EPA Hazardous Pharma Waste Rule Has Wide Reach

By **Andrew Stewart, Anushka Rahman and Renée van de Griend** (February 24, 2021)

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Nearly two years ago, the U.S. Environmental Protection Agency promulgated regulations for the management of hazardous waste pharmaceuticals by health care facilities and reverse distributors, and revised the hazardous waste listing for certain nicotine products.

States without an authorized Resource Conservation and Recovery Act, or RCRA, program became subject to the new regulations as of Aug. 21, 2019, while states that do have an authorized RCRA program must adopt the full regulations by July 1, 2021, unless they require a statutory amendment, in which case they must adopt by July 1, 2022. In addition, a sewer discharge prohibition for hazardous waste pharmaceuticals took effect in all states on Aug. 21, 2019, regardless of RCRA authorization or rule adoption status.

Below we review the background of the rule, new regulatory definitions, compliance considerations — including management of hazardous waste pharmaceuticals — and offer practical guidance to companies potentially affected by the regulation.

At first glance, the rulemaking may appear to affect only the health care and social assistance sectors. However, the definitions in the final rule give it sweeping reach that could affect businesses far beyond the health care space if they simply dispense regulated pharmaceuticals, including over-the-counter medicines.

While some parts of the final rule are not currently in effect in all states, the deadline for adoption is on the horizon. Businesses subject to the rule should be aware that in effective states, the U.S. Environmental Protection Agency will likely monitor compliance, and potentially take follow-up enforcement actions for any noncompliance.

A particular challenge with this rule is that the EPA placed the burden on individual companies to determine whether the pharmaceuticals they dispense are covered by this regulation, rather than providing a comprehensive listing, suggesting in the rule preamble that businesses may retain outside advisors "to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded."

Background

On Feb. 22, 2019, the EPA finalized its rule, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine."

The agency promulgated regulations under the RCRA for the management of hazardous waste pharmaceuticals by health care facilities and reverse distributors, codified at Title 40 of the Code of Federal Regulations, Part 266, Subpart P. The rule also amended the hazardous waste listing for nicotine such that certain nicotine replacement therapies, or NRTs, will no longer be considered hazardous waste when discarded.

The pharma waste regulations apply to health care facilities, broadly defined, and reverse distributors, which must manage their hazardous waste pharmaceuticals under the Part 266, Subpart P, standards instead of those under Part 262.

New Regulatory Definitions

The regulations apply to any health care facility, defined in the traditional sense to include those authorized to provide preventative, diagnostic or therapeutic services, but also including any person distributing, selling or dispensing OTC and prescription pharmaceuticals.

Thus, the regulations could apply in a variety of settings outside of the health care and social assistance sector. Indeed, in its response to comments document, the EPA confirmed that nurses' offices, infirmaries and health care facilities colocated at manufacturing sites all qualify as health care facilities for purposes of the rule.

Although the EPA's primary intent based on statements in the rulemaking record appears to be for the regulations to apply to infirmaries, facility health clinics and other physical locations where a person may receive medical care and pharmaceuticals, the agency did not expressly rule out application to unattended first aid kits and other containers from which pharmaceuticals are dispensed.

There is, however, an escape hatch noted below for health care facilities that are defined as very small quantity generators — i.e., which, in one calendar month, generate no more than 220 pounds of nonacute hazardous waste, 2.2 pounds of certain acute hazardous waste specified in the regulations and 220 pounds of material contaminated from the cleanup of a spill of any acute hazardous waste identified by regulation.

The definition of "pharmaceuticals" under the regulations is broad, and includes any drug for humans or other animals. The EPA did not provide any listing of which drugs are hazardous waste pharmaceuticals once discarded, and which are not. The regulation does not affect pharmaceuticals while they are in use, only when discarded.

Therefore, companies are faced with a choice: They can presumptively assume all pharmaceuticals are hazardous waste once discarded, or they can inventory their pharmaceuticals and determine whether pharmaceuticals dispensed at their facilities are characteristic or listed hazardous waste under RCRA regulations, or otherwise exempt under exclusions for products legitimately used/reused or reclaimed.

Not surprisingly, the EPA has been deluged with applicability questions regarding the regulations. Although the agency updated its FAQs regarding applicability of the regulations last year, uncertainty persists. Companies that in any way generate, accumulate or otherwise handle pharmaceuticals, including OTC products, may be subject to the regulations — and failure to comply could result in enforcement action, including penalties.

Compliance With the New Rules

The regulations impose obligations beyond previously in-place RCRA requirements for notification, generating, handling and disposing of hazardous waste pharmaceuticals by health care facilities and reverse distributors in the states where all of the Part 266, Subpart P, standards are in effect.

In addition, the regulations also modify the obligations for managing nicotine wastes. These

new and modified compliance obligations are summarized below.

Sewer Discharge Prohibition

As of Aug. 21, 2019, all health care facilities and reverse distributors must comply with the regulations' sewer prohibition for hazardous waste pharmaceuticals, which prohibits "discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works."

The sewer ban applies now in all jurisdictions. As a best practice, the EPA recommends facilities refrain from flushing all pharmaceuticals, regardless of waste classification.

Notification as a Health Care Facility

For any entity that qualifies as a health care facility or reverse distributor in a state where all parts of the regulations are in effect, a one-time notification must be submitted to the EPA within 60 days of the regulations becoming effective, or within 60 days of becoming subject to the regulations, that the entity is operating under Part 266, Subpart P.

However, health care facilities that qualify as large quantity generators under the RCRA can submit their notification as part of their biennial reporting schedule, even if that is after the 60-day window. The generator category — e.g., large quantity generator, small quantity generator, etc. — of a reverse distributor, defined as "any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit," does not appear to matter under the regulations.

Management of Pharmaceutical Waste

Once an entity determines that it is a health care facility or reverse distributor in a state where all parts of the regulations are in effect, in addition to complying with the sewer prohibition and reporting requirements, it will have to follow the Subpart P requirements for generating, handling and disposing of wastes. Additional training for employees is also required.

Health care facilities that qualify as very small quantity generators under the RCRA have the option of complying with requirements under Subpart P, or meeting requirements for a conditional exemption under Part 262.14. This means that, unless they opt in, health care facilities that are very small quantity generators are not subject to most requirements under Subpart P, with the exception of the sewer prohibition and empty container standards under Part 266.507, which impose management standards for certain hazardous waste pharmaceuticals remaining in containers.

The Subpart P requirements are based on the following categories of hazardous waste pharmaceuticals set forth in the regulations: noncreditable, potentially creditable or evaluated. Determining the type of hazardous waste pharmaceutical depends on a variety of factors, including whether the pharmaceutical is prescription or OTC, eligible for manufacturer credit, and has "a reasonable expectation to be legitimately used/reused or reclaimed."

Based on the EPA's latest update and a review of relevant state agency websites, the states where the full regulations are currently in effect are Alabama, Alaska, Arizona, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Kentucky, New Jersey, North Carolina, Ohio,

Oklahoma, Pennsylvania, South Dakota, Utah, Virginia, Washington, West Virginia and Wisconsin. Meanwhile, Minnesota is phasing in the regulations, with certain parts effective now, and plans to fully adopt Subpart P in 2022.

To facilitate compliance, companies that qualify as health care facilities or reverse distributors should consider compiling an inventory of the products, substances and materials — including amounts — in their facilities, to determine which, if any, of their pharmaceuticals qualify as hazardous waste pharmaceuticals. These companies should also determine, if they have not already done so, what their current procedures are for handling and disposing of waste pharmaceuticals, including unwanted or expired pharmaceuticals.

P075 Listing for Nicotine

The changes to the P075 acute hazardous waste listing under the RCRA for nicotine and salts have arguably narrower implications than the management standards for hazardous waste pharmaceuticals. The final rule removed U.S. Food and Drug Administration-approved OTC nicotine replacement therapies from the P075 listing.

This means that smoking cessation products such as nicotine patches, gums and lozenges are not regulated as hazardous waste in states that adopted that part of the final rule. However, electronic nicotine delivery systems — e.g., electronic cigarettes and vaping pens — liquid nicotine or e-liquid for use in such systems, and prescription NRTs are still regulated as P075-listed hazardous waste.

Like the pharma waste regulations, this part of the final rule must be in effect in a state before an entity in that state can use the exemption removing OTC NRTs from regulation. Unlike the pharma waste regulations, the rule does not obligate RCRA-authorized states to adopt this exemption.

Based on the EPA's most recent update and a review of relevant state agency websites, the exemption for OTC NRTs was adopted in the following states: Alabama, Alaska, Arizona, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Minnesota, New Hampshire, New Jersey, North Carolina, Oklahoma, Pennsylvania, South Dakota, Virginia, Washington and West Virginia.

Meanwhile, New York issued an enforcement discretion letter allowing use of the amended listing. In all other states, OTC NRTs continue to be regulated as P075-listed hazardous waste. While the P075 delisting serves to provide some regulatory relief, companies that handle nicotine and nicotine wastes are on notice that they may be subject to the RCRA.

Practice Pointers

Companies that operate outside the states listed above as having adopted the regulations for hazardous waste pharmaceuticals should familiarize themselves with the regulations, if their facilities qualify as either health care facilities or reverse distributors, as they will have to comply with Part 266, Subpart P, by July 1 of this year, or by July 1, 2022, in states where a statutory amendment is required.

Furthermore, entities that handle pharmaceuticals and nicotine should monitor the status of both the pharma waste regulations and the P075 delisting, and determine if they are subject to the RCRA. As noted above, this can be a complicated analysis that may require companies to create an inventory of their onsite pharmaceuticals.

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