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EPA's Proposed Rule Regulating Pharmaceuticals Under RCRA

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Environmental

EPA proposed a rule to regulate "hazardous waste pharmaceuticals" – which include a number of FDA-approved drugs – under the Resource Conservation and Recovery Act ("RCRA") on August 31, 2015.[1] RCRA was designed to regulate treatment and disposal of traditional hazardous chemical wastes, and is not tailored to pharmaceuticals. The proposed rule would impose obligations primarily on two categories of regulated entities: (1) healthcare facilities and providers, broadly defined, and (2) entities involved in the reverse-distribution of pharmaceuticals. The applicability of the proposed rule to such entities turns on the definition of "hazardous waste pharmaceutical" and "pharmaceutical," both terms that EPA proposes to define for the first time in this rulemaking. The proposed rule would also apply to pharmaceuticals intended for use on animals as well as veterinary facilities.

The proposed rule would impose a substantial number of requirements on regulated entities relating to storage, management, transportation, and reporting of hazardous waste pharmaceuticals. These requirements are generally more stringent than those required by current law, and the proposal makes clear that EPA intends to become more actively involved in monitoring compliance with the proposed pharmaceutical-specific rule than it historically has been with respect to the general RCRA hazardous waste rules as applied to pharmaceuticals.

EPA has solicited comments on the proposed rule, and provided for a 60-day public comment period after publication in the Federal Register. The proposed rule amounts to a comprehensive new regime for regulating waste pharmaceuticals as hazardous waste under RCRA, a system that was never designed for this purpose. Affected entities are encouraged to review and consider commenting on the proposed rule.

EPA has also requested comments on related items not directly part of this rulemaking. Most notably, EPA has requested input as to criteria and procedures it should use to identify additional pharmaceuticals that should be deemed hazardous and thus subject to the proposed rule when discarded, an issue that may be of interest to pharmaceutical manufacturers. While EPA states that any action on this front would be "part of a separate, proposed rulemaking in the future," it nevertheless has solicited comments on this issue, which it likely will consider in shaping any upcoming proposal. This unusual two step procedure creates a valuable opportunity to influence the agency's thinking at an early stage. Unless the pharmaceutical industry suggests a better practical alternative, EPA may well default to its standard toxicity characteristic leaching procedure (TCLP) which was designed to simulate chemicals leaching

[1] *Available at* http://www2.epa.gov/hwgenerators/pre-publication-copy-management-standards-hazardous-waste-pharmaceuticals-proposed-rule

from a landfill and may not be well adapted to identify what pharmaceutical wastes should be managed and treated as hazardous wastes.

Background

Pharmaceuticals that either bear certain defined characteristics (i.e., they are ignitable, toxic, corrosive, or reactive), or contain chemicals that are on lists published by EPA, have historically been subject to regulation as hazardous wastes under RCRA when disposed of, in the same fashion as any other type of hazardous waste. However, the general RCRA rules are a poor fit for managing pharmaceuticals, and this area has typically not been a priority for EPA. In part in response to such criticisms, in 2008 EPA proposed to regulate pharmaceuticals under its "Universal Waste" program. However, public comments disagreed with that approach, in large measure because of its inconsistency with the extant reverse-distribution system for unused pharmaceuticals. The proposal was never finalized, and is formally withdrawn in this proposed rule. EPA was also criticized in a 2012 report by its Inspector General for not having a nationally consistent approach for implementing RCRA with regards to pharmaceuticals, and this proposal is in part a response to that criticism. EPA is now proposing a new subpart to the RCRA regulations that would apply solely to hazardous waste pharmaceuticals.

Key Provisions of the Proposed Rule

I. Definition and Subcategorization of "hazardous waste pharmaceuticals"

The proposed rule would broadly define a pharmaceutical as not just including drugs as defined by the Federal Food, Drug, and Cosmetic Act, but also dietary supplements. 40 C.F.R. § 266.500 (proposed). The definition also includes animal drugs. Pharmaceuticals are considered hazardous if they bear a RCRA characteristic or are an EPA-listed waste; EPA estimates that 2-6 percent of reverse-distributed pharmaceuticals qualify as hazardous under the current definition (and EPA is considering expanding the categories of hazardous drugs), amounting to approximately 36,000 tons of hazardous waste pharmaceuticals generated each year. Proposed Rule at 159, 211.

Hazardous pharmaceuticals would be considered waste and subject to the proposed rule, when they are "discarded" – i.e., a decision is made to dispose of or recycle them. Proposed Rule at 35. Notably, EPA has proposed that pharmaceuticals are "discarded" as soon as a decision is made to return them to reverse distributors. EPA acknowledges that this is a shift from how it currently treats pharmaceuticals, which are not considered discarded (and so are not considered a "waste") if they are still potentially eligible for manufacturer credit through the reverse distribution system. Proposed Rule at 99-100. As a result, under this new proposed interpretation, "once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste" and so subject to regulation under the proposed rule. Proposed Rule at 102.

Hazardous waste pharmaceuticals would be subdivided into three categories, based on their relationship to the reverse distribution system. First, "potentially creditable" hazardous waste pharmaceuticals would be pharmaceuticals that are potentially eligible to receive a manufacturer's credit, are unused, and are unexpired or less than one year past the expiration date. 40 C.F.R. § 266.500 (proposed). This category is subject to the least-stringent set of regulations in the proposed rule.

Second, there are "non-creditable hazardous waste pharmaceuticals," consisting of those pharmaceuticals that are not potentially creditable. These are subject to more stringent regulations (including collection, labelling, transportation, reporting, and recordkeeping requirements).

Finally, there are "evaluated hazardous waste pharmaceuticals," which are hazardous waste pharmaceuticals that were once potentially creditable, but that have since been evaluated and will not be sent on to another reverse distributor. These are subject to similar requirements as non-creditable pharmaceuticals.

As is discussed in more detail below, EPA is also suggesting that it may initiate a separate rulemaking to expand the category of hazardous waste pharmaceuticals to include additional pharmaceuticals, and invites comments on that issue.

II. Regulated Entities & Substantive Regulatory Requirements

The proposed rule regulates two sets of entities: healthcare facilities and reverse distributors.

Healthcare facilities are very broadly defined to include hospitals, pharmacies, retailers of over-the-counter medicines, and veterinary facilities, among others. 40 C.F.R. § 266.500 (proposed). Under the rule as currently proposed, pharmaceutical manufacturers, wholesalers, or other distributors would not be deemed to be healthcare facilities. Proposed Rule at 42.

Healthcare facilities are subject to a number of standards for managing hazardous waste pharmaceuticals, including training of employees, evaluating pharmaceuticals to determine if they are hazardous, maximum periods of time for accumulating hazardous waste pharmaceuticals, and manifest and labelling requirements for shipments of hazardous waste pharmaceuticals off-site. 40 C.F.R. § 266.502, 508 (proposed). Many of these requirements only apply to non-creditable hazardous waste pharmaceuticals. 40 C.F.R. § 266.503, 509 (proposed).

Pharmaceutical reverse distributors are defined as "any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit," and includes manufacturers if they meet this definition. 40 C.F.R. § 266.500 (proposed). This definition is broader than the DEA definition of a reverse distributor. Proposed Rule at 45. Like healthcare facilities, reverse distributors are subject to a variety of requirements, such as labelling, manifesting, reporting, maximum accumulation, and recordkeeping requirements, and such requirements are relaxed regarding potentially creditable pharmaceuticals.

The proposed rule would also ban all healthcare facilities and reverse distributors from discharging hazardous waste pharmaceuticals to sewer systems. 40 C.F.R. § 266.505 (proposed).

III. Interaction with DEA's Controlled Substances Regime

EPA proposes to exempt hazardous waste pharmaceuticals that are listed on a schedule of controlled substances by the DEA, so long as the hazardous waste pharmaceuticals are managed in compliance with all applicable DEA regulations. 40 C.F.R. § 266.506 (proposed).

IV. Effect on State Programs

EPA has taken the position that its proposed rule is considered "to be more stringent than the current federal standards" and so states authorized to implement RCRA will be required to modify their programs to adopt the amendments. Proposed Rule at 208. States remain free to impose more stringent requirements. Two states (Michigan and Florida) currently have programs regulating hazardous waste pharmaceuticals as universal waste; EPA is proposing that they be required to modify their programs to adopt an approach at least as stringent as the proposed rule. Proposed Rule at 208-09.

The proposed rule appears unlikely to directly impact extant pharmaceutical take-back programs, because hazardous waste pharmaceuticals generated by households (and by all entities other than healthcare facilities and reverse distributors) are exempt from the rules. 40 C.F.R. § 266.501(f) (proposed); *see also* Proposed Rule at 14 ("The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs.").

Additional Issues on Which EPA Solicits Comments

I. EPA Identification of Additional Hazardous Waste Pharmaceuticals

EPA has indicated that it plans to identify and review existing pharmaceuticals to determine if they should be regulated as hazardous waste, and seeks "input on the best course of action concerning regulation of additional pharmaceuticals as hazardous waste." Proposed Rule at 197. It also seeks input on what criteria should be used to decide whether to list pharmaceuticals as hazardous waste. Proposed Rule at 198. These are potentially significant determinations for pharmaceutical manufacturers, whose products would, if listed, be subject to regulation as hazardous waste pharmaceuticals in accordance with these proposed rules. While EPA is seeking input on this issue, it expressly notes that it is not proposing any change at this time, and any such proposal would be the subject of a separate rulemaking.

II. Comments on EPA's Efforts to Amend the Hazardous Waste Listing for Nicotine

EPA currently lists nicotine as a hazardous waste, and is seeking ways to amend the listing so that certain smoking cessation products or low-concentration nicotine products would not be listed as hazardous waste. Proposed Rule at 203-05. This would be a potentially significant change for those who manufacture, distribute, or sell pharmaceutical products containing nicotine.

Conclusion

EPA's proposed rule has wide-ranging implications for pharmaceutical manufacturers and for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Affected entities should carefully review the proposed rule and consider providing comments on the issues raised by the proposal. As a general matter, judicial challenges to the rule will be limited to the issues raised in comments.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Environmental practice group:

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