Managing Pharmaceutical Waste in US Healthcare Facilities: US Environmental Protection Agency Funds 10-Step Blueprint (2022 Edition)

Walter Wright, Jr.
wwright@mwlaw.com
(501) 688.8839

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The United States Environmental Protection Agency ("EPA") funded a document that was recently issued titled:

A 10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities (2022 Edition) ("Blueprint")

The primary author of the Blueprint is Charlotte Smith of GreatWorks, LLC.

The 2022 edition of Blueprint is a subsequent version of the document that was published in 2006.

The document describes its primary purpose as to:

. . . provide a guide to help healthcare facilities, including hospitals, surgery centers, and urgent care facilities understand the applicable regulations so they can develop a compliant, holistic, and cost-effective pharmaceutical waste management program.

Therefore, the Blueprint primarily focuses on EPA Subtitle C Hazardous Waste Regulations as applicable to pharmaceuticals handled as hazardous waste. This issue has become relevant because of EPA's revision of the Resource Conservation and Recovery Act ("RCRA") regulations in 2019 through the issuance of the final rule titled:

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the PO75 Listing for Nicotine (See Volume 84 of the Federal Register Feb. 2019)("Pharmaceuticals Rule")

The Pharmaceuticals Rule added Subpart P to the RCRA Subtitle C regulations found at 40 C.F.R. Part 266. In addition, it addressed an exemption for OCT nicotine patches, gum and lozenges.

Pharmaceutical hazardous waste management is somewhat unique in that the facilities (such as pharmacies, hospitals, nursing homes, etc.) required to meet these requirements have had relatively little exposure to the RCRA cradle-to-grave hazardous waste management system. This is distinctly different from industrial and commercial facilities that have been subject to various RCRA Subtitle C requirements since the mid-1980s. As a result, documents such as the Blueprint have been deemed critical to educating the relevant regulated community.

The 10 steps (i.e., components) in the Blueprint include:

- Step One: Understanding Which Pharmaceuticals are Regulated as Hazardous Waste Pharmaceuticals When Discarded
- Step Two: Reviewing Standards for Healthcare Facilities Operating Under the Hazardous Waste Pharmaceuticals Rule
- Step Three: Determining Which Facilities Must Operate Under Subpart P
- Step Four: Leadership and Current Program Review
- Step Five: Choosing Appropriate Vendors
- Step Six: Implementing a Pharmaceutical Waste Program in the Pharmacy
- Step Seven: Implementing a Pharmaceutical Waste Program in the Nursing Unit and other Patient Care Areas
- Step Eight: Management Responsibilities: Team Management, Policy and Procedure Development, and Process Improvement
- Step Nine: Training Programs – Program Re-launch and Online Training
- Step Ten: RCRA Generator Category for Facilities Operating under Subpart P

Appendices in the Blueprint include:

- Appendix A. Links to the Code of Federal Regulations (40 CFR) for Subpart P
- Appendix B. Common Acronyms
- Appendix C. Quick Start Guide: Management of Hazardous Waste Pharmaceuticals— OTC Nicotine Exemption and Subpart P
- Appendix D. How to Evaluate the Toxicity Characteristic Using Total Constituent Analysis in lieu of the TCLP— Case Study: Thimerosa
- Appendix E. NIOSH Hazardous Drug List
- Appendix F. Step-by-Step Guide to Notifying under Subpart P
- Appendix G. RCRA Hazardous Waste Generator Categories

A copy of the Blueprint can be downloaded here.