot, paid tens of millions of

Attorneys
Daniel Flynn

dollars in fines to resolve enforcement actions brought against them under RCRA.

EPA first attempted to deal with the waste pharmaceutical problem in 2008 by proposing to include pharmaceutical wastes under a simpler regulatory scheme developed for "universal wastes," a category of waste that includes used batteries, fluorescent light bulbs, and recalled pesticides. After review of the comments it received on the proposal and further evaluation, EPA abandoned that approach. EPA later solicited comments from the public regarding difficulties encountered by the retail sector in complying with RCRA and received numerous comments on waste pharmaceuticals. The Hazardous Waste Pharmaceutical Rule was proposed by EPA in September 2015, but remained dormant until approved in its present form in December 2018.

An Overview of the Hazardous Waste Pharmaceutical Rule

The Hazardous Waste Pharmaceutical Rule creates a new subpart of the RCRA regulations that applies only to healthcare facilities and reverse distributors. Any other generator that has to deal with pharmaceutical waste is required to characterize and manage that waste without the benefit of the new flexibility proposed for health care facilities. The management and disposal of non-hazardous pharmaceutical waste and over-the-counter pharmaceutical waste (even if hazardous waste) is also not affected by the new rule.

"Healthcare facility" includes hospitals, ambulatory surgical care centers, outpatient, nursing and long-term care facilities, physicians, veterinary clinics, pharmacies, retailers that sell over-the-counter medicines and dietary supplements, wholesale distributors of pharmaceuticals, third party logistics providers for pharmaceuticals, and ambulance services.

"Reverse distributor" includes any person that receives and accumulates prescription pharmaceuticals from a healthcare facility for the purpose of facilitating or verifying the facility's eligibility for a credit from the pharmaceutical manufacturer. Thus, if a manufacturer agrees to give healthcare facilities a credit for pharmaceuticals returned due to a recall or expired shelf-life, the company that the manufacturer hires to receive and manage the hazardous waste pharmaceuticals would qualify as a reverse distributor. A reverse distributor would not have the authority under the Hazardous Waste Pharmaceutical Rule to receive and accumulate hazardous waste pharmaceuticals that do not have the potential for receiving a credit when returned to the manufacturer.

"Pharmaceutical" includes prescription and over-the-counter medicines in forms ranging from pills to lozenges, ointments, lotions, shampoos, and skin patches, investigational drugs, dietary supplements, e-cigarettes, vaping pens and associated liquid nicotine. As a rule of thumb, if a product is required by FDA to include "Drug Facts" or "Supplement Facts" on the label, it would qualify as a pharmaceutical under the new rule. It also includes the clean-up materials and contaminated personal protective equipment from spills of pharmaceuticals.

WOODBRIDGE OFFICE, 99 WOOD AVENUE SOUTH, ISELIN, NEW JERSEY 08830, T: 732.549.5600 F: 732.549.1881
75 LIVINGSTON AVENUE, ROSELAND, NEW JERSEY 07068, T: 973.535.1600 F: 973.535.1698
750 THIRD AVENUE, 9TH FLOOR, NEW YORK, NEW YORK 10017, T: 212.847.9858

The new rule has three primary innovations:

- It allows a reverse distribution for hazardous waste pharmaceuticals if they have not been dispensed to a patient or repackaged, are not expired by more than one year, and are potentially eligible for a monetary credit from the pharmaceutical manufacturer upon their return. A hazardous waste manifest is not necessary for shipment to the pharmaceutical reverse distributor if the healthcare facility gives advance notice of the shipment and obtains confirmation of delivery. However, all applicable Department of Transportation safety-based labeling and other transport requirements apply to the shipment. Reverse distribution is not available for non-prescription pharmaceuticals or hazardous waste pharmaceuticals when their eligibility for a credit has already been determined by a reverse distributor.
- It allows hazardous waste pharmaceuticals that are not eligible for a credit from the manufacturer to be managed by healthcare facilities under a flexible set of management standards comparable to those that currently apply to small quantity generators (SQGs). A healthcare facility has the option to manage its non-hazardous waste pharmaceuticals under the same management standards.
- It prohibits the disposal of pharmaceuticals by discharge to a sewer. For example, disposal in a sink, floor drain, or commode is banned.

Hazardous waste pharmaceuticals currently regulated as a controlled substance by the Drug Enforcement Agency (DEA) are exempt from the proposed regulations provided they are incinerated in accordance with DEA regulations and other requirements.

Any non-pharmaceutical waste will have to be managed by healthcare facilities and reverse distributors under the same rules applicable to non-healthcare generators. When the amounts of hazardous waste generated per month are low enough, the generators are eligible for the less stringent waste management standards provided for SQGs and very small quantity generators (VSQG). Hazardous waste pharmaceuticals would not be counted in determining a generator's eligibility for SQG or VSQG status. Healthcare facilities that do not currently qualify for these less stringent categories might become eligible once the Hazardous Waste Pharmaceutical Rule becomes effective.

Under the existing RCRA regulations, long-term care facilities can rely on the household waste exemption, which exempts wastes generated in our homes from RCRA regulation. Under the Hazardous Waste Pharmaceutical Rule, the household waste exemption will no longer be available for wastes generated at facilities that meet the new rule's definition for a long-term care facility. Even wastes generated by and remaining under the control of the patients or residents would have to be collected, characterized and managed under RCRA.

Nicotine Products and Reverse Logistics for Retailers

In addition to the new regulatory scheme established for hazardous waste pharmaceuticals, EPA is implementing two related improvements affecting RCRA regulations.

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75 LIVINGSTON AVENUE, ROSELAND, NEW JERSEY 07068, T: 973.535.1600 F: 973.535.1698
750 THIRD AVENUE, 9TH FLOOR, NEW YORK, NEW YORK 10017, T: 212.847.9858

The acute hazardous waste listing for nicotine is amended to exclude over-the-counter nicotine replacement products approved by the U.S. Food and Drug Administration. This is significant because retailers may need to discard nicotine gum or patches for a variety of reasons, including expiration of the product's shelf life or accidental damage to packaging. Prior to this amendment, nicotine waste was regulated under RCRA as acute hazardous waste. Small amounts made a store or other generator discarding the material ineligible for SQG or VSQG status. The exclusion does not, however, extend to e-cigarettes, e-liquids, or prescription nicotine replacement therapies.

The preamble for the Hazardous Waste Pharmaceutical Rule establishes a policy that confirms the conditions under which retailers may manage unwanted, unsold retail items other than prescription pharmaceuticals through a "reverse logistics" approach. Reverse logistics is the practice of returning unsold or unused products to reverse logistic centers established by manufacturers, distributors, or national retailers to assess and manage the ultimate distribution of returned products. Personnel at the distribution center make the determination as to whether the returned product can be used, reused or reclaimed or whether it must instead be managed and disposed of as a waste. Items eligible for management through reverse logistics could include excess inventory, customer returns that are in good condition, products with expired shelf lives, and products subject to a recall supervised by the U.S. Food and Drug Administration or Consumer Product Safety Commission.

Under RCRA, the full panoply of waste management requirements is triggered the moment that an unwanted product is determined to be a "waste." Sending an unwanted item for disposal is an implied determination that it is a waste. EPA's new policy clarifies that shipment of unsold nonprescription pharmaceuticals and retail items to a reverse logistics center is not a disposal that would render them solid wastes if there is "a reasonable expectation of [the returned product] being legitimately used/reused (e.g. lawfully redistributed for their intended purpose) or reclaimed." A reverse logistics center set up by a distributor, manufacturer, or national retail chain will likely have more expertise and management capabilities than local retail stores. If the returned product must be disposed, the point at which the waste is generated, thereby triggering the waste management requirements, is the reverse logistics center, not the retail store from which the product was received. The ability to shift the responsibility for that determination to reverse logistics centers should substantially reduce the regulatory burden on retailers and make RCRA compliance more cost-effective overall.

If you have any questions regarding the issues discussed in this Alert, please contact the author, **Daniel Flynn**.

WOODBRIDGE OFFICE, 99 WOOD AVENUE SOUTH, ISELIN, NEW JERSEY 08830, T: 732.549.5600 F: 732.549.1881
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