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EXPERT ANALYSIS

No More Flushing: EPA Releases New Rules For Managing Pharmaceutical Waste

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On Sept. 25, the Environmental Protection Agency formally published proposed regulations that will, if finalized, change the way that hazardous waste pharmaceuticals are managed at health care facilities (including pharmacies) and at pharmaceutical reverse distributors. The pharmaceutical reverse distributor system is used for outdated or unsold retail pharmaceuticals. *See Management Standards for Hazardous Waste Pharmaceuticals,* 80 Fed. Reg. 58,014 (proposed Sept. 25, 2015) (to be codified at 40 C.F.R. pts. 261, 262, 266, 268, 273).

If finalized, the regulations will add Subpart P to 40 C.F.R. pt. 266, which contains standards for the management of specific types of hazardous waste.

For entities that manage hazardous waste pharmaceuticals — including hospitals, doctors' offices, pharmacies, veterinary clinics, and facilities that sell or dispense over-the-counter or prescription pharmaceuticals — compliance with these new, sector-specific rules would replace the current requirement to comply with broader regulations that apply to all hazardous wastes.

In some respects, complying with the proposed new rules would be less burdensome than complying with current regulations. This is because certain processes would be simplified and streamlined. However, the proposed ban on flushing/draining means that facilities relying on that disposal method will need to adopt new management practices. Moreover, the EPA has said that many health care facilities have been unfamiliar with, and thus been failing to adhere to, the current regulations. Thus, even if these new regulations are adopted, compliance may present challenges or require changes in practices for some facilities.

The EPA has been interested in creating a new waste category for pharmaceuticals for several years. It developed these proposed rules after soliciting comments from a variety of stakeholders, including those in the retail sector (such as pharmacies, grocers and other consumer stores), concerning hazardous pharmaceutical waste management practices. The agency defines the term "pharmaceutical" broadly to include "any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal." *Id.* at 58,084.

Pharmaceuticals can become hazardous waste upon disposal if they are one of the approximately 30 commercial chemical products listed on the Resource Conservation and Recovery Act P- or U- hazardous waste lists, or if they exhibit one of the four characteristics of a hazardous material (ignitability, corrosivity, reactivity or toxicity). Some over-the-counter pharmaceutical products, such as nicotine patches and gums, can be hazardous waste pharmaceuticals if and when retailers discard them. The P list includes hazardous wastes that are especially harmful even in small quantities. U-listed wastes are not acutely hazardous.

Under current rules, hazardous waste pharmaceuticals are subject to the same regulations as any other RCRA Subtitle C hazardous waste. These regulations can be quite burdensome, and they are not especially well-tailored to the unique challenges presented by hazardous waste pharmaceuticals.

THE EPA'S RATIONALE FOR THE PROPOSED RULES

The EPA intends for the proposed rules to address two primary goals: to better protect human health and the environment, and to address the long-standing concerns of stakeholders who have found the existing regulations to be confusing and difficult to implement.

The agency notes that several studies have found active pharmaceutical ingredients and byproducts in surface water and ground-water at levels that have had negative effects on the aquatic environment, and more particularly on fish and animal populations. By prohibiting the current common practice of flushing pharmaceutical wastes, the EPA seeks to eliminate 6,400 tons of hazardous pharmaceutical wastes from being flushed into U.S. water systems annually. The agency also hopes to prevent other improper disposal of hazardous pharmaceutical wastes that may result from confusion over proper disposal methods.

The proposed regulations are aimed at providing the health care industry with clearer, more streamlined rules that are tailored to its sector. By contrast, the current rules are focused on the needs and wastes of heavy industry. Industrial hazardous wastes are typically generated in very large amounts from a small number of point sources. Usually, only a few different types of waste are generated from a particular facility.

In some respects, complying with the proposed new rules would be less burdensome than complying with current regulations, because certain processes would be simplified and streamlined.

Unlike industrial wastes, pharmaceutical wastes are typically generated in very small quantities across numerous points throughout a given health care facility. In addition, there are often hundreds of different types of wastes within one facility. The EPA cites these practical differences between sectors as an underlying basis for the proposed rules, which are intended to be easier for members of the health care industry to follow and implement.

The EPA understands that health care workers are naturally focused on health care rather than on disposal issues, and it has aimed to make compliance with the proposed rules less burdensome and confusing. In making the proposed rules more streamlined, the EPA says it also seeks to prevent the confusion regarding waste regulations that may lead some health care workers and retail pharmacy staff to dispose of hazardous pharmaceuticals as municipal waste or medical waste.

APPLICABILITY AND CATEGORIZATION

The new regulations would apply only to hazardous waste pharmaceuticals and to health care facilities that, under current regulations, are categorized as either small-quantity generators or large-quantity generators. These SQC and LQC classifications are distinguished based on the total amount of hazardous waste they generate per month, and they vary greatly based on the size and type of facility in question. The regulations also set forth new waste management requirements for reverse distributors — entities that collect unused or expired pharmaceuticals for manufacturer credit. Except for a ban on sewer disposal, discussed below, the regulations will not apply to health care facilities categorized as conditionally exempt small quantity generators, or CESQGs — which the EPA estimates comprise 84 percent of health care facilities. Nor will the new rules apply to pharmaceutical manufacturers and wholesalers. If finalized as proposed, the new rules would not eliminate the existing RCRA exclusion for household hazardous wastes. Nursing homes and other long-term care facilities, however, will no longer qualify for the household hazardous waste exclusion.

The new regulations would eliminate the distinction between SQGs and LQGs with respect to hazardous waste pharmaceuticals, such that all health care facilities (except CESQGs) and reverse distributors would be treated under a uniform set of hazardous waste pharmaceutical management standards. Wastes managed under the proposed Subpart P would also not be counted toward a facility's generator category for RCRA wastes as a whole, which may be

a significant change for facilities that generate both pharmaceutical and non-pharmaceutical hazardous wastes.

PROHIBITION ON SEWER DISPOSAL

The EPA recognizes that because sewer disposal is free, simple and readily available, it is often the primary disposal method for health care facilities. This practice has long been permitted because under RCRA only solid wastes are considered hazardous wastes, and "any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment" is not considered a solid waste. 40 C.F.R.261.4(a)(1)(ii).

These mixed waste streams are currently regulated under the Clean Water Act rather than the RCRA. However, the Clean Water Act regulations do not provide limitations or pretreatment standards for pharmaceuticals. Further, the wastewater treatment systems that currently exist — even the more advanced systems — are not designed to process discharges containing pharmaceuticals. As a result, untreated pharmaceutical wastes are regularly discharged from sewage treatment plants.

To protect human health and other environmental receptors from these untreated hazardous wastes, the proposed regulations prohibit the practice of disposing pharmaceutical wastes into sewer systems. This prohibition applies even to health care facilities designated as CESQGs, which are otherwise not affected by these new rules. Given how common sewage disposal of pharmaceuticals has become, this change can be expected to have a significant impact on many health care facilities.

REGULATION OF EMPTY CONTAINERS

Under current regulations, containers that once held pharmaceutical products are regulated as hazardous wastes due to residues that remain after the containers are emptied.

The proposed rules relax these container disposal requirements by deeming certain small containers to be non-hazardous, even if they have not been cleaned to RCRA's specifications for hazardous waste containers. Specifically, the proposed rules deem "unit-dose containers," defined as those that contained no more than 1 liter of liquid or 1,000 pills, to be nonhazardous wastes. Dispensed syringes would also be exempt if they are placed in protective packaging and managed as medical waste. All other containers would be subject to the proposed regulations if the residues are P- or U-listed wastes or if they exhibit one or more hazardous characteristics.

The purpose of this rule is to avoid the sewer disposal that naturally accompanies the rinsing of hazardous waste containers. The rules are also intended to be more tailored to the volume of pharmaceutical waste held by health care facilities, where wastes are typically produced in smaller volumes than in other sectors.

EXCEPTION FOR DEA-CONTROLLED SUBSTANCES

In an effort to reduce regulatory overlap, hazardous waste pharmaceuticals that are also considered controlled substances and regulated under the authority of the U.S. Drug Enforcement Administration would be conditionally exempt from the proposed regulations. However, to qualify for the exemption, pharmaceutical wastes that are also controlled substances must meet two conditions: They must be combusted at a municipal solid waste or hazardous waste combuster, and they must be managed in accordance with applicable DEA regulations. It is unclear how many health care facilities would be able to meet the first condition. We expect this overlap to be a subject of comment on the proposed regulations.

'NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS'

Proposed standards for managing "non-creditable hazardous waste pharmaceuticals" — those that cannot be returned to a reverse distributor for value — include:

The EPA notes that several studies have found active pharmaceutical ingredients and byproducts in surface water and groundwater at levels that have had negative effects on the aquatic environment, and more particularly on fish and animal populations.

Some over-the-counter pharmaceutical products, such as nicotine patches and gums, can be hazardous waste pharmaceuticals if and when retailers discard them.

- A requirement that the health care facility notify the EPA when managing hazardous waste pharmaceuticals.
- Personnel training requirements.
- A requirement that the health care facility take responsibility for making the determination of whether a waste pharmaceutical is hazardous.
- Elimination of central accumulation area and satellite accumulation area requirements.
- Container and container labeling requirements.
- Waste accumulation time limits.
- Land disposal restrictions.
- Procedures for managing rejected waste shipments.
- Reporting and recordkeeping requirements.
- Development of emergency release response procedures.

When shipping "non-creditable hazardous waste pharmaceuticals," health care facilities and reverse distributors would still be required to comply with existing pre-transport requirements for packaging, labeling and marking. However, health care facilities would no longer be required to enter a hazardous waste code on the shipping manifest. Instead, he shipper would be permitted to simply write "hazardous waste pharmaceuticals." This convenience would be available for health care facilities but not for reverse distributors.

Again, compliance requirements for these proposed regulations would replace, rather than supplement, current hazardous waste management requirements for health care facilities and reverse distributors. They may be more onerous or less, depending on the circumstances.

CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS

Some health care facilities send unused or expired pharmaceutical products to reverse distributors, who may then credit the shippers if the product qualifies for a manufacturer buyback program. Under the current regulations, whether and when such products are deemed "waste" is not always clear. The new rules propose a brighter line: A pharmaceutical product would be considered a solid waste — and counted in a health care facility's determination of whether it is a CESQG, an SQG or an LQG — when it is slated for shipment to a reverse distributor.

Under the proposed rules, creditable hazardous waste pharmaceuticals may be shipped to a reverse distributor without a manifest and without the use of a hazardous waste transporter. However, the shipper must notify the receiver that the waste is being sent, and the receiver must communicate to the shipper that the shipment has been received. Both parties must keep records of such shipments for at least three years. Other regulations promulgated by the U.S. Department of Transportation may also apply to the shipment of creditable hazardous waste pharmaceuticals.

REQUIREMENTS FOR REVERSE DISTRIBUTORS

Although reverse distributors receive hazardous wastes, they would no longer be required to obtain RCRA permits. The proposed rules would establish a new category for "pharmaceutical reverse distributors," which would be authorized to receive hazardous waste pharmaceuticals and evaluate them for manufacturer's credit. Such facilities would not be permitted to treat or dispose of hazardous waste pharmaceuticals without obtaining approval as RCRA-permitted or interim status treatment, storage and disposal facilities.

Under the new rules, a pharmaceutical reverse distributor would be required to:

- Notify the EPA that the entity is acting as a pharmaceutical reverse distributor.

- Keep an inventory of all potentially creditable and evaluated hazardous waste pharmaceuticals that are on site.
- Meet certain security requirements to mitigate the threat of narcotics theft.
- Adhere to a 90-day time limit for on-site accumulation of potentially creditable pharmaceuticals.
- Develop a contingency plan for emergency spills.
- Develop a closure plan to control the threat of post-closure releases.
- Report to the EPA when a health care facility ships unauthorized, non-creditable waste to the reverse distributor.
- Adhere to certain recordkeeping requirements.
- Evaluate potentially creditable pharmaceuticals within 21 days of receipt.

Several additional requirements that are applicable only in more limited circumstances are set forth in the proposed rules.

NEXT STEPS

The EPA has extended the 60-day public comment period on the proposed rule to 90 days. Comments must be received by Dec. 24. The agency will review all comments to determine whether revisions to the rules are warranted before making the rules final. This process may take more than a year to complete, depending on the number and nature of comments received. The EPA currently estimates that the rulemaking will be finalized in 2016.

Interested parties should take full advantage of this comment period by carefully reviewing the proposal and comparing it with their current practices to determine the impact of the new rules on their existing operations. Comments that support helpful aspects of the EPA's proposal will make it more likely that those features will survive to the final rules — and survive any later court challenge from groups who may think the rules are not strict enough.

Conversely, changes EPA has proposed that will increase burdens from current practice, with little or no likely environmental benefit or where the same environmental and human health protection can be achieved through a less costly regulatory requirement, should be highlighted in comments. Such comments will provide the EPA a basis to make changes before the final regulations are announced. Securing changes to a finalized rule is very difficult, so waiting for the final rules before seeking any changes is not advised.

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