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New Hazardous Waste Pharmaceutical Rule Imposes New Obligations on Health Care Providers

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U.S. EPA Acting Administrator Andrew Wheeler signed a new hazardous waste pharmaceutical rule on December 8, 2018. This rule will impose significant new obligations on certain health care providers, including pharmacies and long-term care providers, as well as forward and all reverse distributors of pharmaceuticals. The final proposed rule issued on February 22, 2019, will be codified in Subpart P of Part 266 (Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities) of the Resource Conservation and Recovery Act ("RCRA") and will govern qualifying healthcare sector activities in lieu of the obligations contained in 40 CFR §262.

This new rule represents a noteworthy change from EPA's previous policy position that pharmaceuticals in the reverse distribution chain were not "discarded" under RCRA for purposes of waste designation until an affirmative decision was made to treat them as "waste" and discard them. A proposed rule under the Bush Administration would have treated unused prescription and over-the-counter ("OTC") drugs as "universal wastes" subject to less stringent management and disposal rules, but EPA never finalized the proposed regulation as concerns were raised regarding Drug Enforcement Agency regulated narcotics and medications. EPA also felt the need to address its concern that a substantial number of industry representatives were ignoring guidance and treating pharmaceuticals sent through reverse distribution as "not discarded" and therefore, not a regulated waste.

While the rule does not add any pharmaceuticals to the hazardous waste listings or expand the hazardous waste characteristics to include additional pharmaceuticals, EPA outlines almost a dozen new definitions affecting the healthcare sector and its governance under the rule. This includes an expansive definition of "healthcare facility" that encompasses supermarket and other grocery stores, warehouse clubs and supercenters, mail order pharmacies, chiropractors and dentists' offices in addition to the more traditional doctors' offices, hospitals, nursing care facilities and other ambulatory health care services. In particular, long term care facilities, as specifically defined in the rule[1], will be required to follow the new provisions of subpart P instead of benefiting from previously allowed household waste exclusion.

The rule applies to all healthcare facilities that generate above the "very small quantity generators" (VSQGs) monthly quantity thresholds regardless of the amount of hazardous waste pharmaceuticals generated above those limits. Non-pharmaceutical hazardous waste still must be quantified and the appropriate generator category assigned for determination under part 262, but the calculation should not include any hazardous waste pharmaceuticals handled under subpart P. Healthcare facility VSQGs[2] maintain their conditional exemption under 40 CFR §262.14 but may opt into subpart P.

Healthcare facilities that dispose of prescription pharmaceuticals must register with U.S. EPA, provide training to staff, appropriately label containers and segregate listed or characteristically hazardous (toxic, flammable, reactive, or corrosive) pharmaceuticals from unlisted, non-hazardous materials. The rule also creates an exemption from certain existing requirements for discarded containers of medications that would be considered P-listed hazardous waste, such as drugs containing warfarin (e.g., Coumadin). The final rule also contains several critical requirements related to treatment of non-prescription pharmaceuticals (not considered solid waste at the healthcare facility) and prescription pharmaceuticals (considered "solid waste" at the healthcare facility) sent through reverse logistics and reverse distribution[3]depending upon the "reasonable expectation" of legitimate reuse or recycling of the

[1] The agency definition of long term care facility does not include assisted living facilities, and therefore assisted living facilities will still be eligible to use the household hazardous waste exclusion in 40 CFR 261.4.

[2] Reverse distributor VSQGs must comply with subpart P and are not afforded an exemption or opt out provision.

[3] "Reverse Distribution" and "Reverse Logistics" are treated differently under Subpart P. Under reverse distribution, prescription hazardous waste pharmaceuticals that are potentially "creditable" (i.e., have a reasonable expectation of receiving credit from the manufacturer when returned) will not be considered hazardous waste and those that are

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pharmaceuticals. EPA determined that there is no "reasonable expectation" of reuse or reclamation of prescription pharmaceuticals except in rare circumstances (e.g., in the case of lawful donation). Prescription drugs that are returned to the manufacturer for credit are almost always discarded.

The rule also exempts from regulation, medications collected during drug take-back programs and events as falling within the Congressionally-created household hazardous waste exemption. Finally, the rule eliminates the dual regulation of hazardous waste pharmaceuticals under RCRA if they are also regulated by the DEA as "controlled substances."

Of particular significance is the amendment of the P075 listing for nicotine products such that FDA-approved OTC nicotine replacement therapies (e.g., patches, gums and lozenges) will no longer be included under the P075 listing for hazardous waste and may be discarded as a non-hazardous solid waste. This is based upon EPA finding that such drugs do not meet the regulatory criteria for acute hazardous waste (P-code). However, other products, the primary ingredient of which is nicotine (e-cigarettes, prescription nicotine, nicotine used in legacy pesticides and in research and manufacturing), will continue to carry the P075 waste code.

Subpart P takes effect six months after publication on August 21, 2019 only in non-authorized states, Indian Country and U.S. Territories (except Guam). In RCRA-authorized states, Subpart P is effective only after the state adopts Subpart P. However, Subpart P is considered more stringent than current regulations and, therefore, authorized states are required to adopt it by July 1, 2021, unless the state requires a statutory amendment for adoption, in which case, the deadline for adoption of Subpart P is July 1, 2022. The new rule also contains a sewering ban that applies to all healthcare facilities, including VSQGs and is effective in ALL states on August 21, 2019 regardless of whether the state is RCRA-authorized or has adopted Subpart P, and effective on August 21, 2019. Since EPA's promulgation on P075 is less stringent than the current federal standard, RCRA authorized states are not required to adopt its provision. This inevitably will result in a patchwork approach that may prove challenging for multi-state facilities focused on compliance.

Because the final rule makes fundamental changes to long-held EPA policy regarding the point at which a pharmaceutical product is considered a solid waste under RCRA, it may create significant regulatory uncertainty, and potential liability, for entities in the pharmaceutical distribution chain that must evaluate their compliance with the new rule. Furthermore, the RCRA state authorization construct will add even more complexities. This alert provides an overview of the key provisions, timelines and implications, but a more detailed review will depend on specific facts or circumstances and can be provided upon request.

For more information

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non-creditable, because they have no reasonable expectation of receiving credit from the manufacturer, must be disposed of as hazardous waste under RCRA.

Reverse logistics refers to the process by which non-prescription pharmaceuticals and other unsold retail items are sent to a "reverse logistics" center or distributor, at which point the decision will be made to discard these pharmaceuticals. Retailers consider reverse logistics a critical component of inventory management, product recall, thus preventing waste of retail OTC and supplements that are aggregated and redirected as valuable products.