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February 19, 2013

Office of Diversion Control  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, VA 22152  
Submitted via [www.regulations.gov](http://www.regulations.gov)

**RE: Docket No. DEA-316, Proposed rulemaking on disposal of controlled substances**

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the proposed rule on Disposal of Controlled Substances. NACWA represents the interests of nearly 300 public clean water agencies nationwide, and many of NACWA's members are actively involved in efforts to reduce the quantities of potential pollutants, such as pharmaceuticals, that are discharged into the sewer system.

NACWA has communicated in the past with the Drug Enforcement Administration (DEA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) on the need for more practical pharmaceutical disposal options to reduce flushing or down-the-drain disposal of pharmaceuticals into the sewer system. Overall, the proposed rule is a significant step toward providing more convenient, environmentally-friendly methods of disposal for unused pharmaceuticals. The following comments provide NACWA's recommendations for refining the proposal to further facilitate proper disposal of unused pharmaceuticals.

**Non-Retrieveable Standard of Destruction**

NACWA appreciates that DEA proposes a "non-retrieveable" standard of destruction and the statement in the rule preamble that "flushing and mixing controlled substances with coffee grounds or kitty litter are examples of existing methods of destruction that do not meet the non-retrieveable standard." Since flushing has often been recommended as an appropriate disposal option in the past – including, in some instances, by EPA and FDA – the definition of non-retrieveable in the proposed regulation should include a statement that flushing and/or mixing with other materials does not meet the non-retrieveable standard. Without this clarification, the definition could be interpreted as allowing flushing, since treatment of wastewater "renders the controlled substance unavailable and unusable for all practical purposes."

## Collection of Controlled Substances

The proposed rule allows for the collection of pharmaceuticals by reverse distributors, law enforcement agencies, and retail pharmacies through take-back events, mail-back programs, and collection receptacles at collectors' DEA registered locations. The proposal also allows collection of controlled substances and uncontrolled substances together. NACWA supports allowing all of these collectors and collection methods. However, changes to some of the proposed requirements will facilitate the proper disposal of unused pharmaceuticals.

The proposed rule specifies that take-back events accepting controlled substances may only be conducted by law enforcement agencies, although community groups and other entities may partner with law enforcement agencies to hold events. In either case, the rule requires that a law enforcement officer employed full-time by a law enforcement agency must oversee the collection and maintain control and custody of the controlled substances. These requirements increase the cost of take-back events and limit the number of events and their locations, making the safe disposal of controlled substances more inconvenient for the public. The reason for requiring a law enforcement officer that is employed full-time is not clear, and officers that are employed part-time should also be qualified to perform these duties. NACWA recommends that DEA fully evaluate other options to reduce the burden associated with this requirement, including allowing take-back events to operate without a law-enforcement officer if a receptacle that meets the requirements in the proposed rule is used at the event and allowing receptacles at permanent household hazardous waste collection sites.

The proposed rule forbids handling of controlled substances at take-back events by anyone other than a law enforcement officer, and prohibits inventorying of controlled substances. Provisions should be added to the rule to allow the inventory of controlled substances for research purposes under the supervision of a law enforcement officer. This type of data collection can help improve prescribing guidelines and determine if updated guidelines are affecting the amount of wasted pharmaceuticals. The presence of a law enforcement officer during any inventory activities will ensure that the risk of diversion is very low.

The options for disposal of controlled substances at a long term care facility (LTCF) are limited in the proposed rule to retail pharmacies operating at the LTCF and law enforcement officers. Other options must be added to allow for safe disposal at these facilities, since some do not have on-site pharmacies and it may be difficult to arrange for collection by a law enforcement officer.

## Authorization to Transfer Controlled Substances

The proposed rule allows the transfer of controlled substances to authorized collectors by ultimate users, any person lawfully entitled to dispose of a decedent's property, and a LTCF on behalf of an ultimate user who resides or resided at the LTCF. NACWA agrees with this expansion of the people who may transfer and dispose of controlled substances; DEA, however, should further expand this authorization. Spouses and immediate family members, as well as legally recognized caregivers, should also be authorized to dispose of a decedent's unused pharmaceuticals, since the process of determining who is lawfully entitled to dispose of the decedent's property may take some time after the death. These family members and caregivers should also be authorized to dispose of controlled substances for living patients that are unable to transfer the substances themselves due to their physical or mental condition. In addition to LTCFs, hospice and palliative care are options for chronically or terminally ill patients, and disposal of controlled substances in these situations should be addressed in the final rule.

## Environmental Impacts of Pharmaceutical Collection

While NACWA agrees with DEA that “collection and destruction of unwanted and unused pharmaceuticals cannot and will not address water contamination that occurs from other means such as bodily elimination or excretion of such substances,” NACWA still believes that any reduction in the amount of pharmaceutical substances disposed to wastewater is beneficial in protecting the aquatic environment. Public education on the proper disposal of pharmaceuticals also has additional environmental benefits since it raises general awareness of what should and should not be disposed of into the sewer system.

Thank you for your consideration of these comments. Please contact me at [cfinley@nacwa.org](mailto:cfinley@nacwa.org) or 202-533-1836 if you have any questions.

Sincerely,

A handwritten signature in black ink, reading "Cynthia A. Finley". The signature is written in a cursive, flowing style.

Cynthia A. Finley, Ph.D.  
Director, Regulatory Affairs