Client Alert

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EPA's New Draft Hazardous Waste Rules Promote Flexibility, but Devil is in the Details

By Michael Steel, William Tarantino, and Dan Gershwin

On August 31, 2015, EPA released two proposed hazardous waste rules under the Resource Conservation and Recovery Act (RCRA) that will be soon be available for public comment after they are published in the Federal Register. One rule would make significant changes to the basic generator requirements applicable to all businesses. The other would create an entirely new and separate regulatory scheme for pharmaceutical wastes generated at healthcare facilities, including hospitals, clinics, doctor's offices, pharmacies, and retailers of over-the-counter medications. EPA's rationale behind the proposed rules is that RCRA hazardous waste generator regulations, designed for manufacturing, do not fit well with current practices in many industries, particularly the healthcare industry.

The first rule, **the Hazardous Waste Generator Improvements Rule**, is supposed to make the regulations more user-friendly and provide greater flexibility for hazardous waste management. Among other things, this proposed rule would:

- Require a generator to maintain documentation supporting its classification of waste.
- Allow small-quantity generators to retain that status even if on one occasion in a given year they exceed the threshold for large-quantity generators.
- Replace the term "conditionally exempt small quantity generator" with the term "very small quantity generator," which more clearly reflects this category's place at the bottom of the three-tier generator system.
- Allow some "very small quantity generators" to send hazardous waste to "large quantity generators" that are under control of the same parent entity, allowing for organizations with satellite locations to consolidate and more efficiently manage hazardous waste.
- Allow mixing of non-hazardous and hazardous wastes in certain circumstances.

The second rule, **Management Standards for Hazardous Waste Pharmaceuticals**, contains a new set of regulations tailoring the hazardous waste rules to address compliance issues faced by hospitals, pharmacies, and other healthcare facilities. This rule also, however, imposes a significant new prohibition on flushing hazardous waste pharmaceuticals down the toilet or drain, which will apply to the vast majority of healthcare facilities across the country.

The proposed rule attempts to clarify regulations related to management of unused or expired pharmaceuticals through the reverse distribution process. The rule draws a distinction between unused pharmaceuticals that are potentially eligible for manufacturer credits—which will be allowed to be sent to pharmaceutical reverse distributors for processing—and those not expected to be eligible for credits. A "potentially creditable hazardous waste pharmaceutical" is one that has the potential to receive manufacturer's credit and is: (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. The rule would allow the shipment of potentially creditable pharmaceuticals without a hazardous waste manifest or licensed hauler.

Reverse distributors receiving potentially creditable pharmaceuticals would be subject to a new set of regulatory requirements including, among other things:

- Notifying EPA of their status
- Maintaining an inventory of potentially creditable product
- Ensuring site security
- Limiting storage time to 90 days
- Maintaining contingency and emergency plans
- Reporting to EPA receipt of hazardous waste that is not a potentially creditable pharmaceutical
- Maintaining records of shipments received
- Making credit determination within 21 days of receipt

Waste pharmaceuticals that are not creditable may be managed onsite as Universal Wastes and shipped off-site as hazardous wastes.

One key issue for retailers—management of nicotine replacement therapies—is not addressed in the proposed rule, but EPA does acknowledge awareness of the problem and requests comment. The key issue for retailers is that nicotine waste is considered "acutely hazardous," which triggers burdensome Large Quantity Generator requirements when 2.2 pounds are generated in a month. The agency identifies two possible approaches to the problem: either exempt FDA-approved nicotine replacement therapies or exempt such therapies when their nicotine content is below a specific percentage (e.g., 3%). Either approach could provide regulatory relief to retailers unwittingly becoming Large Quantity Generators based on their return processing of nicotine replacement therapy products.

Interested industry groups and individual companies will want to closely monitor the regulatory process and provide targeted comments protecting their interests. Comments on these proposed rules will be due 60 days after their publication in the Federal Register. Morrison & Foerster's team of hazardous waste specialists is here to help guide you through that process and to answer any questions you may have.

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Contact:

Michael Steel
(415) 268-7350
msteel@mofo.com

William Tarantino
(415) 268-6358
wtarantino@mofo.com

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