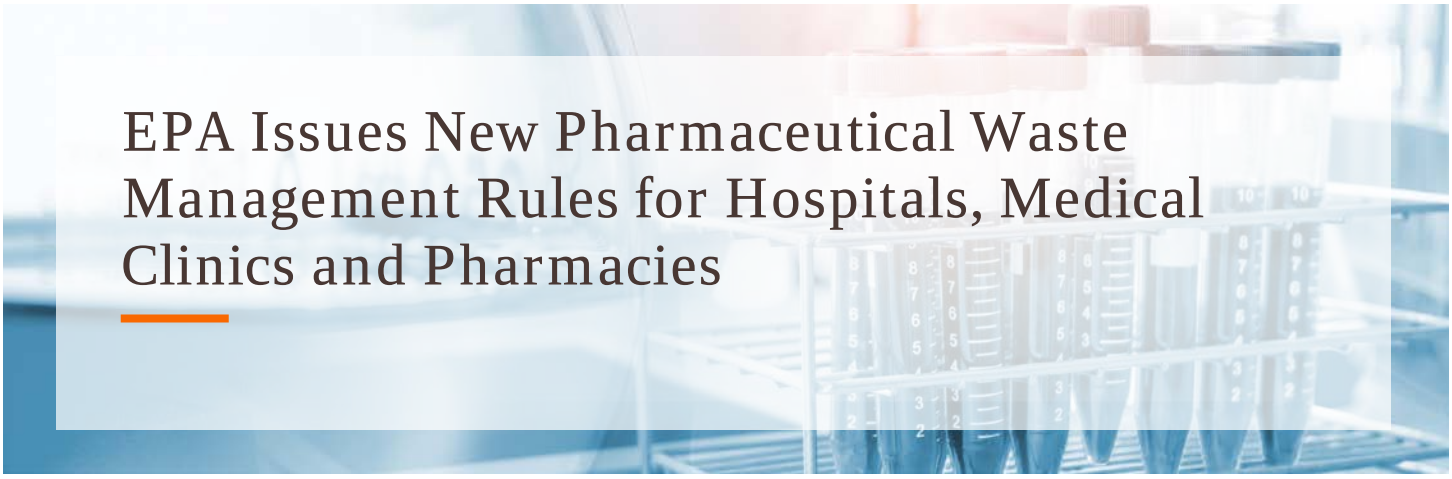


EPA Issues New Pharmaceutical Waste Management Rules for Hospitals, Medical Clinics and Pharmacies

What should hospitals, pharmacies and other retailers do with their expired and waste pharmaceuticals? And are the rules different for prescription versus over-the-counter medications? You need to know the law has changed.

On February 22, the U.S. Environmental Protection ("EPA") published in the Federal Register its final rule, "Management Standards for Hazardous Waste Pharmaceuticals."[1] In issuing these rules, EPA aimed to achieve two objectives: reduce the presence of pharmaceutical compounds in wastewater and balance the support for appropriate recycling or reuse with concerns over proper management of waste pharmaceuticals.

SUMMARY OF NEW RULES

The changes will impact a broad range of healthcare facilities, including hospitals, medical clinics, and retail pharmacies among others. Moreover, the new rules establish standards for the disposal of over-the-counter ("OTC") medications, certain nicotine replacement therapies ("NTRs") and other retail items, promising changes for the broader retail sector. The rules also apply to pharmaceutical manufacturers who act as reverse distributors—managing the disposal and reuse of unused medications. The regulations take effect on August 21, 2019; however, certain requirements will require adoption by the states as discussed below.

The EPA rulemaking retains a controversial definition proposed under the Obama administration that prescription pharmaceuticals are "solid waste" when they leave the healthcare facility. This marks a change from prior practice, where the solid waste determination was often made by the reverse distributor, after pharmaceuticals had left the healthcare facility.

For OTC medications however, the solid waste designation does not apply at the healthcare facility when there is a reasonable expectation of legitimate reuse. In addition, the new rulemaking includes exceptions for certain Food and Drug Administration ("FDA") approved NTRs, and Drug Enforcement Agency ("DEA") controlled substances. For all facilities, the rulemaking also prohibits the sewering or flushing of hazardous waste pharmaceuticals and codifies EPA's prior policy for the disposal of warfarin containers.

For healthcare providers, compliance with RCRA is especially challenging because they handle a wide variety of hazardous pharmaceutical products in small quantities. Because hazardous waste determinations must be made at the point of generation (*i.e.,* at the healthcare facility), healthcare workers will require careful training to comply with the new rules. Failure to adhere to RCRA and underlying regulations can result in penalties of up to $72,718 per violation per day under EPA regulations.

[1] Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 84 Fed. Reg. 5,816 (February 22, 2019) (to be codified at 40 C.F.R. pt. 261).

APPLICABILITY

EPA's new management standards apply to healthcare facilities and reverse distributors. The rule broadly defines "healthcare facilities" as any person lawfully authorized to "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 to "distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals."[2] This definition includes not only hospitals and doctor offices, but retail pharmacies and clinics as well.

Reverse distributors are "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."[3] Additionally, the exception for FDA approved NTRs will impact businesses that sell or manage such products.

Under RCRA, solid waste is considered hazardous waste if it is listed or exhibits characteristics as described in 40 C.F.R. part 261. Once the determination is made at the healthcare facility that the pharmaceutical is a solid waste, it is a hazardous waste if it exhibits one or more characteristics described in 40 C.F.R. part 261. Helpfully, the EPA specifies that "[a] pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed."[4] Moreover, "[a]n OTC 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."[5]

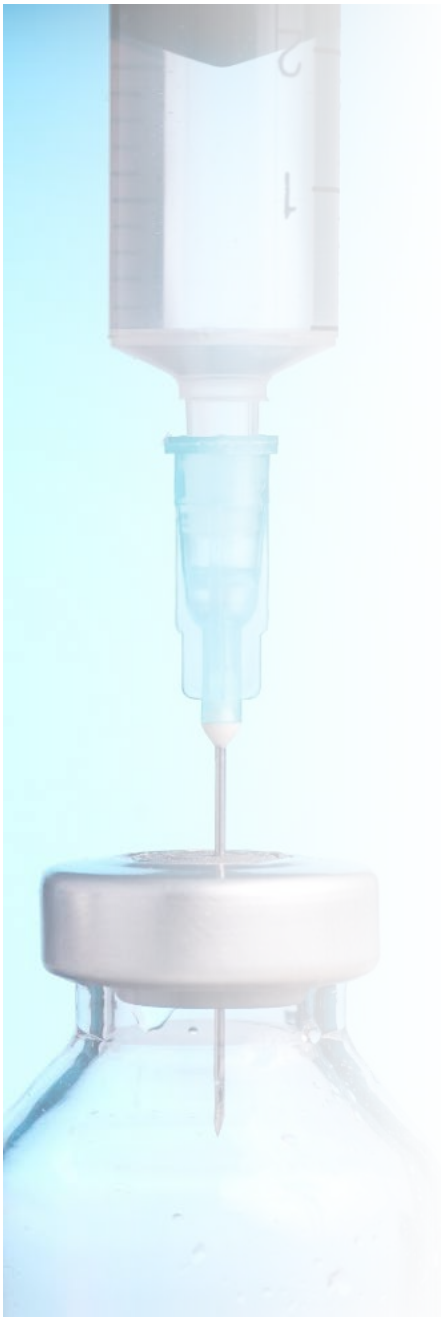
The new rules do not apply to pharmaceuticals that are being managed under FDA or Consumer Product Safety Commission recalls. However, recalls that are initiated through litigation or other processes do not bar applicability of the new rules.

NEW PROCEDURES FOR HAZARDOUS WASTE PHARMACEUTICALS

These rules are contained in a new Subpart P to Title 40 of Federal Code of Regulations Part 266 governing hazardous waste pharmaceuticals, so the good news is that healthcare facilities are treated differently than manufacturing facilities which generate hazardous waste on an industrial scale. For example, healthcare facilities subject to the new rule will no longer have to maintain a central hazardous waste accumulation area and will be able to store pharmaceutical wastes for up to one year, as compared to 90 days under the general Part 262 provisions. Additionally, such facilities will not have to specify hazardous waste codes on their manifests, nor will they have to apply with satellite accumulation area regulations.

Healthcare facilities may differentiate between "potentially creditable" hazardous waste pharmaceuticals" and "noncreditable hazardous waste pharmaceuticals." Creditable hazardous waste pharmaceuticals must have a reasonable expectation to receive manufacture credit in order to be sent to a reverse distributor and are subject to more lenient management and shipping standards under Sections 266.504 and 266.509 of the new subpart. Noncreditable waste however, is subject to stricter management and shipping requirements under Sections 266.503 and 266.508.

[2] *Id.* at 5851.
[3] *Id.* at 5844.
[4] *Id.* at 5843.
[5] *Id.*



A key issue for generators of pharmaceutical waste will be determining the amount of hazardous pharmaceutical waste they generate.

The new shipping and management standards for both categories are meant to ensure improved tracking of hazardous waste prescription pharmaceuticals, and to increase public health protections by minimizing diversion of unused drugs. While the new standards change the point at which the solid waste determination is made, EPA states that a "pharmaceutical may retain monetary value within the reverse distribution system (*i.e.*, potential exists for a manufacturer to issue credit)" after it is determined to be a solid waste under RCRA.[6]

A key issue for generators of pharmaceutical waste will be determining the amount of hazardous pharmaceutical waste they generate. Healthcare facilities that generate more than 100 kg of hazardous waste, or more than 1 kg of acute hazardous waste (e.g., various chemotherapy drugs that are considered p-listed hazardous waste) per month are subject to the new Part 266 subpart P. Healthcare facilities generating hazardous waste pharmaceuticals below the threshold amounts are considered very small quantity generators and are largely exempt from the new subpart. Very small quantity generators are subject to optional provisions regarding hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste allowing for off-site disposal provided certain conditions are met.

NO SEWERING OR FLUSHING OF HAZARDOUS WASTE PHARMACEUTICALS

Notably, all healthcare facilities including very small quantity generators and reverse distributors are prohibited from "sewering" or "flushing" of pharmaceutical waste down drains or toilets. This is the sole provision of the new regulations promulgated pursuant to the Hazardous and Solid Waste Amendments ("HSWA") of 1984, which require states to adopt the standard upon the effective date of the rule. The sewering prohibition is intended to improve environmental protection by ensuring hazardous waste pharmaceuticals are not introduced into local waterways.

REVERSE DISTRIBUTION VERSUS REVERSE LOGISTIC CENTERS

Importantly, the new rules retain the definition that prescription pharmaceuticals are "solid waste" when they are sent to a reverse distributor, creating a trap for the unwary. The new rules differentiate between reverse distributors and reverse logistics centers. Reverse distribution is a general term for the sorting of used prescription and non-prescription pharmaceuticals. By comparison, reverse logistics centers are specific to the retail sector.

[6] *Id.* at 5829.

RULES FOR RETAILERS

The EPA rulemaking codifies the agency's 2016 Retail Strategy to provide a comprehensive approach for retail pharmaceutical management. The Retail Strategy recognized that disposal can be more complicated for retail chains with store locations across the country, where different states have different positions on RCRA applicability. In codifying the Retail Strategy, the rulemaking recognizes the common industry practice to send unsold retail items through reverse logistic centers to determine whether the items can be reused or must be disposed of. EPA's decision is a favorable response to comments submitted by large retailers who sought exemptions from certain RCRA waste management requirements for consumer products such as OTC medications and dietary supplements.

Indeed, the new rule recognizes the difficulties retailers face complying with RCRA. Prior to the Retail Strategy's promulgation, large retailers could qualify as large quantity generators under RCRA when disposing of unsold and expired OTC medications and dietary supplements. Under the new rule, nonprescription pharmaceuticals can go through reverse logistic centers for reuse or disposal when there is a reasonable expectation of their being legitimately used or reused.

EPA stated in the rule preamble that it included this qualifier for a reasonable expectation of reuse because it remains concerned about overuse of reverse logistics centers. Healthcare facilities discarding non-prescription pharmaceuticals may therefore still face some uncertainty in determining when the solid waste exemption applies. For example, unsold retail items that are broken, damaged, or leaking may not have a reasonable expectation of being legitimately used, reused, or reclaimed and must be considered solid wastes at the healthcare facility, depending on the extent of damage to the package. Failure to heed this requirement could lead to RCRA violations as well as Department of Transportation violations related to shipments of hazardous materials.

FDA APPROVED NICOTINE REPLACEMENT THERAPIES ARE EXEMPT FROM HAZARDOUS WASTE MANAGEMENT

In response to retailers' long-standing request, EPA provided an exemption for nicotine replacement therapies under the new rule allowing that FDA approved OTC nicotine patches, gums, and lozenges will be considered nonhazardous wastes not subject to RCRA disposal requirements. Prior to the rulemaking, such substances were considered acute hazardous waste under RCRA which—similar to the prior treatment of OTC medications—often caused retailers to qualify as large quantity generators under RCRA.

The new rules do not provide a similar exemption for e-cigarettes and e-liquids, however, which were sought by certain retailers.

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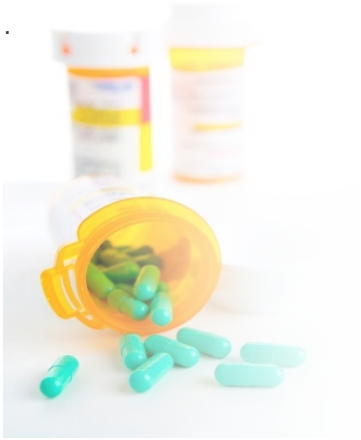

EMPTY WARFARIN CONTAINERS DO NOT COUNT TOWARDS WEIGHT DETERMINATIONS

The EPA rulemaking also codifies 2011 agency guidance on the disposition of warfarin containers commonly used to store p-listed hazardous pharmaceuticals. It provides that only residue remaining in such containers counts towards a facility's generator status. Prior to the 2011 guidance, healthcare facilities would include the weight of empty warfarin containers in their determination of generator status.

The rule also includes a new Section 266.507 which establishes requirements for determining when a container previously holding hazardous waste pharmaceuticals is empty, based on following commonly accepted practices for removal.

DEA-CONTROLLED SUBSTANCES CONDITIONAL EXEMPTION

EPA also provides a conditional exemption for DEA controlled substances when properly handled under the new requirements in order to avoid overlapping regulation. Hazardous waste pharmaceuticals that are also DEA controlled substances are not subject to the new rules if (1) the substances are managed in accordance with the sewering prohibition; (2) the substances are managed and disposed of in compliance with applicable DEA regulations for controlled substances; and (3) the substances are destroyed in accordance with disposal practices permitted by DEA including permitted combustors.

TIMELINE FOR STATE IMPLEMENTATION WILL VARY

While the new rule will take effect at the federal level on August 21, 2019, implementation by states will vary. Similar to other EPA regulations, the agency's RCRA regulations operate in a cooperative federalism framework whereby federal regulations set the floor and states with EPA-approved hazardous waste programs may adopt more stringent standards.

Every state except for Iowa and Alaska has EPA-approved hazardous waste programs. In delegating authority to the states under RCRA, EPA differentiates between regulations promulgated under the Hazardous and Solid Waste Amendments ("HSWA") of 1984, which must be adopted by the states; and those promulgated under different authority. For non-HSWA regulations, if the new rules promulgated are more stringent than prior regulations states must adopt the standards but can retain or adopt stricter standards as well. If the new rules are considered less stringent, however, states have the option to adopt those new standards or not.

EPA specified that only the prohibition for sewering is being implemented under HSWA authority, requiring immediate adoption by states on August 21, 2019, whereas the remaining requirements of the rule require separate state adoption because they are more stringent than prior standards. States must adopt the new requirements under Subpart P to Section 266 for example, but states may retain or adopt more stringent standards on their own.[7] However, the one exception is that the agency considered the exception for NTRs less stringent than prior standards such that states may choose whether to implement this provision.

[7] *Id.* at 5934.

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CONCLUSION

The new regulations introduce a variety of new requirements and codify certain existing policies that will effect change in how healthcare facilities manage hazardous waste pharmaceuticals. Because state adoption of the new rules will vary, healthcare facilities must be careful to understand both the new federal requirements and those of the state(s) in which they operate.

For larger healthcare organizations, the new rules may be implemented by in-house environmental specialists as part of a larger operational protocol. A carefully designed audit and compliance program is recommended to educate staff and document the effectiveness of the training. For smaller organizations, and in addition to the above program, additional steps may be necessary to properly train facility personnel on the new rules and to create guidance manuals and "frequently asked questions" memos. King & Spalding has a national environmental, health and safety practice with extensive experience in assisting health care facilities with their compliance obligations.

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