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EPA's Final Hazardous Waste Pharmaceuticals Rule Has Significant Implications for Pharmaceuticals and Product Recalls

January 8, 2019

Environmental/Life Sciences/Product Safety

Under the Resource Conservation and Recovery Act ("RCRA"), waste deemed "hazardous waste" is subject to onerous regulatory requirements, including: a 90-day storage limitation, shipment to a RCRA-permitted facility for disposal, and tracking from generation to disposal via a manifest system. As a result, disposing of RCRA waste typically costs roughly 5-10 times as much as non-RCRA waste. Moreover, RCRA "hazardous waste" can include a wide variety of products not typically thought of as falling within that category, such as pharmaceuticals, airbags, electronics, and aerosol cans. Against this backdrop, EPA's recently finalized rule regulating "hazardous waste pharmaceuticals" under RCRA has major implications for pharmaceuticals and other types of products.

The rule adopts a specialized regime governing the management of certain hazardous waste pharmaceuticals that are discarded by healthcare facilities or managed by so-called "reverse" distributors—i.e., entities that coordinate return of unwanted, unused, or expired pharmaceuticals, which may be eligible for manufacturer credit when returned. The new regime is generally less onerous than EPA's previous RCRA rules, but will nevertheless pose compliance challenges because EPA has generally not enforced RCRA in the context of pharmaceuticals. EPA and states are likely to significantly increase enforcement efforts in this area once the rule becomes final in six months.

EPA's rule is also significant for product recalls, including outside of the pharmaceutical sector. The rule endorses an emerging EPA policy, including codifying a decision relating to airbags that Covington attorneys initially secured from EPA, that recalled products are ***not*** waste under RCRA if they are subject to judicially or federal agency-imposed preservation obligations. EPA also confirmed its airbag ruling in a recent interim final rule addressing recalled airbags. 83 Fed. Reg. 61,552 (Nov. 30, 2018). Accordingly, companies engaged in recalls of products potentially subject to RCRA's hazardous waste requirements may be able to avoid the application of RCRA by appropriately coordinating with the agency overseeing the recall as well as EPA.

I. Background

Pharmaceuticals that either bear certain defined characteristics (i.e., 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 EPA's general RCRA rules when disposed of. 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, and that rule was never finalized. EPA proposed in 2015 a new subpart of the RCRA regulations that would apply solely to hazardous waste pharmaceuticals, which it has now finalized.

II. Implications of the Rule for Pharmaceuticals

- **Companies Must Determine If a Pharmaceutical Is a "Hazardous Waste Pharmaceutical."** EPA's final rule has not significantly changed the definition of pharmaceuticals that are considered hazardous waste. The rule defines a "hazardous waste pharmaceutical" as a waste that exhibits a characteristic of hazardousness under RCRA or that is a listed waste under RCRA, which is consistent with RCRA's long-standing definition of hazardous waste. 40 C.F.R. § 266.500. However, a "pharmaceutical" for purposes of this rule is defined broadly, and includes not only drugs but also dietary supplements, e-cigarettes, and liquid nicotine.
- **Companies Must Then Determine What Specific Requirements Apply to Their Pharmaceuticals, Based On EPA's New Five-Tier Scheme.** EPA's rule creates a five-tier scheme governing hazardous waste pharmaceuticals. Prescription hazardous waste pharmaceuticals that are "*potentially creditable*" by manufacturers are subject to relatively modest requirements. Once those pharmaceuticals are evaluated by a reverse distributor, they are considered "*evaluated hazardous waste pharmaceuticals*" and must be shipped for disposal. Prescription hazardous waste pharmaceuticals that are *non-creditable* are more rigorously regulated, and are subject to requirements only somewhat less onerous than the traditional RCRA requirements. Finally, *nonprescription pharmaceuticals* are generally not considered hazardous waste. However, if there is no reasonable expectation that such pharmaceuticals will be reused or reclaimed, then they will be considered hazardous waste.

III. Implications of the Rule for Recalls

- **Companies Should Take Steps to Ensure FDA/CPSC Recalls of Pharmaceuticals Are Exempt from RCRA.** Pharmaceuticals subject to FDA or CPSC recall procedures are exempt from RCRA, until and unless the FDA or CPSC approves their plan of destruction. At that point, RCRA's requirements will immediately apply, such as RCRA's 90-day limit on storing hazardous waste without a RCRA permit. Accordingly, in large-volume recalls industry participants should work with FDA/CPSC to have the agencies allow disposal of the recalled items on a phased, rolling basis, rather than all at once. Such coordination will ensure that recalling entities can dispose of the recalled hazardous waste pharmaceuticals without running afoul of RCRA's requirements (for example, not to store hazardous waste for more than 90 days). Covington's cross-disciplinary team of product recall, FDA, and environmental lawyers has successfully navigated this issue in connection with numerous recalls.
- **Companies Should Take Steps to Ensure Any Drug Take-Back Programs Are Exempt from RCRA.** Hazardous waste pharmaceuticals that are collected in take-back programs in conformity with DEA requirements are generally exempt from the rule. Companies managing such take-back programs should ensure that the applicable EPA and DEA requirements are satisfied so those pharmaceuticals are not subject to RCRA.

- **Recall Implications for Other Products.**
  - **Codified EPA Policy That Recalled Products Are Not Subject to RCRA While Subject to Preservation Requirements.** EPA's rule acknowledges that pharmaceuticals stored pursuant to a preservation order, investigation, or judicial proceeding are exempt from RCRA until a decision is made to discard the pharmaceutical. 40 C.F.R. § 266.501(g)(5). This EPA exception builds on previous EPA guidance and codifies a broader EPA policy not limited to pharmaceuticals. For example, in June 2017 Covington attorneys (including the undersigned) secured from EPA a favorable determination that recalled Takata air bag inflators "are not subject to RCRA Subtitle C regulatory requirements while they are being held under the 2015 DOT Preservation Order. This is because EPA does not consider airbag inflators or other explosives to be 'discarded' and therefore subject to the hazardous waste regulations while they are being stored pending judicial proceedings or investigations." EPA specifically mentioned this 2017 determination in its final rule, and noted that it will evaluate recalls "managed by other federal agencies," such as the National Highway Traffic Safety Administration, on a "case by case basis." Accordingly, EPA has in this rule cemented the principle that recalled products subject to a preservation order or other preservation obligation are not subject to RCRA, but are potentially subject to RCRA once the preservation obligation is lifted and the recalled item may be destroyed.
  - **Entities Should Structure Recalls to Minimize RCRA Compliance Obligations.** Consistent with EPA's policy, entities conducting recalls should evaluate whether their recalled products could be subject to RCRA. If so, they should work with the agency overseeing the recall to clarify formal preservation obligations, such that RCRA would not apply until recalled products are "released" from the recall and ready for disposal, and a disposal plan is in place. Covington has successfully coordinated such strategies in the past, and it is important to have a multi-disciplinary legal team that can work with both the recalling agency as well as EPA to secure an optimal outcome.
  - **Products That Can Be Recycled or Reclaimed Are Not Subject to RCRA.** EPA continues to acknowledge that if the recalled item may be reused, recycled, or reclaimed, it is not subject to the hazardous waste rules. EPA explains that pharmaceuticals are "not solid waste" if they are "legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed." 40 C.F.R. § 266.501(g)(1). Thus, if companies can structure their recalls legitimately to reuse, recycle, or reclaim their recalled products, that is a potential avenue to manage recalled products without subjecting them to RCRA.

IV. Likely Increase in Enforcement

- **Traditional Lack of EPA RCRA Enforcement Regarding Pharmaceuticals.** In part due to the awkward fit between the standard RCRA regulations and hazardous waste pharmaceuticals, EPA has historically been relatively inactive in enforcing RCRA regulations regarding pharmaceuticals. For example, a 2012 EPA Office of the Inspector General Report noted that despite what the report characterized as "widespread noncompliance in the health care industry," EPA's RCRA regulations were not being enforced by the agency. The report also noted that many more pharmaceuticals than appeared on EPA's official lists—over 100—likely also qualified as hazardous waste.

- **EPA & States Likely to Seek "Return on Investment" Via Enforcement.** EPA has over the last decade invested significant resources in fashioning a rule tailored to pharmaceuticals, and has made some adjustments and compromises with the industry to achieve a rule that is a better fit with pharmaceuticals. Having made this investment, EPA is likely to increase enforcement efforts if healthcare facilities, reverse distributors, entities conducting recalls, and others in the pharmaceutical sector do not come into compliance. EPA is also likely to evaluate additional pharmaceuticals to determine whether by virtue of their chemical composition they are considered hazardous waste when discarded. Increased enforcement of these new rules would be consistent with the Trump EPA's "return to core mission," which is focused in part on addressing hazardous waste issues.
- **Companies Have Six Months to Come into Compliance.** The rule will become effective 6 months after publication in the Federal Register. Most states have delegated RCRA authority and so will be required to modify their programs to adopt these changes, and may add more stringent or broader requirements. Florida and Michigan will also be required to remove hazardous waste pharmaceuticals from their universal waste programs. Market participants should use this time to prepare to comply with this rule, and should work with counsel to ensure compliance with RCRA's sometimes arcane requirements. They should also conduct reviews of their reverse-distribution contracts and related policies to ensure that they are not unnecessarily causing more pharmaceuticals to fall into the category of hazardous waste. Particularly in light of RCRA's $37,500 per day penalty for each violation and EPA's likely upcoming enforcement efforts, the importance of ensuring compliance should not be underestimated.

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

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