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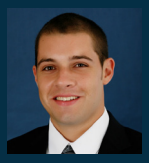
EPA Finalizes Rule Addressing Management of Hazardous Waste Pharmaceuticals – But Is It Helpful?

Authors and Contributors:

Andrew N. Davis, Ph.D.
(860) 251-5839
adavis@goodwin.com

Aaron D. Levy
(860) 251-5893
alevy@goodwin.com



Alfredo G. Fernández
(860) 251-5353
afernandez@goodwin.com

Kristie A. Beahm
(860) 251-5334
kbeahm@goodwin.com

www.shipmangoodwin.com

The U.S. Environmental Protection Agency ("EPA") recently finalized a long-awaited rule specifically addressing the management and disposal of hazardous waste pharmaceuticals by "healthcare facilities" and "pharmaceutical reverse distributors." The rule, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," which EPA Acting Administrator Andrew Wheeler signed on December 11, 2018 (the "Final Rule"), aims to streamline the federal requirements for managing hazardous waste pharmaceuticals in a way that is more in line with the operations of hospitals, pharmacies and other healthcare providers (as opposed to the industrial manufacturing sector) while balancing EPA's mission to protect human health and the environment.[1]

Although the Final Rule is focused only on those pharmaceuticals that qualify as "hazardous waste" under the Resource Conservation and Recovery Act ("RCRA"), the rule has implications for all "healthcare facilities," including: pharmacies, hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long term care facilities, and veterinary clinics. The Final Rule also specifically addresses "reverse distributors," i.e., third-party logistics providers that assist healthcare facilities with managing and returning their unused and expired pharmaceuticals to pharmaceutical manufacturers in exchange for a manufacturer credit.

Highlights of the Final Rule

- Confirms EPA's prior policy and stated regulatory interpretation that:
  - prescription pharmaceuticals moving through reverse distribution are considered "waste" at the healthcare facility level (as opposed to when they arrive at the reverse distributor, pharmaceutical manufacturer or hazardous waste disposal site); and,
  - nonprescription pharmaceuticals and other unsold retail items moving through reverse distribution are not considered solid wastes when the healthcare facility transfers materials to a reverse distributor as long as there is a "reasonable expectation" the product(s) will be used/reused or reclaimed;
- Specifically prohibits healthcare facilities from disposing of hazardous waste pharmaceuticals "down the drain";
- Exempts healthcare facilities from becoming "large quantity generators" ("LQGs") under RCRA when generating more than one (1) kilogram of acutely hazardous

1 The Final Rule will be effective at the federal level six months after it is published in the Federal Register, which has not yet occurred, and will be codified at 40 CFR Parts 261, 262, 264, 265, 266, 268, 270, and 273.

waste pharmaceuticals in a single month, thereby alleviating the need to comply with otherwise onerous RCRA requirements applicable to LQGs (e.g., reporting and record keeping);

- Allows healthcare facilities to accumulate hazardous waste pharmaceuticals on site without a RCRA permit for up to one (1) year; and

- Exempts FDA-approved over-the-counter nicotine replacement therapies from regulation as RCRA hazardous wastes.

Impacts of the Rule to Healthcare Facilities

The Final Rule is intended to provide greater flexibility and clarification for healthcare facilities and reverse distributors handling pharmaceuticals, however it also imposes new restrictions and requirements concerning notification, training, labeling, reporting and record-keeping requirements that will affect the day-to-day operations of many companies in the healthcare and pharmaceutical industries.

In addition, failure to comply with EPA's regulations can lead to enforcement and the imposition of penalties and other sanctions, so it is important that potentially affected entities become familiar with the requirements of the Final Rule, evaluate if and how the Final Rule may impact their business and operations (e.g., by reviewing their pharmacies' formularies and confirming what pharmaceuticals would be considered hazardous waste when discarded or processed through reverse distribution), and revise/update (or if necessary, develop) their hazardous waste (and pharmaceutical waste) management and compliance programs.

As a best management practice, potentially affected entities should continue to ensure they have appropriate internal and external support with respect to environmental, health and safety compliance issues generally, and confirm that appropriate contractual protections are in place in their agreements with vendors and service providers.

Lastly, certain states may have different and, in some cases, stricter requirements than those imposed at the federal level. Accordingly, healthcare facilities (like all regulated entities) should ensure their operations not only comply with the Final Rule, but any additional applicable state regulatory programs as well.

Ultimately, while the Final Rule is a step in the right direction to ease the regulatory burden on healthcare facilities, understanding and confirming what practices and procedures need to be implemented, revised or confirmed at the facility level to ensure compliance going forward will be critical to answer the question of whether the rule is helpful to the regulated community.

Questions or Information:

For further information, please contact: Andrew Davis at (860) 251-5839 or adavis@goodwin.com, Aaron Levy at (860) 251-5893 or alevy@goodwin.com, Alfredo Fernández at (860) 251-5353 or afernandez@goodwin.com, or Kristie Beahm at (860) 251-5334 or kbeahm@goodwin.com.

289 Greenwich Avenue
Greenwich, CT 06830-6595
203-869-5600

One Constitution Plaza
Hartford, CT 06103-1919
860-251-5000

265 Church Street - Suite 1207
New Haven, CT 06510-7013
203-836-2801

400 Park Avenue - Fifth Floor
New York, NY 10022-4406
212-376-3010

300 Atlantic Street
Stamford, CT 06901-3522
203-324-8100

1875 K St., NW - Suite 600
Washington, DC 20006-1251
202-469-7750

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