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EPA Proposes New Standards for Hazardous Waste Pharmaceuticals

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The Environmental Protection Agency (EPA) released its proposed Management Standards for Hazardous Waste Pharmaceuticals Rule. If finalized, it will create an entirely new subpart in the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations to regulate hazardous waste pharmaceuticals (HWPs) that are generated by healthcare facilities as well as those HWPs managed by pharmaceutical reverse distributors. Healthcare facilities that are small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors—regardless of the quantity of HWPs generated per month—will be required to manage HWPs under the new Subpart P of 40 CFR Part 266.

Who Will the Rule Apply To?

Healthcare facilities

As anticipated, the proposed rule contains many broad definitions aimed at leveling the regulatory playing field and easing industry compliance. The rule applies broadly to "healthcare facilities," which the EPA has defined to include entities that provide medical care, such as hospitals, doctors, dentists and long-term care facilities. Retailers of prescription and over-the-counter pharmaceuticals are also considered healthcare facilities. Therefore, the same standard for management of HWPs will apply in a hospital as in a retail or Internet drug store pharmacy.

Pharmaceutical reverse distributors

The second type of entity that the rule would apply to are "pharmaceutical reverse distributors," which is defined by the EPA as "any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit." It includes drug manufacturers and wholesalers if they fall within this definition. While Subpart P of 40 CFR Part 266 creates this new entity, the definition largely reflects the already existing pharmaceutical reverse distributors in the industry.

What Are Hazardous Waste Pharmaceuticals?

The proposed rule applies to hazardous waste pharmaceuticals, which hinges on a definition of "pharmaceutical" that is broader than that of the Federal Food, Drug, and Cosmetics Act (FFDCA). In addition to including drugs (prescription

and over-the-counter) as defined in the FFDCA, it also includes dietary supplements, residues of pharmaceuticals in containers, personal protective equipment contaminated with pharmaceutical residue and cleanup material from the spills of pharmaceuticals. It does not include laboratory waste. While the definition extends to delivery devices that have the primary purpose of delivering or dispensing a pharmaceutical, the definition does not include sharps (e.g., needles from IV bags or syringes), which are regulated on the state level as medical waste and placed in sharps containers. This broad definition enables healthcare facilities to manage hazardous drugs, dietary supplements and equipment, materials and devices related to the administration of the items under the same, simplified standard.

If a pharmaceutical meets the current definition of hazardous waste, and it is generated by a healthcare facility as defined in the proposed regulations, it is included in the proposed rule with the exception of the following noteworthy conditional exclusions:

- Residues of HWPs in fully dispensed syringes, if the pharmaceutical was administered to the patient, the syringe is placed in a sharps container, and the sharp is managed in accord with medical waste regulations;
- Unit-dose containers and dispensing bottles and vials up to 1 liter or 1,000 pills, if all the pharmaceuticals have been removed using commonly employed practices; and
- Controlled substances, if combusted at a permitted or interim status hazardous waste incinerator or a permitted municipal waste incinerator.

It has been challenging for the industry to manage containers—which previously had to be "RCRA empty" to avoid management as hazardous waste—and hazardous controlled substance waste, which is also subject to Drug Enforcement Administration regulation. If the proposed rule is finalized, these items, if the above conditions are met, will no longer be considered hazardous waste.

How Does the Rule Ease Regulatory Burdens for Healthcare Facilities?

The proposed RCRA scheme for the management of HWPs will significantly ease the compliance burden for healthcare facilities because, in the reverse distribution context, there will be a low compliance burden for a "potentially creditable hazardous waste pharmaceutical" and a moderate compliance burden for a "non-creditable hazardous waste pharmaceutical." Additionally, SQGs and LQGs no longer need to count HWPs towards the facility's hazardous waste generator calculations. Removing HWPs, especially acute HWPs, may enable healthcare facilities to more easily shift generator categories and be subject to generator requirements under RCRA that are more appropriate for healthcare facilities.

Management of potentially creditable hazardous waste pharmaceuticals

A potentially creditable HWP must meet three criteria. It must:

1. Have the potential to receive manufacturer's credit;
2. be unused or unadministered; and
3. be unexpired or less than one year past the expiration date.

The term does not include "evaluated hazardous waste pharmaceuticals" (which are defined in the proposed rule as those drugs a pharmaceutical reverse distributor has already evaluated for credit), residues of pharmaceuticals remaining in containers, contaminated personal protective equipment and cleanup material from the spills of pharmaceuticals. Potentially creditable HWPs—including "partials" (which are defined as opened containers with some content removed)—can be sent to a reverse distributor, in accordance with certain standards.

Under the proposed regulations, potentially creditable HWPs would be considered solid waste at the healthcare facility, which would be considered to be the "point of generation." Note that this is a significant change from the EPA's current position, which is that such pharmaceuticals become waste *after* a reverse distributor evaluates it for credit and makes a disposal determination. Under the proposed rule, at healthcare facilities there are no accumulation time limits, container requirements or labeling for potentially creditable HWPs. Healthcare facilities can ship them via common carrier in compliance with Department of Transportation requirements to a pharmaceutical reverse distributor so long as advance notice is provided and a delivery confirmation mechanism is used.

Management of non-creditable hazardous waste pharmaceuticals

Healthcare facilities are subject to more rigorous requirements for the management of non-creditable HWPs, yet these are still far less onerous than current regulation under 40 CFR Part 262. This waste can be accumulated in containers in a convenient manner and merely labeled as "hazardous pharmaceutical waste." This eases the burden on healthcare workers managing waste from formularies with thousands of items. Such waste can accumulate onsite for up to a year, without quantity restrictions, so that healthcare facilities can focus on providing healthcare to patients and schedule pickups when the load size is large enough to be cost-effective. Such pharmaceuticals must still be transported as hazardous waste and sent to a hazardous waste RCRA interim status or permitted facility. In other words, they cannot be sent to a pharmaceutical reverse distributor.

How Does the Proposed Rule Change Management Practices for Pharmaceutical Reverse Distributors?

Subpart P creates a new category of hazardous waste entities: pharmaceutical reverse distributors. In the proposed regulations, the EPA takes a middle-of-the-road approach that applies to all pharmaceutical reverse distributors, no matter what quantity of potentially creditable HWPs it receives. The rule, if finalized, would enable pharmaceutical reverse distributors to manage HWPs under reduced accumulation, storage and labeling requirements. However, new inventory and 21-day processing requirements are triggered in this rule, which may require significant procedural and technological updates at some pharmaceutical reverse distributors.

Will the Proposed Rule Level the State Playing Field?

Unfortunately, no. As the proposed rule is more stringent than existing federal standards, states with authorized RCRA programs will be required to modify their programs to adopt the amendments. When a state adopts the new Subpart P, if elements of the state program are more stringent, the state will have the option of retaining those more stringent elements. States also have the option of adding elements to their programs that are more stringent or broader in scope than the new subpart. No state will be able to add HWPs to their universal waste programs (non-hazardous pharmaceuticals, on the other hand, may be added).

Therefore, while the proposed rule does much to ease compliance burdens and level the playing field through broad definitions of pharmaceutical and hazardous waste, the uncertainty of state-by-state regulation in this area remains. After publication in the *Federal Register*, the EPA will be accepting comments on the rule for 60 days.

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