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CLIENT ALERT

State Implementation of New EPA Standards for Maintenance of Hazardous Waste Pharmaceuticals: Drug Supply Chain Implications

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Earlier this year, the Environmental Protection Agency ("EPA") adopted a final rule imposing new standards for the management of hazardous waste pharmaceuticals ("HWPs")[1] that goes into effect on August 21, 2019 ("Final Rule").[2] This comprehensive overhaul of rules governing the treatment and discarding of HWPs under the Resource Conservation and Recovery Act ("RCRA") is largely intended to provide regulatory clarity and national consistency. However, many of the Final Rule's core provisions must first be adopted at the state level within the next two to three years, meaning that inconsistencies could arise based upon each state's interpretation and adoption of these provisions. This implementation process will therefore be critical to affected pharmaceutical supply chain entities, which will need to proactively engage state lawmakers to ensure efficient management operations.

Final Rule on the Maintenance of HWPs

The Final Rule implements three major regulatory changes. First, the Food and Drug Administration ("FDA")-approved over-the-counter ("OTC") nicotine replacement therapies ("NRTs") will no longer be designated as acute hazardous waste products. Second, the sewering of HWPs will be banned. Finally, and most significantly, the Final Rule introduces new waste handling rules and regulations for HWPs processed through reverse distribution ("Subpart P"). The Final Rule primarily governs "healthcare

[1] "HWPs" are defined as pharmaceuticals that are a solid waste and exhibit one or more characteristics of hazardous waste or are listed in regulations as a hazardous waste. Pharmaceuticals legitimately used, reused, or reclaimed are not HWPs, nor are over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs if they have a reasonable expectation of being legitimately used, reused, or reclaimed. 40 C.F.R. § 266.500 (2019).

[2] EPA, Final Rule, *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, 84 Fed. Reg. 5816 (Feb. 22, 2019), *available at* https://www.federalregister.gov/documents/2019/02/22/2019-01298/management-standards-for-hazardous-waste-pharmaceuticals-and-amendment-to-the-p075-listing-for.

facilities," which are broadly defined to include most pharmaceutical supply chain entities (e.g., wholesalers, third-party logistics providers, hospitals, long-term care facilities,[3] pharmacies, veterinary clinics, and hospitals) other than pharmaceutical manufacturers, reverse distributors, and reverse logistics centers.[4]

RCRA establishes a complex federalism-based framework that governs the implementation of the NRT changes and Subpart P changes. The vast majority of U.S. states (subject to a few exceptions) are deemed "authorized" under RCRA to administer hazardous waste programs in lieu of the federal program.[5] When the EPA conducts rulemaking under the Hazardous and Solid Waste Amendments of 1984 ("HSWA") to RCRA, its regulations are automatically effective as to both authorized and non-authorized states. However, when the EPA conducts RCRA rulemaking outside of its HSWA authority, such regulations are automatically effective only in non-authorized jurisdictions. RCRA mandates that authorized states affirmatively enact regulations or statutes that are at least equivalent to the EPA's regulations in order for the EPA rules to become effective. Notably, for authorized states adopting non-HSWA regulations, the EPA mandate is a floor, such that these states may enact stricter or broader requirements than those mandated by the EPA. If an EPA non-HSWA regulation is seen as loosening federal regulatory requirements, authorized states are not required to adopt the regulation. Given the complexity of this implementation framework, there is substantial potential for state regulatory variation, and drug supply chain stakeholders may be subjected to differing HWP management standards.

Sewering Ban

In the Final Rule, the EPA finalized its proposal to prohibit the sewering of HWPs, which broadly applies to all reverse distributors and healthcare facilities, including facilities deemed to be very small quantity generators. The prohibition is not subject to any exceptions and includes all HWPs. The sewering ban, promulgated under the EPA's HSWA authority, is the one component of the Final Rule that becomes immediately effective in all states on August 21, 2019.

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[3] Hospice facilities to a varying degree are included within the scope of the Final Rule, but in-home medical care, including in-home hospice care, is carved out of the Final Rule through the household hazardous waste exclusion. 84 Fed. Reg. at 5854.

[4] While they do not fit within this definition, reverse distributors are still subject to the Final Rule's new HWPs management standards. A "reverse distributor" is "any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit." 40 C.F.R. § 266.500. Reverse logistics centers manage nonprescription items that have become unsalable at a retail store and are not solid wastes because they have a reasonable expectation of being used, reused, or reclaimed. 84 Fed. Reg. at 5832.

[5] *See* Section 3006 of RCRA, 42 U.S.C. § 6928 and 40 C.F.R. pt. 271 (2018). "Authorized jurisdictions" include the District of Columbia and all U.S. states other than Iowa, Alaska, the territories, and Indian country, which are referred to herein as "non-authorized jurisdictions." The EPA may directly enforce the federal hazardous waste program in all non-authorized jurisdictions. In authorized jurisdictions, the local or state government has primary enforcement authority; the EPA retains enforcement authority in these jurisdictions but cannot enforce requirements that are stricter than the federal standards.

Exemption for NRTs

In the Final Rule, the EPA also announced that it would amend the P075 listing to exempt FDA-approved OTC NRTs, such as patches, gums, and lozenges (but not e-cigarettes, e-liquids, or prescription NRTs). The new exemption automatically goes into effect on August 21, 2019, for non-authorized jurisdictions, but will only become effective in authorized states upon adoption, which is not required.[6]

The agency's move regarding OTC NRTs was made in response to requests by retailers that argued that the disposal of these products, which are not acutely hazardous, was improperly rendering retailers to become large quantity generators ("LQGs") of hazardous waste. Prior to the Final Rule, when OTC NRTs were considered to be an acutely hazardous waste, any retailer handling more than one kilogram of such waste per month would be deemed to be an LQG of hazardous waste and would therefore be required to comply with greater regulatory and recordkeeping burdens. By reducing this regulatory burden, the OTC NRT amendment in the Final Rule is estimated to save $40 million per year spread across the retail sector.

Part 266, Subpart P: Management of OTC Products and HWPs at Healthcare Facilities and Reverse Distributors

A substantial portion of the Final Rule involves new regulations for the handling of HWPs by healthcare facilities and reverse distributors, as set forth in Part 266, Subpart P. These provisions include a series of new standards for healthcare facilities that manage non-creditable and potentially creditable HWPs and reverse distributors that manage potentially creditable and evaluated HWPs.

Under the Final Rule, prescription pharmaceuticals are considered solid waste at the healthcare facility level if they are destined for reverse distribution.[7] The Final Rule mandates that the healthcare facility determine whether or not a waste pharmaceutical is an HWP—representing a change from the existing practice in which this decision is made at the reverse distributor level.

By moving the hazardous waste determination down to the healthcare facility level from the reverse distributor level, the EPA attains jurisdiction over those items that are considered solid waste at the healthcare facility. The shift also encourages healthcare facilities to manage all of their waste pharmaceuticals as hazardous waste, so they do not have to make HWP determinations. Although HWPs are subject to complex handling requirements under the Final Rule, healthcare facilities will no longer have to concern themselves with determining their generator status under RCRA, which depends on their monthly generation of HWPs. Also, they will no longer have to

[6] The EPA considers the NRT regulation to be a loosening of non-HSWA regulations, and, therefore, authorized states are not required to adopt the regulation.

[7] Prescription pharmaceuticals that are legitimately used, reused, or reclaimed are not deemed solid waste at the healthcare facility level and are not subject to the Final Rule. An example might be saleable returns or drugs destined for drug donation programs.

segregate acute and non-acute HWPs, or be subject to the burdensome waste generator regulations that flow from a healthcare facility's generator status.

As noted, there are a myriad of waste handling requirements under Subpart P, including labeling standards, container standards, accumulation times, training, EPA notifications, and standards for shipping to a reverse distributor or a Treatment, Storage, and Disposal Facility ("TSDF"). Beyond the standards applicable to healthcare facilities, there is another layer of regulatory standards for processing HWPs, which apply to the reverse distributors. Overall, EPA considers the sum of these various standards to be streamlined waste handling requirements compared to the pre-Final Rule regulatory waste handling requirements.

While the new regulations may relieve healthcare facilities of certain burdens, the EPA considers the new regulations under Subpart P to impose standards that are more stringent than those currently in application. Accordingly, for authorized jurisdictions, the Subpart P provisions will only become effective at the local level upon state adoption. For non-authorized jurisdictions, the rules become effective on August 21, 2019. Authorized states that must pass new legislation to implement the standards must do so by July 1, 2022, and the remaining authorized states, which use non-legislative rulemaking processes, have until July 1, 2021.

Distinction Between "Reverse Logistics" and "Reverse Distribution"

Even though HWPs are subject to Subpart P, OTC items that have a reasonable expectation of use or reuse are not considered solid waste at the healthcare facility and are not subject to Subpart P requirements. OTC items, including unsold retail items, undergo a reverse logistics process once those products leave the healthcare facility and may potentially be subject to reuse on a secondary market. That said, if an OTC product has no reasonable expectation of use or reuse, then that product is subject to Subpart P requirements as a non-creditable non-prescription hazardous waste pharmaceutical. The healthcare facility must make this determination.

Generally, the Final Rule does not change how OTC products are processed through the reverse logistics process but codifies existing practice and policy into regulation. Ultimately, since many of these products are likely to be used or reused, many of them should not be considered waste at the healthcare facility, which would otherwise trigger application of Subpart P standards.

HWPs, on the other hand, go through a reverse distribution process. In the EPA's view, unused or expired pharmaceutical drugs are generally solid wastes at the healthcare facility and, unlike OTC products, are not subject to further use or reuse once they are destined for reverse distribution. These solid waste pharmaceutical drugs go to reverse distributors, which receive them and then facilitate the process, on behalf of manufacturers, of crediting healthcare facilities for these drugs.

HWPs at the healthcare facility are either non-creditable or potentially creditable, and at the reverse distributor level, they are either potentially creditable or evaluated for credit. While the credit status does not change the EPA's determination that expired or unused pharmaceutical drugs are generally solid wastes at the healthcare facility, it is significant insofar as it determines which standards under Subpart P apply to any given HWP. The Subpart P standards differ depending on the credit status of the HWP because the EPA sought to promulgate a rule that aligns with existing practices for processing HWPs and determining credit.

Significance: Monitoring and Shaping the State Implementation Process

Given the wide-ranging effects of the new standards, and the possibility of significant variation at the state level, stakeholders should carefully monitor the state implementation process during the next three years. This is especially significant for those stakeholders operating in several states and those engaging, or planning to engage, in the disposal or shipping of HWPs across state lines.

Since the sewering ban applies across the country on August 21, 2019, the focus on state action is limited to the nicotine provision and Subpart P. First, as to the nicotine provision, since the Final Rule's provisions are considered less stringent than existing regulation, no authorized state is required to adopt the nicotine changes, and there is no deadline for such state action. OTC NRT products will still be viewed as acutely hazardous waste in those states that fail to adopt the nicotine changes. States will therefore have to make a decision as to whether to maintain the status quo or deregulate per the Final Rule. Unless or until all states make the changes, the retail industry will not be able to fully realize the $40 million in estimated savings.

By contrast, the 48 authorized states must adopt the Subpart P provisions by either July 1, 2021 (if implemented through regulation), or July 1, 2022 (if implemented through legislation). In addition, the Final Rule merely establishes a regulatory floor, and states may adopt more restrictive measures for handling and processing HWPs. This means that unlike the nicotine provisions, there is the potential for significant variation in how states implement Subpart P. For example, certain, but not all, of the states could expand the scope of the term "HWP" to include more than prescription pharmaceuticals under the purview of Subpart P, or could expand the scope of entities that are considered healthcare facilities subject to Subpart P. Variation could also arise with some states restricting commingling of hazardous and non-HWPs. Different states might have different waste container labeling requirements, container standards, or accumulation time limits. There are also shipping standards that could vary from state to state.

For healthcare facilities with facilities in multiple states, state variation would be problematic. For example, a chain pharmacy with pharmacies in all 48 states might have to comply with 48 variations of Subpart P standards. Difficulties could also arise for regulated entities that do not operate in multiple states. Oftentimes, an HWP will travel through multiple reverse distributors before it reaches the TSDF and could

conceivably travel through four locations in four different states before it reaches the TSDF in a fifth state. Because accumulation times are cumulative and consistent labeling is important throughout the reverse supply chain, even those healthcare facilities that operate in a single state could face significant challenges if substantial variations arise at the state level.

Given the importance of achieving state-level consistency for the new regulations governing the handling of HWPs, healthcare facilities and reverse distributors will need to implement a coordinated advocacy campaign at the state level. Unless such efforts are made well in advance of the 2021 and 2022 deadlines, supply chain stakeholders could face substantial headaches in seeking to ensure compliance with Subpart P standards in each state across the country.

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