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EPA to Finalize Hazardous Waste Pharmaceutical Disposal Rule

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The U.S. Environmental Protection Agency is expected to finalize regulatory changes that would provide new requirements for managing hazardous waste pharmaceuticals later this year. This article provides an overview of the proposed regulations, discusses some of the key issues on which the submitted comments have focused, and analyzes some issues that should be addressed by the final rule.

Facilities that generate waste pharmaceutical products are often subject to the onerous hazardous waste requirements imposed by the Resource Conservation and Recovery Act (RCRA), and facilities with even a single shipment of acutely hazardous pharmaceutical waste (1 kg, or 2.2 lbs. in a single month) become subject to RCRA's even more stringent large-quantity generator requirements. The EPA has proposed changes to codify requirements for the common practice of returning these products to manufacturers and to clarify other ambiguities with respect to managing hazardous waste pharmaceuticals (HWP). The EPA hopes that these changes will also reduce the amount of HWP that is poured down drains and often passes through sewer treatment processes, thereby improving water quality in drinking water sources.


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The EPA proposed regulatory changes regarding disposal of HWP on Sept. 25, 2015, 80 F.R. 186, coupled with the more extensive Hazardous Waste Generator Improvements Proposed Rule, which our colleagues Rodd Bender and Brett Slensky addressed in the March 11 edition of The Legal. The comment period for these proposals closed Dec. 24, 2015, and a final rule regarding HWP is expected in 2016.

WHAT IS HWP?

In order to be HWP, a product must first be a hazardous waste under RCRA. Accordingly, it must be a "solid waste," and it must be either a listed hazardous waste or it must exhibit one or more of the characteristics of hazardous waste pursuant to RCRA. The hazardous waste must also then qualify as a "pharmaceutical," which is defined as "any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal, or any chemical or biological product that is intended to affect the structure of the body of a human or other animal." While

the rule's definition of "pharmaceutical" is broadly defined to include "as a rule of thumb" anything with a Drug Facts label, including dietary supplements, delivery devices, and any item containing pharmaceutical residuals, it is worth noting that most devices, supplements, and other over-the-counter items would not constitute "hazardous waste."

REGULATORY CHANGES PROPOSED

Unused pharmaceutical products can often be returned to manufacturers in a process commonly referred to as reverse distribution, and the proposed rule will codify the requirements applicable to managing HWP in such a manner, along with establishing new requirements for HWP that cannot be sent for reverse distribution. To implement these changes, the proposed rule creates two new categories of entities, health care facilities and pharmaceutical reverse distributors, that commonly generate or transport HWP. The proposed rule also bans the practice of discharging HWP to a sewer system and establishes new and relaxed standards for containers with HWP residues to eliminate the practice of rinsing (or triple rinsing) containers to render them "empty" for purposes of RCRA.

HEALTH CARE FACILITIES

The term "health care facility" includes traditional health care facilities like hospitals, clinics and long-term care facilities of a certain size, but also encompasses retailers and pharmacies. Any health care facility that is not a conditionally exempt small-quantity generator (CESQG) will be subject to the new HWP management requirements and must formally declare itself as a health care facility in a one-time submission to the EPA. CESQGs will be allowed to follow the new standards or the CESQG requirements.

The EPA hopes that these changes will also reduce the amount of HWP that is poured down drains and often passes through sewer treatment processes.

Pharmaceutical waste generated by health care facilities will fall into one of three categories: (1) potentially creditable HWP, (2) non-creditable HWP, and (3) non-HWP. Non-HWP will continue to be regulated in accordance with the existing RCRA requirements. Non-creditable HWP may be stored on-site securely in closed containers without a RCRA permit for up to one year, will not trigger biennial reporting requirements, and must be shipped from the health care facility to an RCRA treatment, storage and disposal facility. Finally, potentially creditable HWP—the ultimate target of the new regulations—may be shipped exclusive of other types of wastes through a pharmaceutical reverse distributor, after notifying that facility, for determination of creditability and ultimate return or disposal. Accordingly, when waste pharmaceuticals are generated, health care facilities will need to make an initial determination as to whether that waste qualifies as HWP and whether it is potentially creditable based on the return policies of the pharmaceutical manufacturers from which each item originated. In order to qualify as potentially creditable under the proposed regulation, the HWP must be unused or unadministered and unexpired or less than a year past expiration. The volume of potentially creditable HWP will not count toward a determination of a health care facility's RCRA generator status.

PHARMACEUTICAL REVERSE DISTRIBUTORS

A "pharmaceutical reverse distributor" is "any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit." All facilities that intend to serve in this capacity also must formally declare themselves as such in a one-time submission to the EPA, and certain distribution centers and other supply chain facilities may fall within this category. The management standards for HWP at pharmaceutical reverse distributors are primarily based upon the RCRA standards for large-quantity generators but incorporate additional accumulation, recordkeeping, and notification requirements. For example, potentially-creditable HWP will need to be evaluated within 21 days of arrival at a facility to

determine whether it needs to be shipped to another pharmaceutical reverse distributor for further evaluation, to a pharmaceutical manufacturer for credit, or for disposal, and it ultimately must be shipped offsite within 90 days. A pharmaceutical reverse distributor will also be subject to certain security standards to protect against unauthorized entry to the facility, and reporting will be required if it receives any hazardous waste that it is not authorized to receive, such as noncreditable HWP or non-HWP. A pharmaceutical reverse distributor that receives HWP from a health care facility will be allowed to ship the HWP to another pharmaceutical reverse distributor for further evaluation as to whether it can be returned for credit, and additional accumulation, labeling, reporting and recordkeeping standards will apply once that final evaluation has been made.

COMMENTS TO THE PROPOSED RULE

The EPA received over 200 comments to the proposed rule, and many of those comments focused on issues such as whether HWP should instead be regulated as universal waste, the rule's definitions of key terms (e.g., "pharmaceutical," "health care facility," and "pharmaceutical reverse distributor"), and clarification of training requirements and ambiguities with regard to practical compliance issues within the standards contemplated by the rule.

Many commenters favored the simplicity of the EPA's 2008 proposal that all pharmaceutical waste be treated as universal waste, and it is worth noting that the management standards for noncreditable HWP in the proposed rule are similar to the requirements for universal wastes. Many commenters also focused on the scope of certain definitions that will dictate the breadth of the proposed rule's application. For example, commenters questioned whether the definition of "pharmaceutical," which includes products like dietary supplements, is appropriate. Comments from industry groups often focused on logistical compliance issues that may help streamline compliance upon adoption of the new rule such as the need for further guidance for health care facilities distinguishing between "potentially creditable" and "noncreditable" HWP, clarifying the point of waste generation for purposes of RCRA compliance, and simplifying the proposed requirements regarding the storage and transport of HWP.

POTENTIAL REVISIONS TO BE INCORPORATED INTO FINAL RULE

The EPA has stated that it expects to finalize this rule in 2016, with an anticipated effective date six months after promulgation. Revisions to the rule and the basic framework for HWP management are not expected to be drastic. The EPA did, however, request comment on how certain nicotine products, which often cannot be returned to manufacturers, should be regulated, so it will be interesting to see whether the EPA makes any changes in relation to the comments it received. The EPA should also focus on a couple of key details that will dictate how regulated entities will conform their day-to-day operations to the new requirements. For example, the EPA should consider establishing a detailed procedure for making the two-step evaluation of creditability for each HWP product, as health care facilities must make an initial determination as to "potential" creditability while other facilities will make the final determination as to creditability. The EPA should also consider whether establishing unique accumulation, labeling and recordkeeping requirements for the different types of HWP (unevaluated versus evaluated; potentially creditable versus noncreditable, etc.) will generate unnecessary confusion instead of establishing a more uniform set of regulations.

In addition to the key changes and issues outlined above, the final rule will contain other important provisions that facilities managing HWP will need to be aware of and incorporate into their operational protocols. While intended to clarify and codify the procedures for managing HWP, the revised regulations will also contain a series of pitfalls for the unwary. •

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