

Universal Waste Rule – Addition of Pharmaceuticals

Proposed Rule
December 2, 2008
73 FR 73520

What is this Federal Register About?

This is a proposed rule. Comments are due to US EPA by February 2, 2008.

This action proposes to add pharmaceutical wastes that are RCRA hazardous wastes to the universal waste system. Similar to other universal wastes, pharmaceutical wastes are produced by a large and diverse community of generators, often in small volumes. Pharmaceutical wastes may be hazardous waste because they contain any of 31 listed hazardous waste chemicals or they exhibit one or more of the four hazardous waste characteristics. Generators of these wastes include physicians, hospitals, veterinarians, dentists, pharmacies and nursing homes. In the preamble to the proposed rule, you can find a list of the 31 hazardous waste chemicals.

Expansion of the universal waste system to include hazardous pharmaceutical wastes may lead to better management of these wastes by generators by providing a more streamlined, and effective waste management system. Plus, addition of hazardous pharmaceutical wastes to the universal waste program will facilitate the management of the wastes via pharmaceutical take-back programs by removing RCRA barriers (e.g., hazardous waste determination, storage accumulation and time limits, etc.) for generators, as well as facilitate the collection of pharmaceutical wastes from households.

Summary of Proposed Rule

US EPA proposes the following definitions for the terms “pharmaceutical” and “pharmaceutical universal waste.”

“Pharmaceutical” means any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component.

The proposed definition of pharmaceutical is meant to include, but is not limited to, pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches, and any delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic. It does not include syringes, sharps or other infectious wastes.

“Pharmaceutical Universal Waste” means a pharmaceutical that is a hazardous waste as defined in § 261.3, and containers (e.g., bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under § 261.7. US EPA decided to define “pharmaceutical universal waste” to ensure that any container which has held hazardous pharmaceutical wastes (and thus is also considered a hazardous pharmaceutical waste, unless that container is considered “RCRA empty” could also be managed in the universal waste system.

As for the requirements that handlers of universal waste pharmaceuticals must follow, they pretty much mirror the requirements that currently apply to handlers of other forms of universal wastes. Small and large quantity handlers of pharmaceutical universal waste must respond to releases, label containers, comply with accumulation time limits, train employees and only send universal waste pharmaceuticals to another universal waste handler, transporter or destination facility. In addition, large quantity handlers have the following additional requirements; they must notify the overseeing agency, obtain a hazardous waste ID number (if they do not already have one) and track the universal waste they receive and send off-site.

Nothing in the proposed rule changes the current universal waste requirements for universal waste transporters or destination facilities.

What does this mean to the regulated community?

Adding pharmaceuticals to the universal waste rule will promote and improve compliance with the hazardous waste rules regarding to the proper treatment and disposal of these types of wastes by reducing regulatory burden on handlers. The affected national generator universe is estimated to include over 400,000 entities comprised of physicians, dentists, veterinarians, hospitals, long-term care facilities and retail pharmacies.

What does this mean to DHWM and/or Ohio EPA?

These rule changes are considered by US EPA to be less stringent than the current hazardous waste rules. Therefore, since we have an authorized RCRA program, we are not required to adopt the changes. This also means that until we adopt these changes, hazardous pharmaceutical wastes must be managed under the current hazardous waste rules.

If we decide to adopt these rule changes, if they are finalized, we anticipate that inspectors will need training to learn and enforce the rules, and additional resources will be expended to develop training and specialized inspection checklists. However, these rules do not increase the number of entities subject to regulation under the hazardous waste rules.

Will Ohio EPA comment on these proposed changes?

We haven't decided if we will comment on the rule. We are currently reviewing the proposed rule.

When are these rules effective in Ohio?

This will be determined after US EPA adopts the final rule changes.

Link to Federal Website about the rule:

<http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm>

Link to Federal Register:

<http://www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.pdf>

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