December 23, 2015

US Environmental Protection Agency
EPA Docket Center (EPA/DC)
Mail Code 28221T
1200 Pennsylvania Ave., NW.
Washington, DC, 20460
Transmitted via email: a-and-r-docket@epa.gov
Attention: ***Docket ID No. EPA–HQ–RCRA–2007-0932***

Dear Sir or Madam,

The National Steering Committee (NSC) for the national network of state Small Business Environmental Assistance and Small Business Ombudsman Programs thank you for the opportunity to comment on the proposed Management Standards for Hazardous Waste Pharmaceuticals, published in the *Federal Register* on September 25, 2015 in Docket ID No. ***EPA–HQ–RCRA–2007-0932***.

The state Small Business Environmental Assistance and Small Business Ombudsman Programs (SBEAP/SBO) were created under section 507 of the Clean Air Act Amendments of 1990. For over 20 years, the SBEAP/SBOs have provided extensive, hands-on assistance to small businesses to help them understand environmental regulations such as the New Source Performance Standards (NSPS), National Emissions Standards for Hazardous Air Pollutants (NESHAP), and numerous state-based standards.

The SBEAP/SBOs have submitted comments during the development of prior EPA rules, most notably many of the area source NESHAP standards that regulated many small businesses for the first time. The SBEAP/SBO network, through their Technical Subcommittee, stands ready to work with EPA to develop rule language and implement tools and templates that will greatly enhance the ability of a small business to comply. Comments from the National Steering Committee on the proposed rule reflect the experience of SBEAP/SBOs.

On behalf of the national SBEAP/SBO network, the NSC respectfully submits the following comments:

Preamble and Summary

The NSC supports EPA's efforts to manage hazardous waste pharmaceuticals in a more streamlined fashion which is better tailored to the unique circumstances of the healthcare industry. Pharmaceutical reverse distributors will also be held more accountable for the management of waste they handle under this new rule.

The NSC agrees with the proposed exclusion of hazardous waste pharmaceuticals from being counted towards hazardous waste generator status if they are managed under this regulation. Currently, an acute hazardous waste such as warfarin can transform a pharmacy from conditionally exempt into a large quantity generator of hazardous waste.

It is commendable on the part of EPA to develop the Hazardous Waste Pharmaceuticals web site, http://hwpharms.wikispaces.com, to assist healthcare facilities in identifying solid waste pharmaceuticals as hazardous waste. EPA should promote the use of this website and solicit input not only from healthcare facilities but also pharmaceutical manufacturers.

The NSC also commends EPA for recommending that if a healthcare facility decides to segregate its hazardous and nonhazardous pharmaceuticals, they should follow the BMPs (best management practices) found in the document, "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States."

The NSC suggests that the EPA take a further step and develop an interactive web-based tool based on the 10-Step Blueprint. Such a tool would greatly help a facility to decide when to discard a waste, how to segregate and store it, how to train employees and how to document these practices.

Sewer Ban

The prohibition from discharging hazardous waste pharmaceuticals to a sanitary sewer is a vital step toward keeping harmful chemicals out of water bodies and drinking water supplies. However, since this requirement will go into effect immediately when the rule is finalized, a lot of outreach will be needed to help smaller healthcare facilities and providers, pharmaceutical manufacturers and publicly owned treatment works (POTW) get ready for this significant change. How does EPA plan to get the word out to such facilities?

The NSC agrees with EPA to reduce requirements for managing hazardous waste pharmaceuticals at healthcare facilities. This will greatly encourage them to manage their unused or un-administered pharmaceuticals, expired pharmaceuticals (one year or more past the expiration date), pharmaceutical residues and pharmaceutical hazardous waste under the standards proposed under this rule.

However, there will be additional cost involved in managing all the items indicated above as hazardous waste in lieu of disposing of them in the sewer or segregating certain elements. Outreach will be necessary to educate healthcare facilities on how to make and document a waste determination as well as other components of the rule regarding the potentially creditable hazardous waste pharmaceutical and the role of the pharmaceutical reverse distributor.

Drug Enforcement Administration Schedule of Controlled Substances, 21 CFR 1308

It would help to publish a list of the pharmaceuticals which are both a controlled substance and a non-creditable hazardous waste. The list could be published at http://hwpharms.wikispaces.com.

Additional Clarifications

EPA may want to define "point of generation" in the context of healthcare facilities. The combination of having many different pharmaceutical products and little expertise in

hazardous waste regulations makes it difficult for healthcare workers to make appropriate hazardous waste determinations when the decision to discard them has been made.

If EPA defines a point of generation as being a patient's room in a hospital, would staff be permitted to transport that waste within the hospital to a central storage location where a hazardous waste determination could be made? Otherwise, would the practitioner be required to make this determination? It seems that a pharmacist or other central staff would be much better positioned to do so.

Some healthcare workers visit patient homes and bring pharmaceuticals into the household. Should the healthcare worker take any remaining pharmaceuticals back to the facility to be managed appropriately, or would they be allowed to leave the medications with the patient and to manage any unused pharmaceuticals as household hazardous waste?

The NSC understands that the EPA would like to regulate vape shops. However, vape shops are currently unregulated by EPA rules and thus unprepared to address environmental regulations. Also, they are businesses that have very little in common with healthcare facilities. Therefore, the NSC recommends that vape shops be addressed in future rule-making. If they are included in this rule-making, EPA should be prepared to carry out significant outreach to this business sector.

Reverse Distributors

This rule proposes considerable changes to how reverse distributors manage pharmaceuticals and what types of substances they can accept. The rule requires reverse distributors who receive non-potentially creditable pharmaceuticals from healthcare facilities to report the occurrence to EPA. Does EPA intend to take enforcement action against such healthcare facilities? The NSC recommends that EPA focus more on outreach and education instead of enforcement, at least initially.

Healthcare facilities may believe that the pharmaceutical reverse distributor will make the decision to discard a pharmaceutical and will also make a waste determination. A healthcare facility will need to learn what the pharmaceutical reverse distributor can accept and cannot accept and that they will be responsible for managing other non-creditable hazardous waste pharmaceuticals.

The definition of "Evaluated hazardous waste pharmaceutical" does not explain the evaluative process nor does it elucidate what it means to be creditable (eligible for manufacturer's credit).

Reporting

The proposed rule increases the amount of reporting requirements for affected entities. The NSC wants to make sure that the additional information will be reviewed by EPA and that it will be put to good use. Otherwise, reporting has little value for environmental protection and compliance assurance and increases the administrative burden for small businesses.

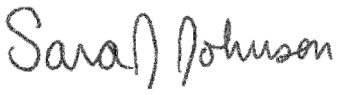
Outreach

The NSC commends EPA for its effort to better tailor hazardous waste pharmaceutical rules to this unique sector. However, this proposal contains many changes that may be confusing to small medical clinics, dental offices, long-term care facilities, veterinary offices, etc. Some of these entities may not have the staff expertise to ensure compliance without significant support and training.

The NSC would like to emphasize the importance of outreach to these entities. SBEAP/SBO programs specialize in such efforts and will be key players in helping businesses comply with the final rule. The NSC strongly encourages EPA to engage with the SBEAP/SBO programs to coordinate outreach and compliance assistance efforts.

We appreciate the opportunity to comment on the proposed Management Standards for Hazardous Waste Pharmaceuticals. If you need any additional information or clarification of our comments, please contact Lisa Ashenbrenner Hunt or Mark Stoddard, Co-Chairs of the NSC Technical Subcommittee. Lisa can be reached at (608) 266-6887 or Lisa.AshenbrennerHunt@wisconsin.gov. Mark can be reached at (317) 233-1039 or mstoddar@idem.IN.gov.

Sincerely,



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