TIP No. 013-0823

Management of Acute (P-Listed) Pharmaceutical Containers

Several United States (U.S.) Environmental Protection Agency (EPA) Resource Conservation and Recovery Act (RCRA) regulations have recently been promulgated for the management of hazardous waste (HW) pharmaceuticals, which include management of acute HW (P-list) pharmaceuticals, their residues, their empty containers, as well as specific changes to the P-listing for certain nicotine products (see Table 1 for examples of P-listed HW pharmaceuticals). Waste streams will be managed dependent on whether each state has adopted any or all of these newer rules. This applies to healthcare facilities (HCFs) located in the continental U.S. (CONUS) and U.S. territories only.

This information paper summarizes the RCRA standards for management of containers that held a P-listed pharmaceutical, to include any remaining residues, depending on where and when the standards are in effect as described in the three scenarios below.

Pharmaceutical containers include pill bottles, blister packs, and wrappers that the pharmaceuticals came in, as well as containers such as paper/plastic dispensing cups (soufflé cups) and intravenous (IV) bags that were used to administer an acute P-listed pharmaceutical to a patient in an HCF.

Table 1. Examples of P-Listed Hazardous Waste Pharmaceuticals

EPA Waste Code	Constituent of Concern	Brand Names	Remarks
P001	Warfarin & salts (Concentration > 0.3%)	Coumadin	Blood Thinner
P012	Arsenic Trioxide	Trisenox	Treatment for Cancer
P030	Cyanides	Nitroprusside	High Blood Pressure
P046	Phentermine	Phentermine	Controlled Substance
P075	Nicotine & Salts	Nicotine patches*, gum*, and lozenges* (e.g., Habitrol, Nicoderm, Nicorette, Nicotrol)	Over-The-Counter (OTC) Nicotine Replacement Therapies (NRTs) (i.e., Smoking Cessation Products)
P188	Physostigmine Salicylate	Eserine Salicylate	Treatment for Glaucoma (Ophthalmic Solution) and Alzheimer's
P204	Physostigmine	Eserine	Treatment for Glaucoma (Ophthalmic Solution) and Alzheimer's

Note: *Exempt from P-listing only if Amendment to P075 listing is in effect (State adoption is optional, not required (see link on page 4 for locations where Amendment is in effect)).

This TIP supersedes APHC FS No. 37-059-0913, dated September 2013

SCENERIO 1. LOCATIONS WHERE THE HW PHARMACEUTICALS RULE (40 CFR 266 SUBPART P) IS NOT IN EFFECT (i.e., the state has not adopted the Pharmaceuticals Rule)

For acute (P-list) pharmaceuticals, the residue remaining in the container (not the container itself) is an acute P-listed hazardous waste when the container is emptied of the pharmaceutical and is intended to be discarded. The residue may be removed from the container, usually via triple rinsing with an appropriate rinsate material, so that the container and rinsate/residue mixture can be managed separately (as non-HW and HW, respectively). However, it is easier to not rinse the container and instead manage the whole container with residue as acute HW at a Satellite Accumulation Area (SAA) established at or near where these pharmaceuticals are dispensed.

When determining the volume of HW for an SAA, only the amount of residue in the containers needs to be counted and not the size/volume of the container itself. This is important because federal regulations allow only 1 quart or 1 kilogram (kg) of an acute P-listed hazardous waste to be accumulated at an SAA. The EPA issued guidance on residue weight calculations in a November 4, 2011 Memorandum, *Subject: Containers that Once Held P-listed Pharmaceuticals*, in which the EPA clarifies that over 10,000 bottles, each containing approximately 100 mg of residue, would be required to amass the 1 kg of residue limit.

Note, states are required to adopt the HW Pharmaceuticals Rule, but the traditional RCRA regulations and management requirements as described above will continue to be in effect until a state formally adopts the new provisions. Contact your local environmental health office and the garrison hazardous waste representative for information regarding the status of the rule in your state, at your installation, and at your HCF.

SCENERIO 2. LOCATIONS WHERE THE HW PHARMACEUTICALS RULE (40 CFR 266 SUBPART P) IS IN EFFECT (either by having been adopted by the state, or the state's environmental program is administered by the EPA and the rule is automatically in effect (i.e., Alaska and Iowa))

In February 2019, the EPA issued a new rule that finalized new standards for the management of pharmaceutical HW. These new regulations are codified in Title 40, Code of Federal Regulation (CFR) Part 266 (40 CFR 266), Subpart P (see Table 2).

Table 2. Managing Residues and Containers that Held Acute HW Pharmaceuticals Under Subpart P

Container Type	Empty Container Requirements
Bottle, ampule, or vial (not exceeding 1 liter or 10,000 pills) OR Unit dose container (packet, wrapper, blister pack, cup, or delivery device)	The container is considered empty, and the residues are not regulated as HW when the pharmaceuticals have been removed from the container using the practices commonly employed to remove materials from that type of container. A container that cannot meet the condition listed above is not considered empty. In this scenario, the container and residue must be managed as HW pharmaceuticals. Note: This regulatory change is significant because it is no longer required to triple rinse containers that held acute (P-list) HW pharmaceuticals for the containers to be considered empty.
Syringe	A syringe that held an acute (P-list) HW pharmaceutical is considered empty, and the residues are not regulated as HW, provided the plunger of the syringe is fully depressed when— • Administering the contents to a patient; • Injecting the contents into another delivery device such as an IV bag; or • Injecting the contents into a HW container. A discarded syringe that cannot meet any of the conditions listed above is not considered empty. In this scenario, the syringe and residue must be managed as HW pharmaceuticals.
IV Bag	An IV bag is considered empty and residues are not regulated as HW, provided the acute (P-list) pharmaceuticals have been fully administered to a patient. An IV bag that cannot meet the conditions listed above is not considered empty. In this scenario, the IV bag and residue must be managed as HW pharmaceuticals.
Other Containers (inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams)	For these other container types that held an acute (P-list) HW pharmaceutical, they cannot be classified as empty. The container and residue must be managed as HW pharmaceuticals.

SCENERIO 3. LOCATIONS WHERE THE AMENDMENT TO THE P075 LISTING FOR NICOTINE <u>IS IN EFFECT</u> (either by having been adopted by the state, or the state's environmental program is administered by the EPA (e.g., Alaska and Iowa))

Previously, the P075 HW listing was applicable to all discarded commercial chemical products containing nicotine as the sole active ingredient, including pharmaceutical products. Unused

dermal patches containing nicotine, nicotine gum, and nicotine lozenges were classified as P075 HW when discarded, as were their “empty” containers (e.g., wrappers, blisters packs).

The new rule amends the acute HW listing for P075 in 40 CFR 261.33(e) by exempting FDA-approved over-the-counter (OTC) nicotine replacement therapies (NRTs). Specifically, the P075 listing for nicotine now includes a parenthetical phrase stating that the listing does not include patches, gums, and lozenges that are FDA-approved OTC NRTs. Therefore, nicotine patches, gums, and lozenges (along with their empty containers) are considered non-hazardous wastes when discarded and can be managed as solid waste.

The new amendment does not exempt e-cigarettes, e-liquids, or cartridges from the P075 HW listing. EPA indicated the FDA considers these items to be tobacco products rather than drugs because the nicotine levels are unregulated. Additionally, the exemption does not apply to prescription NRTs as they contain nicotine at higher concentrations and in a more readily available form (i.e., in liquid and mist) than the OTC NRTs.

Note: This amendment is considered less stringent, and the states are not required to adopt it. If not adopted, nicotine OTC NRTs would be managed the same as other acute (P-list) HW pharmaceuticals per the status of the adoption of the HW Pharmaceuticals Rule as identified above (i.e., depending on if 40 CFR 266 Subpart P has been adopted and is in effect or not). Contact your local environmental health office and the garrison hazardous waste representative for information regarding the status of the rule in your state, at your installation, and at your HCF.

STATE ADOPTION OF EPA PHARMACEUTICAL RULES

The EPA website that tracks the status of the adoption of both rules discussed above by state/territory can be found at: https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075.

ASSISTANCE

For additional information, contact the DHA DCPH-A, EHSD, Waste Management Branch at 410-436-3651 or DSN 584-3651.