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Industries for the Environment

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December 17, 2015

U.S. Environmental Protection Agency
Washington, DC

Re: Management Standards for Hazardous Waste Pharmaceuticals, Docket ID No. EPA-HQ-RCRA-2007-0932

The following comments are submitted on behalf of the Arkansas Environmental Federation (AEF), a non-profit association based in Little Rock, Arkansas. Our organization provides training for environmental professionals and advocates for Arkansas industry regarding environmental policy.

The AEF appreciates the opportunity to comment on the proposed *Management Standards for Hazardous Waste Pharmaceuticals, Docket ID No. EPA-HQ-RCRA-2007-0932.* Our association applauds the Environmental Protections Agency's (EPA) efforts to protect public health and the environment from improper disposal of hazardous waste pharmaceuticals. 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 disposed of in a manner that is detrimental to the environment. The AEF respectfully offers the following comments to make this proposed rule more understandable for the regulated community and provide clearer lines for implementation.

Regulation 266.500
The definition of Pharmaceutical is very broad. The EPA confirmed that alcohol based hand rubs, commonly used as throughout healthcare facilities, and could be considered a pharmaceutical because of their antiseptic use as described in the preamble. Isopropyl alcohol is used as an antiseptic to clean a surface of a countertop, a biological safety cabinet, and the skin of a patient before a needle stick. The broad definition leaves a vast amount of 'grey area' for determinations of what is and is not a pharmaceutical.

Regulation 266.503(a)
Add the word Potentially *"Hazardous waste determination for potentially creditable hazardous waste pharmaceuticals at the healthcare facility."*

Regulation 266.503(a) & 266.503(c)
Healthcare facilities use thousands of individual pharmaceuticals to provide care for its patients. Often due to availability, shortages or supplier changes, a pharmaceutical from one manufacture with one NDC number will be changed to a like pharmaceutical from a different manufacturer with a different NDC number. This requires a waste determination every time a change in a pharmaceutical is made. This is time consuming, adds cost to healthcare operations, and will impact the quality of care delivered to patients. While many healthcare facilities utilize a third-party to assist with waste determinations for

pharmaceuticals, the use of a specific list of hazardous pharmaceuticals would remove uncertainty for healthcare facilities and promote consistency.

Regulation 266.505
According to the EPA, the rule bans the sewering of HW Pharmaceuticals and would be enforceable immediately, even before states adopt these regulations (HSWA – effective immediately). At least one year is needs to be allowed for healthcare facilities to implement process changes to meet this requirement by a specific date.

Sewering of maintenance IV fluids such as sterile water, electrolytes, sugars and salts such as sodium chloride, dextrose and lactated ringers should be exempt from the sewering ban.

Regulation 266.506(b)
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.

Regulation 266.507(a)(2)
The EPA wants original manufacturer product packaging "destroyed prior to disposal in such a manner as would prevent further use of the container." Destroy has been suggested as shred or crush. This can be difficult to manage as shredding or crushing would have to be done inside the pharmacy where it is most likely generated. Will add equipment and maintenance cost to healthcare facility operations.

Regulation 266.507(b)
Dispensed Syringes: The exclusion applies to residues remaining in a syringe provided...

1. Used to administer the pharmaceutical <u>to a patient</u> and
2. The syringe is placed into a sharps container that is managed as a Regulated Medical Waste (RMW).

There are many types of syringes (oral, blunt tip, needled, needle-less) and should be clearly defined. Often in the preparation of pharmaceuticals for administration, syringes never touch the patient. IV's are spiked and vials injected in the pharmacy. The wasted syringes inside the pharmacy never touch a patient.

Although some Arkansas hospitals manage all syringes as a regulated medical waste, this is not a common practice. Many times syringes are disposed in the general trash or a recycling container. Requiring syringes to be managed as a medical waste may prohibit recycling and add cost to healthcare operations.

The proposed rule does not adequately speak to how a partial syringe containing a HWP should be managed. Additionally the proposed rule does not address a partial syringe that contains both a potentially infectious substance, blood, and pharmaceutical.

General Comments
How will trial medications be managed? Per recently submitted comment... "How will EPA handle situations where pharmaceuticals are on trial? The process is that a drug company when able will put a new drug on trial along with a possible comparable (usually from another manufacturer) and when the

trial is over all of the extra is sent back to the manufacturer for verification. It is then disposed of. Under the proposed rules the health care facility is the generator and the pharmaceutical is being sent back to the manufacturer (who is not a port of the proposed rules). How will the process be handled under the new proposal? Seems that this would not be allowed as the generator is sending a possible HW to a facility that is not part of the proposed rules which means that this could be shipping to an unpermitted facility without a manifest. This seems to be over-burdensome on the part of the manufacturer of a pharmaceutical that is on trial to have to manage this material as a hazardous waste as opposed to the proposed Subpart P."

The AEF sincerely appreciates the Agency's thoughtful consideration of the above comments and suggestions.

Respectfully submitted,

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