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December 11, 2015

The Honorable Gina McCarthy  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Dear Administrator McCarthy:

On behalf of your Local Government Advisory Committee (LGAC), we are writing to provide our input on EPA's Hazardous Waste Pharmaceuticals Proposed Rule. Human health and the environment are main concerns of us as local, state and tribal elected and appointed officials. Therefore, we are writing to provide our perspectives on the proposed rule and offer our findings and recommendations concerning it. The LGAC generally supports the provisions of the proposed rule designed to provide more standardized procedures for disposal of hazardous waste pharmaceuticals which will allow for safer, more clarified and streamlined disposal procedures.

**Background:** The EPA announced proposed Management Standards for Hazardous Waste Pharmaceuticals Rule on August 31, 2015, the rule provides for sector-specific regulations for the improved management of hazardous waste pharmaceuticals by healthcare facilities (including pharmacies) and reverse distributors.

The proposed rule intends to provide a greater level of protection to communities by reducing pharmaceutical waste being disposed into waterways and reducing waste being flushed or disposed in sewer drains. Flushing is currently allowed by Resource Conservation and Recovery Act (RCRA) regulation. However, this method of disposal has demonstrated risks to the environment and to human health.

Annually, the proposed rule could prevent an approximately 6,400 tons of hazardous waste pharmaceuticals from entering waterways by banning healthcare facilities from flushing hazardous waste pharmaceuticals down the sink and toilet. The proposed rule will also create a specific set of regulations for these facilities, including

hospitals, clinics, and retail stores with pharmacies and reverse distributors that generate hazardous waste. The proposed rule also specifies the difference in handling Universal Waste from the special precautions of hazardous pharmaceutical waste, which makes it easier for health institutions to differentiate between hazardous and non-hazardous, while generally maintaining safeguards for communities and the environment.

### **LGAC Findings and Recommendations**

**Finding:** The Proposed rule provides for more streamlined approaches for handling pharmaceutical waste and does not regulate household usage. The proposed rule creates a sewer ban for disposal of pharmaceutical waste that will have a predicted \$4.3M cost savings per year for Public Owned Treatment Works (POTWs) which will be effective in all states upon the effective date of the final rule.

**Recommendation:** The LGAC recommends moving forward with the proposed rule as it will have beneficial impacts on local, state and tribal governments by creating consistent regulations to ban flushing by healthcare facilities which generate large volumes of pharmaceutical waste. The proposed rule will also provide for a greater level of protection from risks to the environment and public health.

**Finding:** Effective product stewardship begins with Extended Producer Responsibility (EPR). In the EPR approach, the primary responsibility for minimizing the environmental impacts of a product throughout the life cycle of that product is with the industry producer, which designs, manufactures, and distributes the product for sale. To be effective, product stewardship must include those who sell, use and are responsible for proper disposal of waste product. Medical institutions covered in the proposed rule, working with the pharmaceutical industry on EPR, provide a great opportunity for product stewardship. The product stewardship approach requires that hazardous pharmaceutical creation, use, and disposal be considered at all stages of the product, ensuring the quality of human health and the prevention of contamination. Lifespan monitoring, or “cradle-to-grave” analysis will help to shore up any weak points in contamination regulation. The pharmaceutical industry has the most accurate data concerning the products they produce and can assist the EPA, Drug Enforcement Agency (DEA), medical institutions, and local governments in preventing pharmaceutical waste from entering the water supply. The EPR and product stewardship approach should be incentivized.

**Recommendation:** The LGAC recommends that the EPA seek ways to further incorporate Extended Producer Responsibility and product stewardship principles into the proposed rule. Furthermore, the LGAC recommends that the EPA should incentivize EPR and medical institutions business practices to reduce pharmaceutical waste, especially those considered hazardous. The proposed rule should aim to prevent pharmaceutical waste and contamination at all stages in the process.

**Finding:** Communication is essential in creating regulations and in the rule-making process. Information concerning what the proposed pharmaceutical rule does; how it changes pharmaceutical disposal and waste management; and how it benefits the public is important for local governments and the public.

**Recommendation:** The LGAC recommends that the EPA develop a communication strategy for the final rule targeted at state, local and tribal governments. The strategy should highlight various methods of communication to achieve coordination with state and local governments as well as target pharmacies, reverse distributors, and healthcare facilities. Multi-lingual literature and a simple, direct question-and-answer format could also be helpful, as is already being demonstrated by a LGAC community, in

Tompkins County, New York, with its 'New Med Return' Program providing information and collection for safe drop boxes throughout the county for the opportunity for citizens to safely dispose of unwanted household pharmaceuticals.<sup>1</sup>

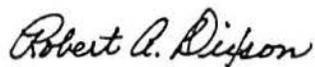
**Recommendation:** The LGAC also recommends that the communication strategy be made available in a user-friendly format for our nation's diverse, rural and disadvantaged communities to better understand the standards and to empower citizens to take action to reduce flushing of household pharmaceuticals.

**In Summary,** the LGAC thanks you, Administrator McCarthy, and the agency for your continued efforts to improve the quality of life for our communities and our shared environment. We also thank you for extending the public comment period for 30 days (until December 24, 2015) to give the public more opportunities to comment and give input to the proposed rule.

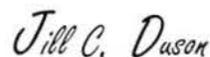
The LGAC acknowledges that the EPA has been responsive to the input received on the proposed rule. The LGAC believes that the final rule and its implementation will be successful if all parties are fully informed on the Final Rule. Towards this end, the LGAC offers our assistance to provide input on communication materials for the final rule for state, local and tribal governments.

Thank you again for this opportunity to provide the EPA feedback on this and other proposed rules.

Sincerely,



Mayor Bob Dixon  
Chairman



Councilor Jill Dason  
Chairwoman, Cleaning Up Our Communities  
Workgroup (CUOC)

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<sup>1</sup> Tompkins County, "New "Med Return" Program Provides Safe, Year-Round Disposal for Medications"  
<http://www.tompkinscountyny.gov/news/new-med-return-program-provides-safe-year-round-disposal-medications>

