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A Closer Look At New Pharmaceutical Hazardous Waste Regs

By **Karlie Webb and Greg Blount** (January 4, 2019, 12:05 PM EST)

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On Dec. 11, 2018, the U.S. Environmental Protection Agency signed the long-awaited final "Management Standards for Hazardous Waste Pharmaceuticals" rule. The proposed rule was published in the Federal Register on Sept. 25, 2015,[1] more than three years before the final rule. The initial draft rule, in which the EPA proposed to manage hazardous waste pharmaceuticals as universal waste, dates from 2008 and was ultimately withdrawn.

The final rule establishes new sector-specific Resource Conservation and Recovery Act regulations for managing hazardous waste pharmaceuticals, which are in a new Subpart P to 40 Code of Federal Regulations Part 266. Importantly, although the final rule is a major step in eliminating the current piece-meal, state-by-state approach to pharmaceutical hazardous waste regulation, because states will still have to adopt the final rule, it may not fully eliminate this patchwork system as unsold pharmaceuticals are shipped in interstate commerce across the country. Although not comprehensive, here we highlight key aspects of the final rule.

Applicability

The final rule applies to "hazardous waste pharmaceuticals" generated or managed by "health care facilities"[2] (which includes, among others, retail pharmacies and hospitals) and "reverse distributors" (of prescription pharmaceuticals).[3] The final rule does not change requirements applicable to management of nonpharmaceutical hazardous wastes or nonhazardous pharmaceutical wastes. Except for the sewer ban (discussed below), only health care facilities that generate above the very small quantity generator, or VSQG, thresholds when combining pharmaceutical hazardous waste and nonpharmaceutical hazardous waste are subject to the new Subpart P. All reverse distributors, regardless of the amount of hazardous waste generated or accumulated, are subject to Subpart P.

Importantly, and as a welcomed change from the proposed rule, although "pharmaceutical"[4] is defined to capture over-the-counter pharmaceuticals, dietary supplements and homeopathic drugs ("nonprescription pharmaceuticals" herein), the final rule's definition of "hazardous waste pharmaceutical" in Section 266.500 excludes these items by stating that "[a]n over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed." The ultimate effect is the following (unless the health care facility is a VSQG and chooses not to manage its pharmaceuticals under Subpart P):

1. Prescription hazardous waste pharmaceuticals are always subject to Subpart P, whether they are sent to a reverse distributor (as "potentially creditable hazardous waste pharmaceuticals") or sent to a treatment, storage and disposal facility, or TSDF, from the health care facility (as

"noncreditable hazardous waste pharmaceuticals").

2. Nonprescription pharmaceuticals are subject to Subpart P when they are discarded by a health care facility, such as when they do not have a "reasonable expectation of being legitimately used/reused ... or reclaimed"[5] and thus cannot be sent to a reverse logistics provider (distinguished from a reverse distributor and discussed in more detail below), in which case they are defined as "noncreditable hazardous waste pharmaceuticals" (assuming they are determined to be hazardous waste. Nonprescription pharmaceuticals that have a "reasonable expectation of being legitimately used/reused ... or reclaimed" are not yet considered a solid waste at the health care facility and thus are not yet subject to the RCRA, including Subpart P. The latter would become a solid waste and thus potentially a hazardous waste subject to Part 262 (not Part 266) when a reverse logistics provider makes the decision to discard.

In addition, the EPA uses the preamble to the final rule to fulfill the EPA's commitment to its retail strategy to develop a comprehensive policy that applies to all unsold consumer products, not just pharmaceuticals. Overall, similar to what the EPA codifies in the final rule regarding nonprescription pharmaceuticals, the EPA states that unsold retail items sent to a reverse logistics provider are not wastes if there is a reasonable expectation of being legitimately used/reused or reclaimed. Instead (and again consistent with nonprescription pharmaceuticals), once the reverse logistics provider makes a decision to discard an unsold retail item, it becomes a solid waste and a hazardous waste determination must be made. These points are discussed in more detail throughout.

Sewer Prohibition

The new Section 266.505 prohibits all health care facilities (including VSQGs) and reverse distributors from the practice of disposing of hazardous waste pharmaceuticals down the drain. The EPA states in the preamble to the final rule that current RCRA and Clean Water Act requirements allow for this practice, notwithstanding potential issues under local sewer ordinances and the Clean Water Act and hazardous waste disposal notification for sewer discharges.[6]

DEA-Controlled Substances

Historically, when a pharmaceutical was both a RCRA hazardous waste and a U.S. Drug Enforcement Administration-controlled substance listed in Schedule II-V, the health care facility was required to comply with both EPA and DEA requirements. The final rule establishes that if the following requirements are satisfied, hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the DEA in 21 CFR part 1308 are not subject to RCRA Subtitle C regulation: (1) the drugs are managed in compliance with the new sewer prohibition in Section 266.505; (2) the drugs are collected, stored, transported and disposed of in compliance with all DEA regulations for controlled substances; and (3) the drugs are destroyed by a method that the DEA has publicly deemed in writing to meet their nonretrievable standard of destruction or combusted at a facility listed as acceptable in the new Section 266.506 (including, for example, a permitted large municipal waste combustor).

Reverse Distribution Versus Reverse Logistics

The EPA regulations have not historically addressed the reverse distribution or reverse logistics processes, which has meant uncertainty and inconsistent regulation and policies across the country. The EPA initially proposed to regulate pharmaceutical reverse distribution in a manner that captured nonprescription pharmaceuticals, but in response to significant public comments, the EPA has now distinguished reverse distribution of prescription pharmaceuticals from reverse logistics of nonprescription pharmaceuticals and other retail items, such as unsold consumer products that could be hazardous waste. Specifically, the final rule does the following:

- ***Reverse Distribution of Prescription Pharmaceuticals:*** Subpart P maintains the EPA's position from the proposed rule — that prescription pharmaceuticals are solid waste at the health care facility,[7] regardless of whether the pharmaceutical may ultimately be issued credit by the reverse distributor.[8] However, 266.501(g)(1) makes clear that if prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered

a solid waste at the health care facility. Subpart P codifies an acceptable process, with required management requirements (discussed below) for health care facilities to send potentially creditable hazardous waste pharmaceuticals to reverse distributors, as well as requirements that reverse distributors must follow.

- ***Reverse Logistics of Nonprescription Pharmaceuticals:*** Section 266.501(g)(2) codifies that nonprescription pharmaceuticals sent to a reverse logistics provider are not solid waste at the health care facility if they have a reasonable expectation of being legitimately used/reused or reclaimed. If there is not a reasonable expectation of being legitimately used/reused or reclaimed, the nonprescription pharmaceutical must be considered a solid waste at the health care facility; if determined to be hazardous waste, the nonprescription pharmaceuticals must be managed as "noncreditable hazardous waste pharmaceuticals,"[9] in accordance with Section 266.502 management requirements and Section 266.508 shipping requirements.

- ***Reverse Logistics of Nonpharmaceutical Consumer Products; Retail Strategy Guidance:*** As discussed above, although not specifically codified by Subpart P, the preamble establishes an EPA policy related to nonprescription pharmaceuticals and nonpharmaceutical retail waste. Overall, the EPA takes the position that retail items that are sent to a reverse logistics provider are not waste if there is a reasonable expectation of being legitimately used/reused or reclaimed. Instead, once the reverse logistics center makes a decision to discard an item, it becomes a solid waste and a hazardous waste determination must be made.

The EPA addresses six issues and problematic areas of reverse logistics as part of its new policy in the preamble, including, for example, unsold retail items that (1) have expired; (2) have been given a destroy disposition by the manufacturer; (3) are subject to a recall; (4) are broken, damaged or leaking.

The EPA continues to assume nonprescription pharmaceuticals and unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed.[10] Conversely, where it is clear that a manufacturer is using a "destroy disposition" and the item is prohibited from being reclaimed, the item is a solid waste at the retail store or health care facility.[11] While the EPA notes that it agrees that nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics when they are broken, damaged or leaking, the EPA recognized the challenge in making this determination.

Recalls

The EPA makes clear in Section 266.501(g)(3)-(4) that pharmaceuticals (prescription and nonprescription) being managed in accordance with a recall strategy approved by the U.S. Food and Drug Administration or the Consumer Product Safety Commission are not subject to RCRA requirements — including Parts 262 and 266. This is true whether the pharmaceuticals are at a health care facility or reverse distributor. The pharmaceuticals would become subject to the RCRA requirements once the FDA or CPSC approves destruction of the recalled items. In the preamble, the EPA also makes clear that it also does not apply RCRA requirements to recalls of other unsold retail items provided the recall is overseen by the FDA or CPSC until after the FDA or CPSC approves destruction of the recalled items. Recalls initiated by other processes, such as voluntary or litigation driven recalls, are not addressed.

Subpart P Management Requirements for Health Care Facilities and Reverse Distributors

The final rule allows health care facilities to send "potentially creditable hazardous waste pharmaceuticals,"[12] and prohibits sending "noncreditable hazardous waste pharmaceuticals," [13] to reverse distributors. Although the EPA expressly rejects credit potential as a basis for deferring the point of waste determination, the "reasonable expectation to receive manufacturer credit" is the litmus test for determining whether a hazardous waste prescription pharmaceutical meets the definition of "potentially creditable hazardous waste pharmaceutical" and is thus eligible to be sent to a reverse distributor.

Once a "potentially creditable hazardous waste pharmaceutical" reaches the reverse distributor, it maintains this same name until the credit evaluation is conducted, at which time it is considered an

"evaluated hazardous waste pharmaceutical"[14] (unless it will go to another reverse distributor) and is then subject to separate Subpart P management requirements. The new Subpart P establishes mandatory management and shipping requirements for health care facilities (except VSQGs) and all reverse distributors (regardless of the amount of hazardous waste generated or accumulated).

Noncreditable hazardous waste pharmaceuticals are subject to Section 266.502 management requirements and Section 266.508 shipping requirements, similar to current small-quantity generator, or SQG, requirements. Potentially creditable hazardous waste pharmaceuticals are subject to relaxed management standards in Section 266.504 and shipping standards in Section 266.509. Reverse distributors must comply with the Section 266.510 requirements, which are akin to large-quantity generator, or LQG, standards, with some similarity to TSDF management requirements. The EPA also establishes notification and tracking requirements, including, for example, a requirement that a reverse distributor submit to the EPA (or the authorizing state) an unauthorized waste report if a health care facility sends unauthorized waste to the reverse distributor. [15]

Importantly, the Subpart P requirements only apply to hazardous waste pharmaceuticals, and thus a health care facility must either (1) determine whether a particular noncreditable or potentially creditable (as the case may be) pharmaceutical is hazardous waste and then segregate and manage the hazardous waste pharmaceuticals in accordance with Subpart P requirements; or (2) manage all noncreditable or potentially creditable pharmaceuticals (as the case may be) as hazardous waste pharmaceuticals under the Subpart P requirements.

Nicotine Replacement Therapies

Historically, many retailers with pharmacies have been regulated as LQGs. Currently, retailers most often become LQGs because of the amount of p-listed acute hazardous waste generated (a facility is an LQG if it generates more than 2.2 pounds of acute hazardous waste on site at any one time). Nicotine replacement therapy, or NRT, products, which include gums, lozenges and patches, that cannot be sold have historically been considered acute hazardous waste, thus quickly triggering LQG requirements, particularly for retail pharmacies.

Retailers have been asking the EPA for relief from these common items for years, and the EPA has now finalized an amendment to the hazardous waste listing for hazardous waste code P075 in 40 CFR 261.33(e) to exempt FDA-approved over-the-counter NRTs, and the regulation will specifically note that the P075 listing does not include patches, gums and lozenges that are FDA-approved over the counter. Once the final rule is effective, these over-the-counter NRTs will be considered nonhazardous wastes and are thus not subject to hazardous waste regulations (subject to state adoption). This means that many retailers that are currently LQG will likely become VSQGs or SQGs. The EPA is not exempting e-cigarettes, e-liquids or prescription NRTs from the P075 hazardous waste listing.

Empty Warfarin Containers

In addition to nicotine, warfarin is also a p-listed hazardous waste (P001) and historically often caused health care facilities to trigger LQG generator status. On Nov. 11, 2011, the EPA issued a guidance document confirming that for containers that previously held p-listed pharmaceuticals, only the residue must count toward the facility's generator status.[16] The EPA specifically stated that the weight of the container does not count toward the facility's generator status. By relying on this EPA guidance, health care facilities were able to significantly reduce the amount of acute hazardous waste generated onsite because they stopped counting the weight of empty warfarin containers.

The final rule formalizes the November 2011 guidance, with some additional detail. Specifically, Section 266.507 states that stock and dispensing bottles, vials and ampules (not to exceed 1 liter or 10,000 pills) or a unit-dose container is considered empty and the residues are not regulated as hazardous waste where the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule or the unit-dose container using the practices commonly employed to remove materials from the type of container. Section 266.507 also includes provisions specific to determining whether syringes, IV bags and other containers are considered empty.

Generator Status and Determining Whether Subpart P Applies to Your Facility

With respect to determining whether a facility must manage its hazardous waste pharmaceuticals

under Subpart P (rather than the current Part 262 hazardous waste generator requirements), all reverse distributors (including VSQGs) must manage hazardous waste pharmaceuticals under Subpart P.

If a facility is above the VSQG quantity thresholds when combining both nonpharmaceutical hazardous waste and pharmaceutical hazardous waste (including potentially creditable hazardous waste pharmaceuticals sent to a reverse distributor), then it is subject to Subpart P for its hazardous waste pharmaceuticals and Part 262 for its nonpharmaceutical hazardous wastes. We think of VSQG health care facilities in two categories:

1. A facility is a VSQG after it combines the hazardous waste generated from hazardous waste pharmaceuticals (including potentially creditable hazardous waste pharmaceuticals sent to a reverse distributor) and nonpharmaceutical hazardous waste and thus Subpart P management requirements are not mandatory for the facility, except for the sewer prohibition. In this instance, the EPA clarifies that the VSQG health care facility may choose to operate as a health care facility under Subpart P or may instead operate as a standard VSQG under Part 262 and still utilize the optional provisions in 266.504.

2. A facility is a VSQG for its nonpharmaceutical hazardous waste (under Part 262) because its hazardous waste pharmaceuticals are being managed under the new Subpart P and thus do not count toward the facility's overall generator status and thus does not push the facility to a higher generator category.

In either case, we anticipate that many health care facilities — particularly retailers — that have historically been subject to the stringent LQG requirements in Part 262 will be able to manage at least their nonpharmaceutical hazardous wastes under the less stringent generator requirements for SQGs and, for many, even under the VSQG regulations.

Effective Date and Impact to States

The final rule will become effective at the federal level six months after publication in the Federal Register. We anticipate that the final rule will be published in the Federal Register in the coming weeks.

With respect to when the final rule will become effective at the state level, it depends on the state. Iowa and Alaska do not have EPA-authorized hazardous waste programs, and thus the final rule, in its entirety, will become effective in those states on the rule's effective date — six months after publication in the Federal Register.

For the remaining states, the effective date of the rule depends on whether the new EPA regulation is issued under the authority of the Hazardous and Solid Waste Amendments of 1984, or HSWA, and whether the new regulation is more stringent or broader than existing federal requirements. New regulations apply on their effective date for provisions enacted pursuant to the EPA's HSWA authority. The EPA states that only the prohibition against sewering hazardous waste pharmaceuticals is enacted pursuant to HSWA authority, and thus only this part of the rule will be effective in all states on the rule effective date.

The EPA states that the remainder of the final rule, which adds a new Subpart P to 40 C.F.R. Part 266, is enacted pursuant to the EPA's non-HSWA RCRA regulations. States are only required to adopt non-HSWA portions of the final rule that are considered more stringent than the existing federal regulations. Except for the amendment to exempt from the P075 listing the nicotine patches, gums and lozenges, the EPA states that the final rule is overall more stringent than the current federal standards and thus that states are required to modify their programs to adopt the amendments to the existing hazardous waste regulations made by the final rule.

However, the EPA also states: "When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart."[17] The EPA

states that states with a universal pharmaceutical waste, or UPW, rule (Michigan and Florida) must remove hazardous waste pharmaceuticals from their UPW programs when the states adopt the new Subpart P. With respect to the revision to the P075 listing, the EPA asserts that this is less stringent than the current hazardous waste regulations, and thus that states are not required to adopt this change.

Conclusion

After a decade of debate, the EPA states that it has tried to capture as best it could the status quo for current best management practices in the U.S. regarding unsold pharmaceuticals and unsold retail items. Because the nation's drug supply is dependent on both the forward, as well as reverse, flow of pharmaceuticals across many states, the next step in securing this interstate system that assures readily available medicines, will be state approval and adoption of these elaborate, but preferential, new RCRA requirements tailored to this vital sector of our economy and personal well-being.

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[1] Hazardous Waste Generator Improvements Rule, 80 Fed. Reg. 57,918 (Sept. 25, 2015).

[2] Health care facility means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers. To be codified 40 C.F.R. § 266.500.

[3] Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. New 266.500. Note that in the final rule, the EPA changed the term used from "pharmaceutical reverse distributor" to only "reverse distributor," and the EPA added the word "prescription" to the definition to clarify that "reverse distributor" does not include reverse logistics centers that receive nonprescription pharmaceuticals or other unsold retail items being evaluated for legitimate use/reuse or reclamation. To be codified 40 C.F.R. § 266.500.

[4] Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., prefilled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in nonempty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps. To be codified 40 C.F.R. § 266.500.

[5] See To be codified 40 C.F.R. § 266.501(g).

[6] See 40 C.F.R. § 403.12(p).

[7] Prepublication Preamble, 366.

[8] The EPA states in the preamble: "An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive." Pre-publication Preamble, 62.

[9] See 40 C.F.R. § 266.500 (definition of noncreditable hazardous waste pharmaceutical).

[10] Prepublication Preamble, 67.

[11] Prepublication Preamble, 68.

[12] Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs and dietary supplements.

[13] Noncreditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by health care facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals. To be codified 40 C.F.R. § 266.500.

[14] Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit. To be Codified 40 C.F.R. § 266.500.

[15] To be Codified 40 C.F.R. § 266.510(a)(9).

[16] See Rudzinski to RCRA Division Directors, Nov. 11, 2011, RCRA Online #14827.

[17] Prepublication Preamble, 436.
