October 14, 2015

EPA Proposes Long-Awaited Rule Addressing Management of Hazardous Waste Pharmaceuticals by Healthcare Facilities

Author:

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

The U.S. Environmental Protection Agency ("EPA") recently issued a proposed rule to specifically address the management and disposal of hazardous waste pharmaceuticals by healthcare facilities (e.g., hospitals, physicians' offices, long-term care facilities, pharmacies) and "pharmaceutical reverse distributors." The proposed rule, "Management Standards for Hazardous Waste Pharmaceuticals," was published in the Federal Register on September 25, 2015 and is available at https://www.federalregister.gov/articles/2015/09/25/2015-23167/management-standards-for-hazardous-waste-pharmaceuticals. EPA is accepting comments on the proposed rule until **November 24, 2015**.

Why is EPA Proposing this Rule?

Management of hazardous waste pharmaceuticals is currently regulated by federal law under the Resource Conservation and Recovery Act ("RCRA") and state analogs. Under RCRA, EPA established a comprehensive set of regulations addressing the management, generation, transportation, treatment, storage and disposal of hazardous waste. The requirements applicable to any particular facility depend (in large part) on the facility's RCRA generator status, i.e., whether the facility is considered a Conditionally Exempt Small Quantity Generator ("CESQG"), Small Quantity Generator ("SQG"), or Large Quantity Generator ("LQG"), which is based on the volume of hazardous waste the facility generates.

The current regulatory framework, however, was originally developed to address the management of hazardous waste from industrial and manufacturing businesses, not the healthcare industry. As a result, under the current set of regulations, many healthcare facilities (including retail pharmacies) are considered SQGs or LQGs and are subject to onerous RCRA requirements that, in some instances, are unwieldy and/or overly burdensome.

EPA acknowledged in its rulemaking that healthcare facilities have reported difficulties complying with applicable RCRA regulations for three main reasons:

1. Healthcare workers (e.g., nurses, doctors, pharmacists), whose primary focus is caring for patients, are not generally knowledgeable about applicable RCRA regulations, but are often involved in their implementation.

2. A healthcare facility can have thousands of different pharmaceuticals, making it difficult to determine which ones are classified as hazardous waste under RCRA when disposed of (in contrast, manufacturing facilities typically generate fewer and more predictable waste streams that can more easily be identified as hazardous or non-hazardous waste).

3. Some active pharmaceutical ingredients are listed as acute hazardous waste under RCRA, which are regulated in very small amounts.

4. EPA's proposed rule is intended to specifically address these issues (among others) by creating a tailored, sector-specific regulatory framework for the healthcare industry.

Highlights of the Proposed Rule

- ***Who would be impacted?*** Healthcare facilities that are considered SQGs or LQGs, which may include pharmacies, hospitals, outpatient care centers, physicians' offices, dentists' offices, nursing care facilities and pharmaceutical reverse distributors.

- ***What regulatory framework would apply?*** If finalized, the rule would create a sector-specific regulatory framework that would apply to healthcare facilities, regardless of their status as an SQG or LQG (with CESQGs largely exempt from the new requirements) and all pharmaceutical reverse distributors.

- ***Relaxed standards for potentially creditable hazardous waste pharmaceuticals:*** "Potentially creditable hazardous waste pharmaceuticals" (i.e., unused hazardous waste pharmaceuticals within a year of their expiration date that have the potential to receive a manufacturer's credit) would be subject to less stringent on-site management requirements than non-creditable hazardous waste pharmaceuticals. For example, potentially creditable hazardous waste pharmaceuticals could be sent offsite (to a pharmaceutical reverse distributor) by common carrier, without the need for a hazardous waste manifest. Healthcare facilities, however, would be subject to new notification and tracking requirements for shipments of potentially creditable hazardous waste pharmaceuticals.

- ***"Down the drain" banned:*** Healthcare facilities would be prohibited from disposing of hazardous waste pharmaceuticals "down the drain." EPA estimates that this new restriction would prevent more than 6,400 tons per year of hazardous waste from entering our waterways. The proposed rule would not prohibit the sewering of non-hazardous waste pharmaceuticals (although EPA does not recommend this practice). Notably, while healthcare facilities that are considered CESQGs (as opposed to SQGs or LQGs) would not be subject to most of the requirements of the proposed rule, the sewer ban would apply to CESQGs.

- ***Other key changes:*** The proposed rule also would: confirm that hazardous waste pharmaceuticals would not count toward monthly hazardous waste volumes, which determine the facility's RCRA generator status (i.e., CESQG, SQG, LQG); include a conditional exemption for hazardous waste pharmaceuticals that also are controlled substances under the jurisdiction of the Drug Enforcement Agency ("DEA") and managed in accordance with all applicable DEA requirements; and create a new set of management standards specifically for pharmaceutical reverse distributors (similar to those applicable to LQGs).

Conclusion

One of EPA's goals in proposing the rule was to reduce the burden on healthcare workers and pharmacists by creating a tailored, sector specific set of regulations. While an admirable goal, implementation of the rule would result in a new set of detailed regulatory requirements that would need to be fully understood by those affected and successfully incorporated into day-to-day operations and corporate regulatory compliance programs. Regardless of whether the proposed rule is finalized, healthcare facilities should be advised that proper management of regulated waste, particularly including hazardous waste pharmaceuticals, is a hot button issue for the EPA and state environmental regulatory agencies.

Questions?

If you have questions regarding the proposed rule, please contact Aaron Levy at (860) 251-5893 or alevy@goodwin.com.

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

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

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

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

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

www.shipmangoodwin.com

SHIPMAN & GOODWIN LLP®
COUNSELORS AT LAW