

On December 11, 2018, the Acting Administrator of the U.S. Environmental Protection Agency (EPA or “the Agency”) signed a final rule establishing special management standards for pharmaceutical wastes that are classified as hazardous wastes under the Resource Conservation and Recovery Act (RCRA). The Final Rule culminates a decade-long effort to tailor the federal hazardous waste program for these wastes, including a 2008 proposal (in the waning days of the Bush Administration) to classify and regulate the wastes as “universal wastes” and a 2015 proposal (in the next-to-last year of the Obama Administration) to establish an entirely new framework for pharmaceutical wastes. *See generally* Beveridge & Diamond PC, [EPA Proposes New Rules for Pharmaceutical Wastes That Qualify as RCRA Hazardous Wastes](#) (September 10, 2015). The Final Rule tracks the 2015 proposal fairly closely, but with a number of significant modifications.

Key highlights of the Final Rule are presented briefly below, followed by a more detailed summary of the scope of the Rule and its new regulatory requirements. The Rule has not yet been officially promulgated through publication in the Federal Register, perhaps in part because of the ongoing partial federal government shutdown. Once the Rule is published, it will take effect six months later at the federal level. However, as discussed in the final section below, it may take months or years for most of the Rule to become effective in the vast majority of states, and portions of the Rules might not ever be adopted by some states (although EPA encourages them to do so).

Highlights

- The Final Rule prohibits sewerage of hazardous waste pharmaceuticals by healthcare facilities (defined to include pharmaceutical distributors and retailers) and by reverse distributors of prescription pharmaceuticals.
- The Rule reaffirms long-standing EPA guidance that products handled in reverse logistics systems are generally not solid or hazardous wastes, but departs from that guidance for prescription pharmaceuticals sent to reverse distributors to facilitate or verify return credits from a manufacturer – effectively moving the point at which such products are classified and must be handled as wastes back to the originating healthcare facilities.
- The Rule establishes new standards for healthcare facilities (as broadly defined) and for reverse distributors of prescription pharmaceuticals, including detailed requirements for storage, labeling, recordkeeping, reporting, and off-site shipment.
- The Rule revises the RCRA definition of “empty” for containers of hazardous waste pharmaceuticals (including delivery devices such as syringes, intravenous (IV) bags, inhalers, and nebulizers) so as to facilitate handling of used pharmaceutical containers in an environmentally protective manner, without always requiring containers that were formerly used for acutely hazardous pharmaceuticals to be triple-rinsed or requiring containers formerly used for other (non-acutely) hazardous pharmaceuticals wastes to be evaluated to determine the amount of residues remaining.
- The Rule exempts over-the-counter (OTC) nicotine gums, lozenges, and patches that have been approved by the Food and Drug Administration (FDA) as nicotine replacement therapies, thereby correcting the historical misclassification of these items as acutely hazardous wastes, which caused large numbers of retailers to be regulated as large quantity generators of hazardous wastes whenever they had to discard just a few boxes of expired or damaged products. However, the exemption does not extend to other low-concentration nicotine products such as prescription nicotine replacement therapies, electronic cigarettes (“e-cigarettes”), vaping pens, and “e-liquids” (*i.e.*, refills for e-cigarettes and vaping pens).
- The Rule establishes new conditional exemptions for hazardous waste pharmaceuticals that qualify as controlled substances under the rules of the U.S. Drug Enforcement Administration (DEA) and/or are collected in household pharmaceutical waste takeback programs or events.
- The Rule establishes new exclusions for pharmaceuticals being managed pursuant to recalls, litigation holds, or FDA-approved new drug investigations, until the materials are released from applicable legal controls and/or a decision is made to discard the materials.

Scope of the Final Rule

The Final Rule substantially changes the requirements governing the generation and management of “hazardous waste pharmaceuticals” by “healthcare facilities” and “reverse distributors.” Because these terms are defined in somewhat non-intuitive ways, it is important to focus on the definitions in order to understand the full scope of the Rule.

Pharmaceuticals

The Final Rule defines “pharmaceutical” broadly to include all the products that are normally associated with that term, as well as many products and other materials that might not be. For example, the definition covers prescription drugs, OTC drugs, and investigational new drugs for both humans and animals. However, it also covers dietary supplements, homeopathic drugs, residues of pharmaceuticals remaining in non-empty containers (as discussed further below), personal protective equipment contaminated with pharmaceuticals, and clean-up materials from pharmaceutical spills. Moreover, the definition includes e-cigarettes, vaping pens, and e-liquids (see also the discussion of nicotine-containing wastes, further below). Dental amalgam and sharps are not included (although, as discussed below, syringes containing pharmaceutical residues may be regulated as non-empty containers).

Hazardous Waste Pharmaceuticals

Under the Final Rule, “hazardous waste pharmaceuticals” are those pharmaceuticals that are defined as solid wastes and are either explicitly listed as hazardous wastes or exhibit a hazardous waste characteristic (*i.e.*, ignitability, corrosivity, reactivity, or toxicity as measured under the Toxicity Characteristic Leaching Procedure (TCLP)).

Importantly, the Rule changes long-standing EPA policy on when pharmaceuticals become solid wastes (and thus potentially hazardous waste pharmaceuticals), at least in certain circumstances. Historically, the Agency took the position that pharmaceuticals sent to a reverse distributor (for prescription pharmaceuticals) or to a reverse logistics center (for non-prescription pharmaceuticals) are generally not wastes until they have arrived at and been evaluated by such facilities. In the Final Rule, EPA essentially reaffirms this position with respect to *non-prescription* pharmaceuticals, stating that OTC pharmaceuticals, dietary supplements, and homeopathic drugs are not solid wastes as long as they have a reasonable expectation of being legitimately used/reused (*e.g.*, lawfully redistributed for their intended purpose) or reclaimed. However, the Agency departed from the past policy with respect to *prescription* pharmaceuticals, asserting that they are wastes when sent to a reverse distributor, because the potential for use/reuse or reclamation is very limited and the fact that the prescription pharmaceuticals may be evaluated for potential manufacturer credit is not sufficient to make the materials non-wastes.

The importance of this change in policy is that prescription pharmaceuticals destined for a reverse distributor will now be viewed by EPA as solid and potentially hazardous wastes in the hands of the originating facilities and while being shipped from such facilities to a reverse distributor – not just after they have arrived at and been evaluated by the reverse distributor. Since the handling of these materials by the originating facilities and the transporters was not previously deemed to involve solid or hazardous wastes, there was no basis for regulating the materials unless and until the reverse distributor determined any applicable manufacturer credits and made a decision to discard the materials. The new EPA policy effectively moves the “point of generation” of the materials as solid wastes back to the originating facilities, and thus serves as the asserted legal basis for much of the new regulations (*e.g.*, the regulations for healthcare facilities sending prescription pharmaceuticals to reverse distributors).

Healthcare Facilities

The Final Rule defines “healthcare facilities” broadly to include a wide range of facilities that would normally be viewed as such, as well as many that might not be. For example, the definition includes hospitals, ambulatory surgical centers, health clinics, physician’s offices, optical and dental providers, long-term care facilities, and ambulance services. However, the definition also extends to persons that distribute, sell, or dispense pharmaceuticals (as broadly defined), including pharmaceutical distributors, pharmacies (both brick-and-mortar and mail-order), and retailers of pharmaceuticals (including OTC

medications, dietary supplements, and homeopathic drugs). Veterinary clinics, hospitals, and offices are also included.

Reverse Distributors

Under the Final Rule, “reverse distributors” are defined as any persons that receive and accumulate *prescription* pharmaceuticals that are hazardous waste pharmaceuticals in order to facilitate or verify manufacturer credits. There must be a reasonable expectation that the hazardous waste pharmaceuticals handled by reverse distributors are eligible to receive credit, and the pharmaceuticals must be in the original manufacturer packaging (except in the case of a recall), undispensed, and either unexpired or less than one year past expiration. As discussed in more detail below, prescription hazardous waste pharmaceuticals not meeting these criteria generally must be sent to a RCRA-permitted hazardous waste facility, rather than a reverse distributor. As noted above, *nonprescription* pharmaceuticals sent to a reverse logistics center are generally not solid wastes until the materials arrive at and are evaluated by the center, at which point the center becomes subject to the ordinary hazardous waste generator rules for any hazardous pharmaceuticals discarded, rather than the new rules for reverse distributors.

Requirements for Healthcare Facilities and Reverse Distributors

The Final Rule establishes detailed requirements for both healthcare facilities and reverse distributors that generate or manage hazardous waste pharmaceuticals. The requirements are set forth in a new “Subpart P” in 40 C.F.R. Part 266, which is the part of the RCRA regulations reserved for standards governing specific categories of hazardous wastes or waste management facilities. Key requirements under Subpart P are summarized below.

Sewering Prohibition

The Final Rule prohibits all healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals through a public sewer system (e.g., by pouring them into a sink, toilet, or floor drain). This prohibition applies even to healthcare facilities that qualify as Very Small Quantity Generators (VSQGs) and therefore are generally exempt from RCRA, including the new Subpart P (as discussed further below). EPA notes that the prohibition does not extend to households and does not cover non-hazardous waste pharmaceuticals. However, the Agency strongly discourages anyone – including households – from sewerage any waste pharmaceuticals (hazardous or non-hazardous).

Healthcare Facility Requirements

Healthcare facilities covered by the Final Rule will be required to meet different requirements for the management of: (1) “non-creditable hazardous waste pharmaceuticals” (defined to include both *prescription* hazardous waste pharmaceuticals not expected to be eligible for manufacturer credit and *nonprescription* hazardous waste pharmaceuticals that do not have a reasonable expectation of being legitimately used/reused or reclaimed); and (2) “potentially creditable hazardous waste pharmaceuticals” (defined to include *prescription* hazardous waste pharmaceuticals that have a reasonable expectation to receive manufacturer credit and are in the original manufacturer packaging (with limited exceptions), undispensed, and either unexpired or less than one year past expiration). (Nonprescription hazardous waste pharmaceuticals that do have a reasonable expectation of being legitimately used/reused or reclaimed generally do not trigger any requirements because they are not solid wastes, as discussed above.)

For the management of non-creditable hazardous waste pharmaceuticals, healthcare facilities will be required to:

- Notify EPA that they are healthcare facilities operating under Subpart P (and withdraw the notification if/when they are no longer operating under Subpart P);
- Make a hazardous waste determination for solid wastes that are non-creditable pharmaceuticals (although the facilities may elect to manage their nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under Subpart P);
- Accumulate and transport non-creditable hazardous waste pharmaceuticals in containers that are structurally sound, not leaking/spilling, and labeled or marked “Hazardous Waste Pharmaceuticals”;

- Separately contain non-creditable hazardous waste pharmaceuticals that are prohibited from being combusted (under the RCRA land disposal restrictions program), and mark such containers with all applicable waste codes;
- Accumulate the wastes onsite for no longer than one year (longer storage would trigger RCRA permitting requirements as a hazardous waste storage facility);
- Prepare the wastes for offsite transport in accordance with applicable U.S. Department of Transportation (DOT) requirements (e.g., with respect to packaging, labeling, marking, and placarding);
- Ship the wastes offsite to a “designated facility” (e.g., a permitted hazardous waste treatment, storage, or disposal facility) using a hazardous waste manifest and a hazardous waste transporter (although wastes codes do not have to be included on these manifests);
- Submit an “exception report” to EPA if a signed copy of the manifest is not received from the designated facility in a timely fashion; and
- Keep records of manifests, exception reports, and analyses supporting hazardous waste determinations.

Healthcare facilities will also have to comply with requirements related to personnel training, land disposal restrictions, rejected shipments, and release response.

The Final Rule has much more limited requirements for healthcare facilities when managing potentially creditable hazardous waste pharmaceuticals, because these pharmaceuticals by definition are generally in the original manufacturer packaging and there is an economic incentive to deliver the materials to a reverse distributor quickly to obtain any applicable credits, such that the risks to the environment and the risks of diversion are minimized. Under the Rule, healthcare facilities generating potentially creditable hazardous waste pharmaceuticals must make a hazardous waste determination for such wastes (although the facilities may elect to manage their potentially creditable nonhazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under Subpart P). Healthcare facilities will be prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. When shipping potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor, healthcare facilities will not need to use a hazardous waste manifest or a hazardous waste transporter. However, the facilities will have to comply with applicable DOT requirements for transport (e.g., relating to packaging, labeling, marking, placarding, and shipping papers). The reverse distributor receiving the wastes will be required to provide a confirmation that the shipment arrived (as discussed further below), and the healthcare facility will have to maintain records of the shipping papers and the confirmations of receipt.

A healthcare facility that qualifies as a VSQG, taking into account both hazardous waste pharmaceuticals and non-pharmaceutical hazardous wastes, will not be subject to the above requirements (except the sewerage prohibition), but will instead be subject to the normally applicable RCRA requirements for VSQGs (unless they elect to comply with Subpart P). However, these VSQG healthcare facilities will have the option of sending their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. They will also be allowed to send their hazardous waste pharmaceuticals to a related healthcare facility, in which case the receiving facility will not be subject to RCRA permitting requirements as long as they keep certain records and manage the received wastes in accordance with Subpart P. For purposes of these VSQG provisions, long-term care facilities with 20 beds or fewer are presumed to be VSQGs, while facilities with more than 20 beds are presumed not to be VSQGs; however, both presumptions can be overcome with sufficient evidence by EPA (for the smaller facilities) or by the long-term care facility (for facilities with greater than 20 beds).

Finally, if a healthcare facility qualifies as a VSQG counting only its non-pharmaceutical hazardous wastes, but exceeds the VSQG limits once its pharmaceutical hazardous wastes are also counted, the pharmaceutical wastes must be managed in accordance with Subpart P, but the rest of the wastes (i.e., the non-pharmaceutical hazardous wastes) may be managed in accordance with the general RCRA rules for VSQGs. Stated another way, hazardous waste pharmaceuticals managed under the new Subpart P will no longer have to be counted in calculating a site’s RCRA generator category.

Reverse Distributor Requirements

Under the Final Rule, reverse distributors can accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate such wastes and/or “evaluated hazardous waste pharmaceuticals” without becoming subject to RCRA permitting (or interim status) requirements, as long as they comply with certain requirements. For these purposes, evaluated hazardous waste pharmaceuticals are prescription hazardous waste pharmaceuticals that have been evaluated by a reverse distributor to determine their eligibility for manufacturer credit and that will not be sent to another reverse distributor for further evaluation or verification of credit.

To qualify for this permitting exemption, reverse distributors must meet the following requirements:

- Notify EPA of the reverse distributor’s operations;
- Maintain an inventory of all potentially creditable and evaluated hazardous waste pharmaceuticals accumulated on-site;
- Secure areas where potentially creditable and evaluated hazardous waste pharmaceuticals are kept;
- Prepare and follow a contingency plan;
- Report any receipt of unauthorized hazardous waste (*e.g.*, non-pharmaceutical hazardous waste) to EPA and the originating healthcare facility (or other facility); and
- Maintain certain records, including the notification of regulated activity, the shipping papers and delivery confirmation for each shipment of potentially creditable hazardous waste pharmaceuticals received, the current inventory, and any unauthorized hazardous waste reports.

Additionally, a reverse distributor will be required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 days of arrival to establish whether they will be transported to another reverse distributor for verification of manufacturer credit, or to a hazardous waste treatment, storage, or disposal facility. Reverse distributors without a permit or interim status can only accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 180 days, beginning when the potentially creditable pharmaceuticals are evaluated (although if the potentially creditable pharmaceuticals are unexpired and are being held pending expiration, the reverse distributor can accumulate the materials until 180 days after the expiration date). EPA expanded these timeframes from the ones originally proposed to reflect the way that reverse distributors generally operate and the relatively low risks involved.

By the end of the 180 days, the potentially creditable hazardous waste pharmaceuticals must be managed in one of the following ways:

- If they are from a healthcare facility, they may be transported to another reverse distributor;
- If they are from a reverse distributor, they may be transported to another reverse distributor that is also a pharmaceutical manufacturer; or
- If they are from either source, they may be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals (described below).

For evaluated hazardous waste pharmaceuticals, a pharmaceutical reverse distributor without a permit or interim status must meet additional requirements, which are intended to resemble the requirements for central accumulation areas at large quantity generator facilities. These requirements include: designating an on-site accumulation area for the evaluated hazardous waste pharmaceuticals, inspecting that area weekly, labeling containers, ensuring the containers meet certain standards, separately containing evaluated hazardous waste pharmaceuticals that are prohibited from being combusted, marking containers with relevant hazardous waste code(s) prior to offsite shipment, training personnel, following specified procedures for rejected shipments, complying with land disposal restrictions, biennial reporting, exception reporting, and recordkeeping. Reverse distributors shipping evaluated hazardous waste pharmaceuticals to an off-site permitted or interim status treatment, storage, or disposal facility will be required to comply with hazardous waste manifest requirements (including the requirement to list hazardous waste codes), use a hazardous waste transporter, and meet all applicable DOT requirements.

Reverse distributors shipping potentially creditable hazardous waste pharmaceuticals off-site to another reverse distributor will not need to use a hazardous waste manifest or a hazardous waste transporter.

However, such reverse distributors must comply with applicable DOT requirements (e.g., with respect to packaging, labeling, marking, placarding, and shipping papers). The reverse distributor receiving these shipments must provide a confirmation that the shipment arrived, and if the originating reverse distributor fails to receive such a confirmation within 35 days, it must follow up with the carrier and the intended receiving facility. (EPA originally proposed that reverse distributors initiating these shipments would have to provide the receiving reverse distributors advance notice of the shipments, but it did not finalize this requirement.)

Miscellaneous Provisions

The Final Rule contains several additional provisions that apply not only to healthcare facilities and reverse distributors, but also to other entities. Several of these provisions are discussed briefly below.

Revised Definition of "Empty" for Containers of Hazardous Waste Pharmaceuticals and Related Requirements for Management of Residues in Containers

The Final Rule amends the RCRA definition of an "empty" container as it applies to containers of hazardous waste pharmaceuticals, as well as the requirements for managing containers with remaining residues of such pharmaceuticals. The details vary depending on the specific type of container, but are designed to facilitate handling of used pharmaceutical containers in an environmentally protective way without always requiring containers formerly used for acutely hazardous pharmaceuticals to be triple-rinsed or requiring containers formerly used for other (non-acutely) hazardous pharmaceutical wastes to be evaluated to determine the amount of residues remaining.

- For stock bottles, dispensing bottles, vials or ampules (in each case not exceeding 1 liter of liquid or 10,000 pills), the residues (and containers) will not be regulated as hazardous wastes if all pharmaceuticals are removed using "common practices." The same will be true for unit dose containers (e.g., unit dose packets, cups, wrappers, or blister packs). Although EPA originally proposed that containers in both categories would also have to be destroyed to prevent further use, the Agency decided not to finalize that requirement, in part due to concerns about worker exposures during container destruction. EPA also increased the maximum size of the bottles eligible for this new provision from 1000 pills to 10,000 pills (although the 1 liter limit for liquids was kept unchanged from the proposal).
- Residues in a syringe will not be regulated as hazardous wastes provided that the plunger of the syringe has been fully depressed. If a syringe has not been emptied in this way (and the residues remaining are hazardous), it must be managed in accordance with the Subpart P requirements for non-creditable hazardous waste pharmaceuticals and any applicable requirements for sharps and/or medical wastes. Importantly, the Final Rule rescinds prior EPA guidance that said residues remaining in syringes have been "used" and thus are not covered by any of the hazardous waste listings for (unused) commercial chemical products.
- IV bags, like syringes, will be deemed empty if the contents have been "fully administered to a patient." Non-empty IV bags with hazardous residues will have to be managed under the Subpart P requirements for non-creditable pharmaceuticals, unless the bags held non-acutely hazardous waste pharmaceuticals and meet the long-standing definition of "empty" under RCRA.
- Other containers (e.g., inhalers, aerosol cans, nebulizers, and tubes of gels, ointments, or creams) containing residues of hazardous waste pharmaceuticals will have to be managed under the Subpart P requirements for non-creditable pharmaceuticals, unless the containers held non-acutely hazardous waste pharmaceuticals and meet the general RCRA definition of "empty."

New Exclusion for Nicotine Gums, Lozenges, and Patches that Are FDA-Approved OTC Nicotine Replacement Therapies

The Final Rule modifies the P075 hazardous waste listing for nicotine (and salts) so that it now excludes nicotine gums, lozenges, and patches that have been approved by FDA as OTC nicotine replacement therapies. The new exclusion reflects the fact that these products do not meet the "acutely hazardous" criteria for which nicotine was originally listed, and it provides significant regulatory relief to retail facilities which, under the pre-existing rules, frequently became subject to regulation as large quantity generators

of hazardous waste whenever they had to discard just a few boxes of these products due to expiration, damage, product discontinuation, or other factors.

EPA did not extend the exclusion to other low-concentration nicotine products, such as prescription nicotine replacement therapies (e.g., inhalers and nasal sprays), e-cigarettes, vaping pens, and e-liquids. The limited scope of the exclusion limits to some degree the benefits to the retail industry. However, since these products (when discarded) are covered by the new definition of hazardous waste pharmaceuticals, they may be managed pursuant to the Subpart P regulations, in which case they would not have to be counted in determining the status of the generating retail (or other) facility as a large, small, or very small generator of hazardous wastes.

New Conditional Exemptions for Hazardous Waste Pharmaceuticals that are DEA Controlled Substances and/or Collected in Household Waste Pharmaceutical Takeback Programs/Events

In order to eliminate duplicative regulation of hazardous waste pharmaceuticals that are also DEA controlled substances, the Final Rule conditionally exempts such wastes from all RCRA Subtitle C requirements, including the new Subpart P. The Rule also conditionally exempts household waste pharmaceuticals that are collected in a takeback program or event, whether or not controlled substances are among the collected wastes (effectively modifying the long-standing rule that household wastes are excluded from RCRA regulation – without condition – during all phases of management, including during and after collection, although the Rule keeps that broad exclusion for household waste pharmaceuticals managed outside a collection program/event, such as in the ordinary municipal waste stream).

To qualify for either exemption, the hazardous waste pharmaceuticals must be: (1) managed in accordance with the sewerage prohibition discussed above, (2) managed and disposed of in compliance with all applicable DEA regulations, and (3) destroyed either by combustion in certain types of units (i.e., a permitted large or small municipal waste combustor (MWC), a permitted hospital/medical/infectious waste incinerator (HMIWI), a permitted commercial/industrial solid waste incinerator (CISWI), or a permitted hazardous waste combustor) or by another method that DEA has publicly determined meets its standard of “non-retrievable destruction.” The exemptions, as finalized, provide more flexibility than the proposed exemptions, primarily by allowing destruction in additional types of combustion units, as well as in non-combustion units publicly determined by DEA to be acceptable.

New Exclusions for Pharmaceuticals Being Managed Pursuant to a Recall, Litigation Hold, or FDA-Approved New Drug Investigation

The Final Rule includes exclusions from the RCRA hazardous waste regulations (including the new Subpart P) for pharmaceuticals being managed in accordance with a recall strategy approved by FDA or a recall corrective action plan accepted by the Consumer Product Safety Commission (CPSC). In both cases, however, once the relevant agency has approved destruction of the recalled items, they may become subject to hazardous waste regulation, including Subpart P (e.g., if the items are in possession of a healthcare facility). Similarly, the Rule excludes pharmaceuticals stored pursuant to a preservation order, investigation, or judicial proceeding, as well as investigational new drugs under FDA supervision, until a decision is made to discard the materials. EPA issued these exclusions in recognition of the facts that the materials in these situations may not be solid wastes, the relevant agency rules or court orders generally provide adequate protections, and compliance with RCRA under these circumstances may not be practical.

No Action on Strategy for Listing of Additional Pharmaceutical Wastes as Hazardous

In the proposed rule, EPA requested comments on potential methods for identifying new pharmaceuticals that should be listed as RCRA hazardous wastes, as well as on specific candidates for such listing. The Agency made this request based on input from the EPA Office of Inspector General and others that the Agency has failed for decades to evaluate new pharmaceuticals for potential listing. In the Final Rule, EPA did not take any action on the comments received, but noted that the Rule will encourage all waste pharmaceuticals – including those that are currently classified as nonhazardous – to be managed in accordance with the Subpart P requirements for hazardous waste pharmaceuticals.

Effect of the Rule in the States

EPA notes that the Final Rule will generally not take effect in most states until the states act to adopt the Rule as a matter of state law, because most portions of the Rule are not being issued pursuant to the Hazardous and Solid Waste Amendments of 1984 (HSWA), which, unlike the rest of RCRA, provides for a uniform effective date in all states for certain rules (generally six months after publication in the Federal Register). The main exceptions are for the few states that do not have "authorized" RCRA programs (e.g., Alaska, Iowa, and Puerto Rico) and for the small number of additional states that automatically adopt new federal rules under RCRA (e.g., New Jersey and Pennsylvania). In addition, the new prohibition on sewerage of hazardous waste pharmaceuticals will take effect in all states at the same time, because EPA takes the position that the prohibition is being issued pursuant to HSWA.

The Agency claims that the Final Rule "on the whole" is more stringent than current federal regulatory requirements for hazardous waste pharmaceuticals, and therefore will have to be adopted by all RCRA-authorized states. However, EPA acknowledges that some elements of the Rule may be less stringent, such that they will not have to be adopted by the states. In particular, the Agency notes that the new exemption for FDA-approved OTC nicotine replacement therapies (i.e., nicotine gum, patches, and lozenges) is less stringent and will not have to be adopted by the states.

Finally, the Agency points out that two states (Florida and Michigan) have classified pharmaceutical wastes as "universal" hazardous wastes, thereby subjecting them to fewer regulatory requirements than currently apply under federal law. EPA specifies that these states will also have to adopt the new Rule, and will have to remove hazardous waste pharmaceuticals from their universal waste programs (although they may continue to regulate non-hazardous waste pharmaceuticals as universal wastes, if they so choose).

Beveridge & Diamond assists clients in a wide range of industrial sectors with solid and hazardous waste regulatory issues under RCRA, its state counterparts, international treaties, and the laws and regulations of countries around the world. We regularly help clients in understanding and complying with the regulatory requirements for discarded pharmaceuticals and other consumer products, including the threshold issues of when these materials qualify as "wastes," when wastes qualify as "hazardous," and when hazardous wastes are eligible for regulatory exemptions or exclusions. We have been lead counsel in many cases challenging key portions of the RCRA regulations, and defend companies in related enforcement actions. For more information about EPA's Final Rule on pharmaceutical wastes, please contact the author, [Aaron Goldberg](#), or any other member of our [RCRA/Hazardous Waste practice group](#).