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March 4, 2009

RCRA Docket

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW Mailcode 2822T

Washington, DC 20460

Attn: Docket ID No. EPA-HQ-RCRA-2007-0932

Via Email: rcra-docket@epa.gov

Dear Sir or Madam:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the proposed addition of hazardous pharmaceutical wastes to the Universal Waste Rule (December 2, 2008; 73 *Fed. Reg.* 73520). NACWA and its nearly 300 public wastewater treatment utility members are acutely aware of the potential impacts that can arise when unused pharmaceuticals are mishandled or inappropriately disposed. Recent press coverage and Congressional interest in the quantities of pharmaceuticals being detected in the Nation's waters is focusing attention on the need for proper handling and disposal of pharmaceuticals by health care professionals and the general public. In principle, NACWA agrees with inclusion of hazardous pharmaceuticals in the Universal Waste Rule (UWR), but believes that more coordination at the federal level on a comprehensive strategy for managing unused pharmaceuticals is needed and that outreach and education on the UWR's applicability will be necessary to ensure that it does not create confusion among handlers of pharmaceutical wastes.

Hazardous pharmaceuticals clearly meet many of the Agency's criteria for designation as a universal waste, including being generated by a large number, and wide variety, of entities. Full regulation under the Resource Conservation and Recovery Act's (RCRA) hazardous waste generator and transporter regime seems inappropriate given the types of wastes that program was designed to address. As is clear from EPA's own research, however, there is currently a very low level of awareness among the health care industry regarding the potential applicability of the hazardous waste regulations. Designation as a universal waste, therefore, without sufficient outreach and education, is likely to have little impact within the health care community and may complicate management for other handlers of unused pharmaceutical wastes.

UWR Limited in Scope, Could Cause Confusion Among Pharmaceutical Waste Handle

NACWA believes the universal waste designation could complicate pharmaceutical

waste handling more broadly by adding another layer of perceived regulatory control, even though the rule's applicability is limited and it is designed to streamline existing rules. Specifically, NACWA is concerned about unintended consequences for the management of the vast majority of pharmaceuticals, those not considered RCRA-hazardous, due to the perception that these wastes would not be covered by the UWR. NACWA believes the UWR is widely misunderstood, especially outside the RCRA community, and some believe UWR designation would require all pharmaceutical wastes to be handled as universal wastes, including household generated pharmaceutical waste.

The issue of how to best manage unused pharmaceuticals has been the subject of much debate recently. Guidance from the federal government, including the Office of National Drug Control Policy (ONDCP), outdated prescription inserts, wastewater utility outreach and a long list of other resources have been sending mixed messages on the handling of unused pharmaceuticals. Stakeholders have asked the federal government to provide one consistent message for the nation, and progress on that front is being made, but no single message has yet been developed and embraced by the various government agencies with jurisdiction over this vital issue. Many stakeholders are looking to the UWR for guidance, but the rule is limited in its scope and, therefore, does not provide the needed comprehensive solution.

The proposal states, UWR designation could "facilitate the management of non-RCRA pharmaceutical wastes," but such regulation is not required. Within the health care industry commingling of hazardous and nonhazardous pharmaceuticals as universal wastes could streamline waste management (no need to identify and separate wastes as hazardous) and would ensure that all the wastes are properly disposed of and not discarded in the solid waste stream or down the drain. This is where the UWR has the most potential benefit – streamlining the storage and transportation requirements for commercial and retail generators of pharmaceutical waste. The UWR has been misinterpreted in the past, however, as requiring management of all designated wastes, in this case all pharmaceuticals regardless of whether they are RCRA-hazardous or not, as universal wastes. In reality, the UWR does not change the status quo for NACWA's members collecting unused pharmaceuticals. Sufficient outreach and education about the rule's impact is needed to ensure stakeholders clearly understand its scope.

Take Back Programs Unaffected, Some Collection Efforts May Benefit

Many of NACWA's members conduct household pharmaceutical take back programs either in addition to or in conjunction with existing household hazardous waste collection programs. These communities understand the RCRA household hazardous waste exemption and know that it continues to apply to any hazardous wastes, including hazardous pharmaceuticals, once they are collected. Universal waste designation for unused pharmaceuticals, therefore, will likely not provide any major benefits to these take back efforts. Instead, the effectiveness of these programs is most limited by the requirements imposed by the Controlled Substances Act regarding the collection of controlled substances.

For some communities the UWR has allowed the wastewater treatment plant hazardous waste collection program to accept universal wastes from small commercial or retail generators. Where these programs exist, pharmaceutical waste designation under the UWR would allow the utility to also accept hazardous pharmaceuticals from small clinics, long-term care facilities, etc., for ultimate management as a hazardous waste.

In all cases outreach and education will be key to ensure the requirements, or lack thereof, under the UWR is clearly understood by wastewater treatment plants conducting take back and collection programs.

EPA Waste and Water Offices Should Coordinate Efforts on Pharmaceuticals

EPA's Office of Water is currently planning to conduct a comprehensive survey of pharmaceutical waste disposal practices in the health services industry under its Effluent Guidelines program to determine if Clean Water Act regulation is necessary to control this potential source of pharmaceuticals to the Nation's wastewater treatment plants. At least one report has already been prepared on waste pharmaceutical management practices to support the water office's efforts and EPA recently sought comment on a draft Information Collection Request (ICR) that seeks information from hospitals, long-term care facilities, hospices and veterinary hospitals. Given the information collected for the development of the UWR and the potential overlap with the Office of Water's efforts, NACWA suggests that the two efforts be coordinated going forward if that has not already been done.

More Federal Coordination, Potential Changes to Controlled Substances Act Needed

As EPA notes in the UWR proposal, designation as a universal waste will not affect the applicability of the Controlled Substances Act or any associated regulations issued by the Drug Enforcement Agency (DEA). NACWA believes EPA and DEA must better coordinate their efforts to ensure there is a single, consistent message sent to the Nation on the handling of unused pharmaceuticals and to facilitate proper drug disposal. The DEA in a January 21, 2009, *Federal Register* notice sought comment on options for the disposal of controlled substances and NACWA understands that the White House's ONDCP may be considering a revision to its 2007 disposal guidelines, which still recommend flushing of drugs in some instances. All of these efforts to address this issue must be coordinated to ensure the health services industry, the Nation's waste and wastewater managers, and the general public receive consistent messages on the handling of unused pharmaceutical wastes.

NACWA appreciates the opportunity to comment on the proposed designation of hazardous pharmaceuticals as a universal waste. Please contact me at 202/833-9106 if you have any questions.

Sincerely,



Chris Hornback
Senior Director, Regulatory Affairs