December 17, 2015

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

Submitted to the Federal eRulemaking Portal: http://www.regulations.gov

Thank you for the opportunity to provide comments on the proposed addition to Subpart P of 40 CFR part 266, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities." The proposed rule strives to make it easier for healthcare facilities, vet clinics, dental offices, pharmaceutical reverse distributors, assisted living facilities, and owners or operators of treatment, storage, and disposal facilities engaged in the management of hazardous waste pharmaceuticals (HWPs) to comply with the Resource Conservation and Recovery Act (RCRA) as it pertains to pharmaceuticals, and to protect the environment from improperly disposed of pharmaceuticals.

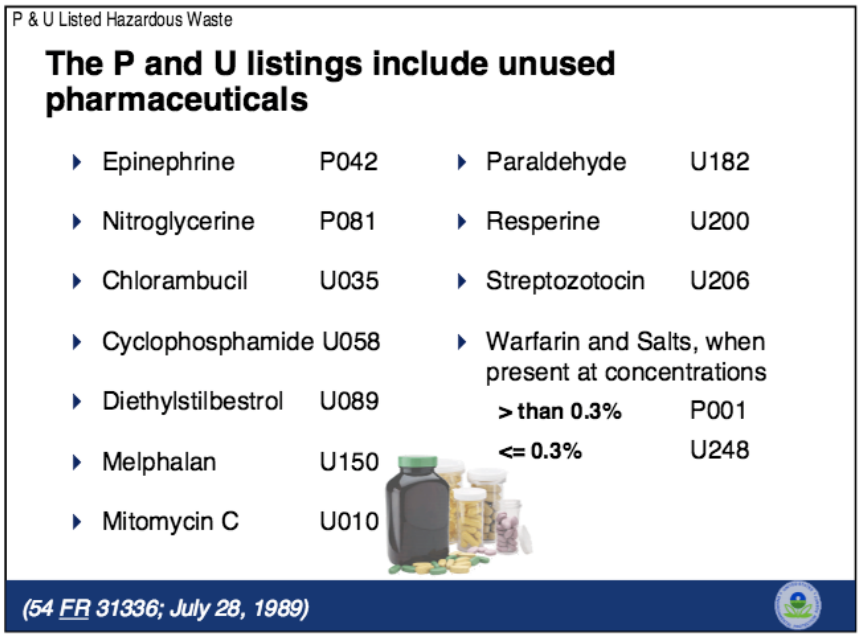
Public Employees for Environmental Responsibility (PEER) is a Washington D.C.-based non-profit, non-partisan public interest organization concerned with honest and open government. Specifically, PEER serves and protects public employees working on environmental issues. PEER represents thousands of local, state and federal government employees nationwide; our New England chapter is located outside of Boston, Massachusetts. PEER's comments will be limited to whether the proposed rule will in fact protect the environment from improperly disposed pharmaceuticals.

Background. Pharmaceuticals have been found in treated wastewater effluent, streams, rivers, ponds, lakes, groundwater, and the ocean. Traces have also been found in sediments and in tissues of aquatic organisms. Some of these pharmaceuticals are also considered hazardous due to the characteristics of the compound. Although many of these pharmaceuticals end up in water resources through flushing of human waste containing the medicines, a small portion are from improper disposal of pharmaceuticals (e.g., flushing or disposing down the drain). Because the U.S. Environmental Protection Agency (EPA) does not currently use its authority under RCRA to regulate pharmaceuticals as hazardous wastes, there is a very real risk that HWPs are being released into the environment together with all the non-hazardous pharmaceuticals.

Unfortunately, there are thousands of different pharmaceuticals being used at healthcare and assisted living facilities, nursing homes, vet clinics, dental offices and the like, and employees at these facilities often do not have the ability or knowledge to make appropriate hazardous waste determinations during pharmaceutical disposal. And, to complicate matters further, conflicting advice exists as to how to dispose of unused pharmaceuticals. Disposal of pharmaceuticals down the drain is common practice, yet there is a plethora of evidence that these pharmaceuticals have a negative impact on the aquatic environment and possibly on human health. Despite this, the Food and Drug Administration's website still recommends this method of disposal for certain medications; see http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm).

The definition of hazardous waste pharmaceuticals is too narrow. EPA proposes to prohibit facilities from disposing of HWPs down the toilet or drain. Section 266.500 of the proposed rule defines a HWP as "a pharmaceutical that is a solid waste, as defined in §261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C." In other words, only pharmaceuticals that meet the definition of hazardous waste when disposed of are included under this rule. Although the P (acutely hazardous wastes) and U (wastes containing toxic constituents) lists are fairly extensive (see 40 CFR §261.33), they are only considered hazardous wastes when they are not used for their intended purpose. Moreover, they only include a very limited list of pharmaceuticals (see Figure 1, http://www3.epa.gov/epawaste/hazard/correctiveaction/curriculum/download/hwid-list.pdf)

Figure 1



If a discarded pharmaceutical is not on the P or U list, it may be a hazardous waste if it exhibits one or more of the following hazardous waste characteristics: ignitable, corrosive, reactive, or toxic. In addition, pharmaceuticals prepared in alcohol may be hazardous due to ignitability even if the active pharmaceutical ingredient itself is not considered hazardous waste.

These definitions limit the universe of HWPs to a very small number. In fact, according to the EPA's "Hazardous Waste Pharmaceuticals Wiki," which is a website designed to "allow collaboration amongst healthcare professionals and stakeholders in determining whether the pharmaceuticals they discard meet the Resource Conservation and Recovery Act (RCRA) definition of hazardous wastes," there are 6 discrete P-listed HWPs, 12 U-listed HWPs, 17 ignitable HWPs, 2 corrosive, 0 reactive, and 14 toxic HWPs (see http://hwpharms.wikispaces.com/.) Therefore, only a total of approximately 51 pharmaceuticals meet the hazardous waste definitions and would be subject to this proposed rule. The FDA has approved 1,453 drugs through 2013, and according to the Center for Disease Control (CDC), 48.7% of people in the United States have taken at least one prescription drug in the past 30 days (see http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm). Under this current definition, only 3.5% of drugs approved through 2013 would be subject to the proposed rule.

Moreover, the rule specifically defines the term "non-hazardous waste pharmaceutical" to mean a pharmaceutical that is a solid waste as defined in §261.2, but that is not a listed hazardous waste and does not exhibit any characteristics of hazardous waste (*i.e.,* ignitable, corrosive, reactive, toxic). These non-hazardous waste pharmaceuticals are comprised of the vast majority of pharmaceuticals (96.5%) that are getting into our water supply and contaminating the environment. The proposed rule, therefore, covers only a drop in the proverbial bucket.

RCRA is too restrictive to address the underlying issues. PEER agrees with the EPA regarding the proposed change to consider long-term care facilities to be healthcare facilities instead of households. Currently, in a long-term health care facility, a particular pharmaceutical could be considered a HWP if it is in the pharmacy of the facility, but once in a patient's room and under control of the patient, may be tossed down the drain with impunity because it is considered a household waste exempt due to RCRA's household waste exclusion. PEER believes that this is confusing, and non-sensical – a drug should not be regulated or exempt depending on which room of a facility it is in. The proposed change would treat long-term healthcare facilities more like hospitals than households, and regulate the disposal of the HWPs regardless of where they are located, which in turn will help protect the environment. In this very narrow case, then, RCRA will be helpful in preventing HWPs from entering the aquatic environment.

However, a majority of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste. This proposal does allow healthcare facilities to manage their solid pharmaceutical waste and HWPs together (this mixture

would then all be considered HWPs). If this occurs, all pharmaceutical wastes from these facilities will be disposed of in a manner protective of the aquatic environment. However, facilities are also allowed to segregate their HWPs from other pharmaceutical solid waste. Therefore, it is likely that a large proportion of non-hazardous pharmaceuticals at these facilities will continue to be flushed and sewered.

Moreover, these hospitals, nursing homes, vets, dentists, and other facilities generate a lot of pharmaceutical waste; but some experts estimate that they are responsible for only "20 to 30 percent of the pharmaceuticals disposed intentionally into the waste system" (see https://www.nrdc.org/health/files/dosed4pgr.pdf, citing personal communication with experts). If this estimate is accurate, then 70 to 80 percent of pharmaceuticals disposed intentionally (i.e., flushed) come from households and other commercial facilities. As such, the proposed rule does not go far enough to address the environmental and health hazards posed by pharmaceutical waste. In other words, given the household waste exemption, RCRA is not the solution to the pharmaceutical contamination problem. PEER urges EPA to continue looking for a safe disposal method for all pharmaceuticals, both hazardous and non-hazardous, at all locations.

Hazardous waste pharmaceuticals that are also controlled substances. Under current regulations, a healthcare facility that deals with a HWP that is also a controlled substance according to the Drug Enforcement Administration (DEA) must comply with the RCRA hazardous waste requirements *and* the requirements of the Controlled Substances Act and other applicable DEA regulations. DEA regulations require that controlled substances be eradicated in such a way that they are "non-retrievable," and they specifically state that flushing does not meet this non-retrievable standard. Because controlled substances can be diverted from an intended waste stream and sold or misused, it is preferable to permanently dispose of these pharmaceuticals onsite. The proposed rule will conditionally exempt from RCRA HWPs that are also a DEA controlled substance, provided that they are combusted at a hazardous waste incinerator or a permitted municipal solid waste incinerator. Although there are only five commonly used drugs that are both HWPs and controlled substances (chloral/chloral hydrate; fentanyl sublingual spray; phenobarbital; testosterone gels; and injectable valium), complying with the stringent requirements of both RCRA and DEA leads to these drugs being sewered more frequently. While exempting these from RCRA reduces the regulatory burden somewhat, the DEA regulations are still cumbersome for some of these smaller healthcare facilities. PEER is concerned that these controlled substances, and the pharmaceutical wastage of these HWPs, will still be sewered on site. Therefore, while this portion of the proposed rule is a step in the right direction, we do not believe that it will prevent these HWPs from entering the aquatic environment.

Conclusion. PEER commends EPA for its clear and unambiguous statement that traditional wastewater treatment operations at privately owned treatment works (POTWs) are not designed to remove pharmaceuticals, and that even advanced treatment technologies at these POTWs are not designed to remove pharmaceuticals. Moreover, it is refreshing to see EPA admit that the pharmaceuticals entering the environment, through flushing or other means, are negatively impacting aquatic ecosystems and on fish

and wildlife. The sewer ban on all HWPs is a good first step for a large and complicated problem. However, PEER would like to see a healthcare facility ban on flushing all medications, both hazardous and non-hazardous, into public sewers or septic systems. In addition, since households are an even more significant source of pharmaceutical waste in the sewers, we urge EPA to consider ways to ban flushing of all pharmaceuticals, including disposal into septic systems.

Given RCRA's constraints of regulating only hazardous wastes and exempting households, PEER believes EPA and other agencies need to develop a new, mandatory regulatory framework where *all* pharmaceuticals are collected and incinerated. RCRA is not suited for the regulation of pharmaceuticals, and as such, a new law is needed. A single standard for all pharmaceuticals (regardless of the generator), together with education and training, would improve compliance and reduce the pharmaceutical pollution currently polluting our waterways.

Thank you for the opportunity to comment.

Sincerely,

Kyla Bennett, Director
New England PEER
P.O. Box 574
North Easton, MA 02356
508-230-9933
nepeer@peer.org