EPA's Final Hazardous Waste Pharmaceuticals Rule

Implications for California, Reverse Distribution and Reverse Logistics

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Roadmap

- History of Rule Relative to California
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History of Rule Relative to California

- **Rationale for the Final Rule:** ***The impetus behind this final rule is to address the various concerns raised by stakeholders regarding the difficulty in implementing the RCRA Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities.*** **Page 15, Pre-Publication Copy, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (December 11, 2018)("pre-publication version new Rule")**

- ***The third goal [of the new Rule] is to clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired [prescription] pharmaceuticals, known as reverse distribution*****. Page 19, pre-publication version .**

- ***A number of states have taken enforcement actions against retailers that have raised awareness about the reverse distribution of pharmaceuticals. In particular, California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations*****. Id.**

History of Rule Relative to California

- ***In at least two settlement agreements, California directed the defendants (CVS and Costco) to "initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, The U.S. Food and Drug Administration, and the DTSC, and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of non-dispensable pharmaceuticals, including OTC medications, through 'reverse distribution."*** **Page 20, Id.**

- ***Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems*.** **Id.**

- ***The California legislature directed DTSC to convene a Retail Waste Working Group with the aim of developing recommendations to the legislature for how to address many retail waste issues, including reverse distribution/logistics. *** The group's work has highlighted the need for a national policy in this area.*** **Id.**

Recap of Key Provisions

- **Creates a new Subpart P to 40 CFR Part 266 for management of hazardous waste pharmaceuticals.**
  - **New unique management standards specific to healthcare facilities, including retail operations, separate from traditional VSQG/SQG/LQG requirements.**

- **Who:**
  - **“Healthcare facilities” and “Reverse distributors”**

- **What:**
  - **Hazardous waste pharmaceuticals, but does not directly address non-pharmaceutical hazardous waste; non-hazardous pharmaceutical waste; or OSHA regulated “hazardous drugs.”**
  - **A healthcare facility may choose to manage its non-hazardous waste prescription pharmaceuticals under Subpart P (to avoid the need to determine which prescription pharmaceuticals are haz and which are non-haz).**

- **Non-Pharmaceutical Retail Items: Preamble establishes guidance regarding retail items, including over-the-counter medications and other unsold consumer products, but does not change the definition of “solid waste” or point of generation for these products sent to a revese logistics facility.**

Retail Strategy Guidance in Preamble

- **In addition to the new regulations specific to pharmaceutical hazardous waste, EPA uses the preamble to establish guidance regarding non-pharmaceutical retail waste.**
- **Fulfills EPA's commitment in its Retail Strategy**
- **EPA's overall position is that retail items that are sent to a reverse logistics facility (distinguished from reverse distributors) are not waste at the healthcare facility if there is a reasonable expectation of being legitimately used/reused or reclaimed.**

Retail Strategy Guidance in Preamble

- **EPA addresses six issues related to nonprescription pharmaceuticals and non-pharmaceutical retail reverse logistics.**

1. **EPA recognizes that unsold retail items returned to a manufacturer or vendor have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed, as compared to the revese distribution of prescription pharmaceuticals.**
2. **Expired nonprescription pharmaceuticals and unsold retail items are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed and the FDA allows for the donation of some expired products.**
3. **If a manufacturer has clearly established a "destroy disposition," the item is hazardous waste at the healthcare facility or retail store.**
4. **Credit is not relevant to the waste status for unsold retail items. The decision point on whether a retail item is a solid waste is when the decision has been made to discard the material.**
5. **RCRA does not apply to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall overseen by FDA or CPSC.**
6. **Broken, damaged, or leaking. EPA acknowledges uncertainty surrounding when an item is broken, damaged, or leaking. E.g., if the outer cardboard box is damaged, but the vials containing nonprescription pharmaceuticals are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.**

Pages 66-73 of Pre-publication version preamble.

Effective Date and State implementation

- **Effective at the federal level six months after publication in the Federal Register.**
- **Effective in states without an authorized RCRA program (Alaska, Iowa, Puerto Rico) six months after publication in the Federal Register.**
- **Sewer ban is effective six months after publication in the Federal Register for all states – regardless of whether the states have their own RCRA program.**
- **For the remaining issues addressed in the Final rule, states with authorized RCRA programs must adopt portions of the Final rule that are more stringent than existing federal regulations.**
  - **Overall, EPA says Subpart P is more stringent and that states must adopt. However, EPA notes that states may choose to keep components of state programs that are more stringent than the Subpart P requirements.**
  - **The exemption for OTC NRT is less stringent than existing hazardous waste regulations, and thus states may choose whether to adopt.**

How Will Rule Potentially Dovetail with California Law

- **Sewer Ban for Disposal of All Hazardous Waste Pharmaceuticals by Healthcare Facilities and Reverse Distributors**
- **FDA-Approved, OTC Nicotine Replacement Therapy (NRT) Exempt from P075 Listing**
- **Certain Empty P-Listed Containers Are Considered Empty and Residue Is RCRA Exempt**
- **Recall Strategy Approved by the FDA and CPSC RCRA Exempt**

How Will Rule Potentially Conflict with California Law

- **RCRA Exemptions in Rule that Are Less Stringent than Current California Law May Not Be Adopted**
- **Prescription Non-RCRA Pharmaceuticals managed under Subpart P and the California Medical Waste Management Act**
- **Non-prescription Non-RCRA Pharmaceuticals managed under Subpart P and the California Medical Waste Management Act**
- **Non-pharmaceutical Retail Hazardous Waste Managed Under EPA Policy per the Rule's Preamble**

Implications for Reverse Distribution and Reverse Logistics

- **Will California align with EPA's goals for national chains and pharmaceutical supply chain?**
- **Will California align with EPA's policy regarding unsold consumer products and retail waste?**
- **If yes, what changes in law or policy likely needed?**
- **If no, what are the implications for consumers, healthcare, business and the environment?**

Path Forward

- **Collaborative Negotiation by Stakeholders**
- **Prioritization**
- **Leadership**
- **Engagement**

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