EPA's Three-Part RCRA Hazardous Waste Rx for Retailers: Proposed Regulatory Changes for Pharmaceutical Waste and Generator Requirements To Be Followed by New Retail Sector Guidance

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In 2014, the United States Environmental Protection Agency (EPA) solicited information from the retail sector regarding difficulties encountered in managing hazardous waste under the federal Resource Conservation and Recovery Act (RCRA). EPA's request followed a wave of enforcement actions in which a "who's who" of national retailers, including Home Depot, Walmart, Target, CVS and Walgreens, paid penalties that ranged from $800,000 to $22.5 million for improper handling and disposal of hazardous wastes.

In response, retailers pointed out that the RCRA regulatory scheme for hazardous waste was designed with industrial generators in mind, and does not work well in retail scenarios such as the management of expired pharmaceuticals and products returned by customers.

A number of suggestions were offered to the EPA for fixing the problem, including:

- Exempt pharmaceutical and other products intended for human consumption
- Expand the universal waste scheme to include retail product waste
- Exempt disposal or recycle of products packaged for sale to consumers
- Require manufacturers to provide end-of-life waste characterization for products

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- Allow reverse distribution logistics for returned, damaged, expired materials
- Allow alternative methods for calculating waste accumulation to avoid loss of small generator status due to episodic generation of waste

With the benefit of these comments, the EPA developed a three-part solution. The first two parts took the form of regulatory amendments published on September 25, 2015. One proposed amendment would change the RCRA requirements for management of hazardous waste pharmaceuticals. The second proposed amendment would rearrange and update RCRA requirements generally applicable to all generators of hazardous waste. **Comments on these proposals must be submitted no later than November 24, 2015.**

The third part of the EPA's solution, which has not yet been published, is expected to take the form of a new guidance document for the retail sector. Rather than proposing further regulatory amendments, the EPA will explain how retailers can work within the existing regulations, as modified by the amendments published in September, to manage or avoid the problems previously experienced in complying with RCRA. Since the guidance may be affected by any changes made by the EPA when finalizing the two proposed regulations, the guidance document is unlikely to be published before the final version of the hazardous waste pharmaceutical and generator improvements rules are published.

The following are brief overviews of the two proposed amendments:

Management of Hazardous Waste Pharmaceuticals

The hazardous waste pharmaceutical proposal applies only to health care facilities and pharmaceutical reverse distributors. Any other generator that has to deal with pharmaceutical waste would be required to characterize and manage that waste without the benefit of the new flexibility proposed for health care facilities.

"Health care facility" includes hospitals, ambulatory surgical care centers, outpatient, nursing and assisted living care facilities, physicians, veterinary clinics, pharmacies, and stores that sell over-the-counter medicines and dietary supplements.

"Pharmaceutical reverse distributor" is any person that receives hazardous waste pharmaceuticals from a health care 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 health care 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 pharmaceutical reverse distributor.

"Pharmaceutical" includes prescription and over-the-counter medicines in forms ranging from pills to lozenges, ointments, lotions, shampoos, and skin patches. As a rule of thumb, if a product is required by FDA to include "Drug Facts" on the label, it would qualify as a pharmaceutical under the proposed RCRA amendment.

The proposed rule has three primary innovations. First, it would allow a reverse distribution for hazardous waste pharmaceuticals if the waste pharmaceuticals have not been used, are not expired by more than one year, and are eligible for a monetary credit from the pharmaceutical manufacturer upon their return. A hazardous waste manifest is not necessary for the shipment to the pharmaceutical reverse distributor if the health care 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 would apply to the shipment.

The second primary innovation would allow hazardous waste pharmaceuticals that are not eligible for a credit from the manufacturer to be managed by health care facilities under a flexible set of management standards comparable to those that currently apply to small quantity generators (SQGs).

The third primary innovation would prohibit the disposal of pharmaceuticals by discharge to a sewer. For example, disposal in a sink or floor drain or flushing in a commode would be banned.

Waste pharmaceuticals currently regulated as a controlled substance by the Drug Enforcement Agency (DEA) would be exempt from the proposed regulations provided they are incinerated in a proper hazardous or solid waste incinerator in accordance with DEA regulations and other requirements.

Of course, any non-pharmaceutical waste will have to be managed under the same rules applicable to non-health care 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 conditionally exempt small quantity generators (CESQG). Hazardous waste pharmaceuticals would not be counted in determining a generator's eligibility for SQG or CESQG status with respect to management of non-pharmaceutical hazardous waste. Pharmacies and other health care facilities that did not previously qualify for these less stringent categories might become eligible once the proposed amendment is finalized.

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 proposed Management of Hazardous Waste Pharmaceutical amendment, the household waste exemption would no longer be available for wastes generated at a long-term care facility. Even those wastes generated by and remaining under the control of the patients or residents would have to be collected, characterized and managed under RCRA.

Hazardous Waste Generator Improvement

The EPA's stated goals for this proposed amendment are to improve compliance, address regulatory gaps, give hazardous waste generators greater flexibility, make the regulations more user-friendly and implement some technical corrections. The EPA specifically notes that several of the proposed changes respond to comments received from the retail sector in 2014. These include a provision allowing SQGs and CESQGs to maintain their less stringent category even if they have an episodic event once a year that would otherwise bump them up to a more stringent category. The proposed amendment would change

the CESQG name to very small quantity generator (VSQG).

Another change would allow a company that has both VSQG and large quantity generator (LQG) facilities to consolidate waste from the VSQG facility at the LQG facility for management without having to obtain a treatment, storage or disposal permit for the LQG facility. This allows some reverse distribution logistics, but does not go as far as retailers had sought because it requires both facilities to be under common ownership. Thus, a "big box" retail chain with retail stores that qualify as VSQGs could send waste, including products having an expired shelf life, to its distribution hubs for management by employees who specialize in waste classification and management. On the other hand, a "mom and pop" retail store supplied by an independently-owned wholesaler would not have an equivalent option.

Most of the other changes in the hazardous waste generator improvements proposal would increase the regulatory burden on generators, including:

- Increased information required to be included on hazardous waste container labels
- Enhancement of requirements applicable to LQGs and SQGs for preparedness, prevention, planning and emergency procedures
- Increased information required to be retained relating to a generator's determination that a material is a waste and, if so, the generator's classification of that waste (documentation for determinations that a material is not a hazardous waste must also be retained)
- A requirement that VSQGs obtain EPA ID numbers and that VSQGs and SQGs renotify EPA as to their generator status every two years
- New closure requirements for central accumulation units (commonly referred to as
- New biennial reporting requirement for owners and operators that recycle hazardous waste without storing it prior to recycling

Other provisions of the proposed amendment purport to codify EPA interpretations of existing regulations, sometimes overruling prior positions expressed by the agency. They include:

- A requirement that hazardous waste classification determinations be made not only when a material is determined to be a waste, but also each time in the subsequent course of management that the waste has or may have changed its properties, and
- A clarification that if a VSQG or SQG exceeds the applicable monthly cap for either acute or non-acute hazardous waste, it loses its VSQG or SQG status for that month for both types of waste even if one of them had not exceeded the applicable cap.

The proposed rule includes an additional "clarification" that raises a serious concern for all categories of generators, except perhaps those that have a formal RCRA treatment, storage and disposal permit. The new regulatory language would divide all requirements applicable to generators into two categories: "conditions for exemption" and "independent requirements." Violation of an independent requirement is

punished as a violation of that requirement only. Thus, an error in a hazardous waste manifest would be treated as a single violation for enforcement purposes.

Violation of a condition for exemption, on the other hand, has more draconian consequences. The generator would lose eligibility for the less stringent category, for example VSQG or SQG. Instead of facing a penalty for violating one regulatory provision, the generator becomes subject to penalties for a multitude of requirements that apply to the most heavily regulated category of generators, those for which a treatment, storage and disposal permit is required.

The loss of category eligibility is currently understood to be triggered by exceedance of the monthly amount of waste allowed per category or the limit on length of storage allowed. However, loss of category eligibility is not commonly understood to be triggered by violations of ancillary requirements such as the details required for a waste container label. Although every violation of a regulatory requirement is arguably serious, it is important for the EPA to retain some sense of proportionality. A simple error on a container label by someone operating in good faith as a VSQG or SQG does not justify punishment for a plethora of regulatory requirements that a VSQG or SQG would not be expected to even attempt to meet. However, that will be the enforcement exposure for generators if the EPA is not persuaded to modify this aspect of its proposal prior to finalizing the amendment.

If you have any questions regarding the issues discussed in this Alert, please contact the authors, **Daniel Flynn or David A. Roth**.