

NCPA's Summary of EPA's Final Rule on Management Standards for Hazardous Waste Pharmaceuticals

NCPA Advocacy at Work

NCPA presented the small business perspective to the Environmental Protection Agency (EPA) and the Office of Management and Budget (OMB), which lead to a broad definition of potentially creditable product. NCPA supports the broad definition of potentially creditable product as a way to maintain community pharmacies' longstanding relationship with reverse distributor businesses.

NCPA successfully advocated for the exclusion of OTC products from the requirements under this final rule. The EPA exempted OTC products so long as there is a reasonable expectation that a particular OTC product could be legitimately used, reused, or reclaimed.

NCPA successfully secured the exclusion of Assisted Living Facilities (ALFs) from the Long Term Care Facility definition, effectively exempting ALFs from many provisions in the final rule.

Checklist to understand the final rule:

- ✓ Pharmacies must first determine the generator category for their pharmacy. A pharmacy that disposes of less than 100 kg of pharmaceutical hazardous waste per month is considered a very small quantity generator ("VSQG") and is not subject to subpart P of the final rule, which is the new streamlined waste disposal procedures outlined in the final rule and this summary. However, pharmacies that are VSQGs are still required to comply with the sewerage prohibition outlined in the final rule and in this summary.
- ✓ Pharmacies who fall under the purview of subpart P in the final rule must now make the determination at the store level on whether a hazardous waste pharmaceutical is potentially creditable or non-creditable before sending the pharmaceutical to a reverse distributor.
- ✓ If a hazardous waste pharmaceutical is potentially creditable, it may be sent to a reverse distributor.
 - A pharmacy who sends potentially creditable hazardous waste pharmaceuticals to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 C.F.R. §§ 171-180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 C.F.R. § 171.8.
- ✓ If a hazardous waste pharmaceutical is non-creditable, it must be disposed of via a designated disposal facility.

- Shipping non-creditable hazardous waste pharmaceuticals to a designated facility (not a reverse distributor) must follow very specific requirements, including packaging, labeling, and marking outlined in the final rule.
- ✓ Pharmacies are prohibited from disposing of hazardous waste pharmaceuticals to a sewer system that passes through to publicly-owned treatment works.

What just happened?

On February 22, 2019, the EPA finalized its rule regarding management standards for hazardous waste pharmaceuticals, which goes into effect on August 21, 2019.¹ The final rule outlines what kinds of products are considered solid waste and thus, would be subject to EPA's streamlined regulations in the final rule (outlined later in this summary). The final rule also requires healthcare facilities (including pharmacies) that are subject to subpart P of the final rule (meaning those pharmacies that generate over 100 kg of hazardous waste material per month at a pharmacy) to determine what are hazardous or non-hazardous waste pharmaceuticals and whether this waste is potentially creditable or non-creditable at their pharmacy prior to sending the pharmaceutical to a reverse distributor. If the pharmaceutical is hazardous waste but potentially creditable, it must be sent to a reverse distributor via a manner outlined in the final rule. If the pharmaceutical hazardous waste is non-creditable, it may not be sent to a reverse distributor and must be disposed of through the pharmacy's disposal channels.

NCPA has prepared this summary to outline the major portions of the final rule that are important to community pharmacies. However, NCPA urges you to review the rule for any specific requirements that may be applicable to your situation.² NCPA recommends that you discuss upcoming changes that may occur at your pharmacy with your reverse distributors before August 21, 2019.

What does the final rule do?

Quantity generators

Pharmacies must first determine the generator category for the pharmacy. A pharmacy that disposes of less than 100 kg of hazardous waste per month is considered a very small quantity generator ("VSQG") and is not subject to subpart P of the final rule, which are the new streamlined waste disposal procedures outlined in this summary. For more information on the EPA's classification of hazardous waste generators, please visit the EPA's website.³ However, pharmacies that are VSQGs are still required to comply with the sewerage prohibition outlined in the final rule.

¹ 84 Fed. Reg. 5816 (Feb. 22, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf>.

² *Id.*

³ EPA, *Hazardous Waste Generator Regulatory Summary*, available at <https://www.epa.gov/hwgenerators/hazardous-waste-generator-regulatory-summary>.

OTC products

The final rule distinguishes between OTC and prescription drugs when determining which products are to be considered solid wastes at a pharmacy and thus, would be subject to EPA's streamlined regulations in the final rule.

OTC products (including expired OTC products) are not considered solid wastes at the pharmacy and can be sent to a reverse distributor as long as the pharmacy has a reasonable expectation that the OTC product could be legitimately used, reused, or reclaimed. However, if the OTC product does not fall under this expectation and the product is a hazardous waste pharmaceutical, then the OTC product is considered a solid waste and the pharmacy must follow EPA's streamlined regulations for handling the waste in the final rule.

Prescription drugs

Prescription drugs are considered solid waste at the pharmacy and thus, are subject to the EPA's streamlined regulations in the final rule regardless of whether such hazardous waste is potentially creditable or non-creditable. The EPA makes clear that a pharmacy must make the potentially creditable and non-creditable distinction at the pharmacy store level.

Definition of potentially creditable hazardous waste pharmaceutical

Under the final rule, the EPA states a 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's packaging (except pharmaceuticals that were subject to recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. Again, if a hazardous waste pharmaceutical is potentially creditable, it may be sent to a reverse distributor.

EPA's streamlined regulations re shipping potentially creditable hazardous waste pharmaceuticals to a reverse distributor

A pharmacy who sends potentially creditable hazardous waste pharmaceuticals to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 C.F.R. §§ 171-180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 C.F.R. § 171.8. For many community pharmacies, your reverse distributor may handle these shipping requirements for your pharmacy already. NCPA recommends you discuss this provision with your reverse distributors should you have any concerns.

The final rule states that reverse distributors must provide delivery confirmation of shipped pharmaceuticals to the shipper and that delivery is not complete until the pharmaceutical is under the custody and control of the receiving reverse distributor. The EPA clarifies that carriers like USPS, UPS, and FedEx can be used for such shipping granted reverse distributor personnel are present to

receive and take control of the shipments upon arrival. A shipper must provide delivery confirmation within 35 days after shipment of the pharmaceutical. If delivery confirmation is not received, the shipper must take specific action to locate the shipment.⁴

Definition of non-creditable hazardous waste pharmaceutical

Under the final rule, the EPA states that a non-creditable 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 healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and cleanup material from the spills of pharmaceuticals. A hazardous waste pharmaceutical that is non-creditable may not be sent to a reverse distributor.

EPA's streamlined regulations re shipping non-creditable hazardous waste pharmaceuticals to a disposal company

Shipping non-creditable hazardous waste pharmaceuticals to a designated facility (not a reverse distributor) must follow very specific requirements, including packaging, labeling, and marking.⁵ NCPA recommends you discuss these shipping requirements with companies that handle disposal of pharmaceuticals at your pharmacy.

Controlled substances

The EPA's final rule conditionally exempts controlled substances that are hazardous waste from the final rule's regulations so long as the substances are managed in compliance with DEA regulations. This includes controlled substances obtained via take-back programs

Prohibition of sewerage hazardous waste pharmaceuticals

All healthcare facilities (including pharmacies) and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to publicly-owned treatment works.

When does this final rule go into effect?

The final rule is effective on August 21, 2019.

⁴ These shipping requirements can be found on page 5946 of the final rule.

⁵ The requirements can be found on page 5946 of the final rule.