Transforming the Regulatory Landscape for Hazardous Waste Pharmaceuticals

by Daniel S. Flynn and Daniel R. Farino

On Aug. 31, 2015, the Environmental Protection Agency (EPA) administrator signed the proposed management standards for hazardous waste pharmaceuticals rule, which would amend the way the Resource Conservation and Recovery Act (RCRA) regulates hazardous waste pharmaceuticals. The proposed amendment would apply to generators who qualify as 'healthcare facilities.' Healthcare facilities include a broad range of businesses that deal with pharmaceuticals, including hospitals, assisted living care facilities, physicians, pharmacies and retail stores that sell over-the-counter medicines and dietary supplements. Other generators would be largely unaffected. With respect to healthcare facilities, it would no longer matter whether the facility is considered a small-quantity generator or large-quantity generator. All management, handling, collection, and disposal of hazardous waste pharmaceuticals (HWPs) would be controlled, and largely streamlined, by the new subpart P of 40 CFR part 266, instead of 40 CFR part 262.

The proposed RCRA amendment for HWPs should result in a substantial improvement over the existing industrial waste-oriented provisions of RCRA by eliminating the current 'square peg in a round hole' regulatory problem, reducing complexity, and providing clear standards for the management, shipping, and disposal of HWPs on a uniform, national basis. Chief among the proposed sector-specific rule are the newly created reverse distribution system for healthcare facilities to obtain manufacturer's credits for 'potentially creditable' HWPs via pharmaceutical reverse distributors, and the simplified disposal of 'non-creditable' HWPs. Given the importance and prevalence of the pharmaceutical and medical industries to the state, the proposed amendment is particularly important to New Jersey businesses and practitioners alike.

Acknowledging the Need for Change

The proposed amendment is an implicit acknowledgement that the existing regulatory scheme does not work well for HWPs and the types of businesses that deal with them. The RCRA regulations that currently apply to HWPs were designed with industrial generators and industrial wastes in mind. They include extensive regulation of storage time, storage areas, labels, manifests, recordkeeping, and employee training, among other things. Every entity that handles the hazardous waste after it leaves the hands of the generator must have a RCRA treatment, storage, or disposal (TSD) permit.

Many of these requirements have proven to be unnecessarily cumbersome and a regulatory trap for the unwary in the typical retail or healthcare situation. A pharmaceutical product can turn into waste without having been removed from its package simply because its shelf life expired or it has been recalled. The most logical process for handling such wastes is to return them to the manufacturer or distributor and let it deal with disposal, but this is strictly forbidden under the current RCRA regulations once the pharmaceuticals are determined to be waste.

To provide some relief for companies that only handle small amounts of hazardous waste, the existing RCRA regulations relax the regulatory burdens for generators that qualify as 'small-quantity generators' or 'conditionally exempt small-quantity generators.' This scheme is not perfect, but provides welcome relief in the industrial sector. It is less effective for businesses that deal with HWPs. Businesses that generate or store more than one kilogram (2.2 lbs.) per month of 'acute hazardous waste' are not eligible for the reduced burden status. Some pharmaceutical constituents qualify as acute hazardous waste when disposed, which makes it difficult for a pharmacy or hospital to consistently rely on the small-quantity status.

As enforcement agencies have started to give the pharmaceutical distribution chain some of the focus they have given the industrial sector for decades, a flurry of high-profile enforcement settlements have occurred. For example, Walmart, Walgreens, Target, CVS and Safeway agreed to settlements ranging from $10 million to $81.6 million between 2010 and 2015. The enforcement agencies have not given the same degree of focus to 'mom and pop' stores and other small businesses, but it is hard to imagine that those smaller businesses would be more adept at navigating the RCRA compliance maze than the big box retail chains.

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The EPA first attempted to fix the pharmaceutical waste problem in 2008 by proposing to add HWPs to the types of hazardous wastes that could be managed as universal wastes, which would have provided a little more flexibility in managing the waste. After receiving comments, the EPA set that proposal aside and went back to the drawing board.

Rather than trying to shoehorn HWPs into one of RCRA's existing schemes, the EPA's 2015 proposed fix establishes a protective harbor for healthcare facilities when managing HWPs. Both of these terms are carefully defined by the agency. Within that harbor, the EPA sets up a new scheme for the management and disposal of HWPs that would protect human health and the environment, but does so in a way that enables generators to comply more naturally and cost-effectively. Outside of the protective harbor, the regular requirements of the RCRA would still apply. Thus, a healthcare facility managing hazardous waste other than HWPs would be subject to the same regulatory requirements that apply to everyone else with respect to that hazardous waste.

The Nuts and Bolts of Reverse Distribution of Potentially Creditable HWPs

Under the proposed amendment, a facility currently considered a generator that will qualify as a 'healthcare facility' for HWPs would no longer be required to count HWPs when determining its generator category. With HWPs excepted, many healthcare facilities are expected to avoid large-quantity generator status, and all of its associated requirements. Moreover, healthcare facilities would no longer be required to include HWPs in their biennial report for hazardous waste shipped off site to a treatment, storage or disposal facility (TSDF). This represents a particularly important relaxation of burdens for many generators, particularly those that might generate relatively small and unpredictable quantities of hundreds of different HWPs within their facilities.

However, the major innovation created within the proposed amendment is a system of reverse distribution of 'potentially creditable' HWPs by healthcare facilities to a newly created category of hazardous waste entity, dubbed 'pharmaceutical reverse distributors,' as well

as simplified disposal of non-creditable HWPs. Potentially creditable HWPs are generally unused or unadministered HWPs that are unexpired or less than one year past their expiration date, and excludes non-creditable HWPs, evaluated HWPs, pharmaceutical residues in containers, contaminated personal protective equipment, and clean-up material from pharmaceutical spills. As recognition that healthcare facilities will usually ship potentially creditable HWPs fairly quickly to obtain credit, the proposed amendment allows substantial flexibility in the management and storage requirements for potentially creditable HWPs at healthcare facilities prior to shipment. For example, the amendment imposes no specific labeling or accumulation time limits upon healthcare facilities for potentially creditable HWPs, and would allow healthcare facilities to commingle potentially creditable HWPs with potentially creditable non-HWPs, as recognition that both are typically transported to a reverse distributor together.

The proposed amendments also relax the requirements upon healthcare facilities when shipping those potentially creditable HWPs to a pharmaceutical reverse distributor. Notably, a healthcare facility would not be required to provide a hazardous waste manifest or use hazardous waste codes when shipping those potentially creditable HWPs to a pharmaceutical reverse distributor, and may use a common carrier such as UPS or FedEx for transport rather than a hazardous waste transporter. However, the healthcare facility would be required to provide advance notice of the shipment to the recipient pharmaceutical reverse distributor, comply with certain pre-transport packaging, labeling, marking, and placarding requirements, and keep records of those shipments to the pharmaceutical reverse distributor.

The 'pharmaceutical reverse distributor' is a newly created statutory category of hazardous waste entity that will not be regulated as either a hazardous waste generator or a TSDF. Instead, the proposed amendment creates a new set of rules for this entity, which receives and accumulates potentially creditable HWPs to help healthcare facilities calculate and receive manufacturers' credits. The pharmaceutical reverse distributor would receive potentially creditable HWPs from a healthcare facility and evaluate those potentially creditable HWPs within 21 days of arrival, to establish whether the HWPs will be transported to another pharmaceutical waste distributor for further evaluation or verification of manufacturer's credit, or an offsite TSDF for disposal. Unlike healthcare facilities, pharmaceutical reverse distributors would only be permitted to accumulate potentially creditable HWPs onsite for up to 90 days from arrival. No RCRA storage permit would be required, and no specific labeling or container standards are proposed for storage and management of the potentially creditable HWPs by pharmaceutical reverse distributors. However, a pharmaceutical reverse distributor would not be permitted to accept HWPs known to be non-creditable, and must reject any such shipments.

After receiving and evaluating potentially creditable HWPs, a pharmaceutical reverse distributor would then be permitted to ship the potentially creditable HWPs to another pharmaceutical reverse distributor for further evaluation. In that case, a hazardous waste manifest with specific waste codes and a hazardous waste transporter are not required, but the pharmaceutical reverse distributor would be required to keep a record of all such shipments, and that recipient reverse distributor must confirm receipt of the shipment.

In contrast, if a potentially creditable HWP has been evaluated by a pharmaceutical reverse distributor to determine eligibility for manufacturer's credit, and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification, the HWP would then be considered an 'evaluated' HWP, which means it has to be sent for disposal. A more restrictive set of rules would apply to the management, storage, and shipment of that evaluated HWP. For example, those evaluated HWPs would be required to be stored in a designated, secure onsite accumulation area that must be inspected weekly, and wastes that cannot be incinerated must be accumulated separately. Additionally, when the evaluated HWPs are shipped off site, a shipping manifest with hazardous waste codes is required, and they must be shipped by a hazardous waste transporter, unlike potentially creditable HWPs.

As mentioned above, the proposed amendment does not allow for reverse distribution of hazardous wastes other than HWPs; however, the proposed amendment does provide somewhat relaxed requirements for the management, storage, and shipment of non-creditable HWPs (*i.e.*, HWPs not expected to be eligible for a manufacturer's credit). Under the proposed amendment, a healthcare facility would be permitted to accumulate non-creditable HWPs on site without a RCRA permit for one year, which is an increase of 275 days over the current generator regulations. Moreover, hazardous waste codes would not be required on accumulation containers; instead, the containers would simply be labeled, "Hazardous Waste Pharmaceuticals," with the exception that non-creditable HWPs that cannot be incinerated must be accumulated separately for proper treatment by a TSDF. And, while a healthcare facility must ship HWPs known to be non-creditable to a TSDF rather than a pharmaceutical reverse distributor, the accompanying waste manifest for that non-creditable HWP shipment need not specify hazardous waste codes, and can

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simply be labeled "Hazardous Waste Pharmaceuticals."

Anticipated National and Local Impacts from the Proposed Amendment

These proposed changes with respect to the management, storage, and shipment of HWPs reflect the EPA's recognition that the current industry-oriented framework of the existing RCRA regulations is not easily applied to the healthcare sector. The proposed amendment would reduce complexity and provide clear, industry-specific standards for the management of HWPs, and should streamline the process for obtaining manufacturers' credits while simplifying the shipment and disposal process. This, in turn, encourages responsible disposal practices by facilities of all sizes.

The creation of a role for pharmaceutical reverse distributors would give rise to a new business opportunity in the waste management business. Existing RCRA TSDFs may branch out to perform this function. A cottage industry may also spring up to grasp the opportunity, or pharmaceutical distributors could leverage their connections with manufacturers and healthcare facilities to take on this new line of business.

The proposed amendment would also raise some new questions about generator responsibility for remediation of contamination resulting from a release of hazardous waste pharmaceuticals. Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) §107(a)(3), any person who "by contract, agreement, or otherwise arranged for disposal or treatment…of hazardous substances owned or possessed by such person, by any other party…at any facility," may be found liable for contamination.[1] With a new framework involving pharmaceutical reverse distributors, it is unclear how courts will determine the stage at which there is an arrangement for disposal of hazardous waste pharmaceuticals. Will courts consider the point at which a healthcare facility contracts with a pharmaceutical reverse distributor to ship potentially creditable HWPs to be the arrangement for disposal or treatment? Or will the moment at which a pharmaceutical reverse distributor arranges to ship evaluated HWPs to a TSDF be considered to be the point at which the HWPs are arranged for disposal or treatment? This determination of potential CERCLA liability would affect both healthcare facilities and pharmaceutical reverse distributors.

Aside from these nationwide effects, passage of the proposed RCRA amendment would have two unique impacts in New Jersey. First, the bio-pharmaceutical and medical technology industries have been called the 'crown jewel' of the New Jersey economy. Industry leaders with headquarters in the state include Johnson & Johnson, Merck, Bristol-Myers Squibb, and Novartis. The economic impact generated for New Jersey by these industries in 2012 exceeded $26 billion.[2] The proposed amendment will be particularly beneficial to New Jersey, as it should make compliance with RCRA much easier and cost effective for these industries, their distributors, retailers and healthcare customers.

Second, if the proposed RCRA amendment is finalized by the EPA, its roll out in New Jersey will have a significant complication not found in other states, which could cause delays in full implementation. The pharmaceutical reverse distributor is instrumental to the success of the new waste management scheme. Recognizing the difference between HWP and other hazardous wastes, the proposed amendment would require a pharmaceutical reverse distributor to register with the EPA and subject it to other regulation, but would exempt it from the more onerous and lengthy permitting requirements that apply to other hazardous waste TSDFs.

Thus, as far as RCRA is concerned, pharmaceutical reverse distributors should be able to open for business relatively quickly once the proposed amendment takes effect. However, New Jersey requires at least two other types of approval for a business engaged in the collection, storage, treatment, or transfer of hazardous waste that are not dependent on RCRA, and that typically require at least 11 to 18 months to complete.

The A-901 license is required under N.J.S.A. 13:1E-126, *et seq*., and N.J.A.C. 7:26-16.3 as part of the state's effort to ensure the integrity of the solid and hazardous waste industry within its borders and protect it from infiltration by organized crime. It is administered by the New Jersey Attorney General's Office and involves fingerprinting and a State Police investigation of all principals of entities and their parents applying for the license.

The certificate of public convenience and necessity is an aspect of New Jersey's regulation of public utilities. It is required by N.J.S.A. 48:13A-6 and is administered by the New Jersey Department of Environmental Protection. Applicants must be found "qualified by experience, training, or education to engage in such business" and be able to "furnish proof of financial responsibility." The application requires the applicant to disclose its proposed schedule of rates for the services to be provided.

The A-901 license must be obtained before a potential pharmaceutical reverse distributor can start the application process for the certificate of public convenience and necessity. Even if the Attorney General's Office and the Department of Environmental Protection cooperate to expedite the review and approval of applications by pharmaceutical reverse distributors that want to locate in New Jersey, it is likely New Jersey's large bio-pharmaceutical and medical technology industries will have to

rely upon out-of-state companies or existing RCRA-permitted TSDFs to fill this pivotal role during the first year or so the HWP RCRA amendment is in effect.

The Proposed Amendment's Likely Effective Date

The proposed amendment will likely become effective at the federal level six months after it is promulgated. At that time, the authorized RCRA states will be required to adopt the amended rule and modify their RCRA programs to retain their authorized status, which could cause additional delay in execution of the proposed amendment's provisions in certain states. However, New Jersey regulations automatically adopt federal RCRA amendments as they are promulgated.[3] Therefore, unlike most states where the amendment will not become effective until the state takes affirmative action, the amended rule will become effective in New Jersey as soon as it becomes effective at the federal level. This will necessitate faster implementation in New Jersey.

Conclusion

This is the EPA's second attempt to address the hazardous waste pharmaceutical issue. The first attempt, published in 2008, tried to shoehorn hazardous waste pharmaceuticals into the scheme previously set up for universal wastes, such as waste oil and fluorescent light bulbs. The feedback it received during the comment period apparently convinced the agency to go back to the drawing board. It collected more information from the regulated community and continued to study the issue. The 2015 proposed amendment that resulted from this effort may be finalized later in 2016. ⚖

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ENDNOTES

1. 42 U.S.C. § 9607(a)(3).
2. Lauren Wanko, NJ Trying to Keep Hold on Pharmaceutical Industry, http//www.njtvonline.org/news/video/nj-trying-to-keep-hold-on-pharmaceutical-industry Nov. 29, 2013; accessed April 27, 2016).
3. Effective Jan. 19, 1999, the New Jersey Department of Environmental Protection amended New Jersey's hazardous waste regulations, N.J.A.C. 7:26G-1 *et seq.*, to allow for prospective incorporation by reference.