



**Walter Wright, Jr.**  
wwright@mwlaw.com  
(501) 688.8839

# Pharmaceutical Hazardous Waste: Arkansas Environmental Federation Submits Comments on Proposed U.S. Environmental Protection Agency Resource Conservation and Recovery Act Management Standards

## Arkansas Environmental, Energy, and Water Law Blog

01/07/2016

The Arkansas Environmental Federation ("AEF") has submitted December 17<sup>th</sup> comments to the United States Environmental Protection Agency ("EPA") on its proposed rule: *Management Standards for Hazardous Waste Pharmaceuticals*. 80 Fed. Reg. 58013 (Sept. 25, 2015) ("*Proposed Rule*").

EPA proposed revisions to the Resource Conservation and Recovery Act ("RCRA") regulations to address "hazardous waste pharmaceuticals."

EPA's rationale for the *Proposed Rule* is to better consider the unique aspects of health care operations in regulating pharmaceuticals under the RCRA regulations.

EPA states that it has proposed:

... a tailored, sector-specific set of regulations for the management of hazardous waste pharmaceuticals by health care facilities (including pharmacies) and reverse distributors. It will provide standards to ensure the management of hazardous waste pharmaceuticals is safe and workable within the healthcare setting.

The goals of the *Proposed Rule* are generally stated to include:

- Restrict health care facilities from disposing of hazardous waste pharmaceuticals into drains (i.e., health care facilities and pharmaceutical reverse distributors would be prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works)
- Clarification of the relationship between the RCRA Subtitle C hazardous waste program and the Drug Enforcement Administration rules for controlled substances
- Improve management of hazardous waste pharmaceuticals at a wide variety of facilities such as:
  - Physicians' offices
  - Dental offices
  - Other health practitioners
  - Pharmacies

- Outpatient care centers
- Veterinary clinics
- Hospitals
- Nursing care facilities
- Continuing care retirement communities
- Medical examiners and coroner offices
- Reverse distributors

A new RCRA Subpart P in the Code of Federal Regulations would be applicable to the management of hazardous waste pharmaceuticals.

The term “pharmaceutical” is defined in the *Proposed Rule* 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. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.

Hazardous waste pharmaceutical is defined to include:

... a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C.” Proposed Rule 40 C.F.R. § 266.500.

AEF notes in the introduction to its comments:

The AEF members represent Arkansas industries, hospitals, publically and privately owned wastewater treatment facilities. Certain Arkansas industries also have health care facilities located on their campuses. We feel that common sense source control for these types of hazardous waste pharmaceuticals are appropriate, and that these types’ waste pharmaceuticals should not be disposed of in a manner that is detrimental to the environment.

The organization’s comments on the *Proposed Rule* address issues such as:

- Concern about the breadth of the definition of “pharmaceutical”
- Need for a specific list of hazardous pharmaceuticals to remove uncertainty for health care facilities and promote consistency
- Allow one year for health care facilities to implement process changes to meet ban on sewerage of hazardous waste pharmaceuticals
- As to 266.506(b), it is noted:

Hospitals commonly waste controlled substance waste from patient care floors in sinks. This has been a state wide practice for decades. Time will be needed to implement changes. At certain hospital(s) in Arkansas, controlled substances that are non-creditable and generated in the pharmacy are commonly sent to the Arkansas Department of Health & Human Services Pharmacy Services and Drug Control. The Arkansas Department of Health accumulates these controlled substances, then sends them to a RCRA permitted TSDF for incineration.

- Concern is expressed about the costs associated with destruction of original manufacturer product packaging
- Notes the proposed rule does not adequately address how a partial syringe containing a hazardous waste pharmaceutical should be managed
- Asks how trial medication will be managed?

RCRA delegated states, such as Arkansas, will eventually manage these new requirements once they are finalized. Therefore, a number of states have filed comments.

[An example are the Oklahoma Department of Environmental Quality comments which can be found here.](#)

[The AEF comments can be accessed here.](#)