



Healthcare Waste Institute

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Via Electronic Transmission: hwtrulemaking@ecy.wa.gov

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Re: Draft Amendments to the Dangerous Waste Regulations Chapter 173-303 WAC

The Healthcare Waste Institute (HWI) of the National Waste & Recycling Association (NWRA) is pleased to offer comments on the draft amendments to the Dangerous Waste Regulations by the State of Washington Department of Ecology (Ecology). The HWI represents manufacturers and service providers as well as other professionals in the healthcare waste management industry. Our members provide transportation and treatment of regulated medical wastes and pharmaceutical waste to the healthcare sector. The NWRA is a not-for-profit trade association representing private solid waste and recycling collection, processing and management companies. HWI and its members have reviewed the draft amendments and submit for consideration by Ecology the following comments.

COMMENTS

General Comments:

We understand that Ecology is proposing these regulations in anticipation of the Environmental Protection Agency's (EPA) proposed Management Standards for Hazardous Waste Pharmaceuticals (Pharmaceutical Rule). It is important that this rule be consistent with EPA's rule for simplicity and to support companies that do business in multiple states. We will provide specific comments on some of the items that are not consistent with the proposed rule that could create issues. Additionally, we highly recommend that Ecology not move forward with new regulations without seeing the outcome of the EPA's Pharmaceutical Rule because there are several issues that were still being contemplated by EPA and the final rule may be substantially different than the draft rule. The decisions that EPA make on these sections will

significantly impact how the industry will need to manage these waste streams. In an effort to be transparent HWI has included as an attachment to this submittal the comments submitted to the EPA that place our position. We believe proposing regulations prior to EPA finalizing their regulations would be premature.

Specific Comments:

Definition for "Creditable Dangerous Waste Pharmaceutical"

We request that the definition of "creditable dangerous waste pharmaceutical" be modified. As written, this definition is very limiting and could result in compliance challenges. HWI recommends that the definition of "creditable dangerous waste pharmaceutical" not include a specific expiration date or time limit of the pharmaceutical product. Ecology's proposed definition for creditable dangerous waste pharmaceuticals is limited to products less than one year past the expiration date of the product. While HWI recognizes that it is not a common practice for pharmaceutical manufacturers to provide credit past one year, the period in which products receive credit vary. Therefore, HWI strongly recommends that the proposed definition be amended as follows:

(a) "Creditable dangerous waste pharmaceutical" means a pharmaceutical that has the potential to receive manufacturer's credit and is (1) in unused, or partially used containers or un-administered; and (2) expired, unexpired, or likely creditable based on the manufacturer's published returns policy or specific contractual Agreement."

HWI understands that different healthcare facilities negotiate terms with their wholesalers/distributors or directly with pharmaceutical manufacturers on an individual basis. Therefore, the limitation that the pharmaceutical will no longer be considered creditable the first time no credit is given should be eliminated to be consistent with industry practices between manufacturers and distributors.

Syringes

While we support Ecology's proposal to exempt fully depressed syringes, we also recommend following EPA's proposed exemption for partially depressed syringes. And although we appreciate Ecology's intent, there are practical considerations that make compliance with these requirements challenging. This creates a dual waste which would mean that more waste would be required to go into hazardous waste containers that are also labeled for medical waste which is both more costly and difficult for generators to manage. For those trying to avert these costs there may be a temptation to depress the remainder in the hazardous waste container and then take the sharp to a sharps container. This could create risk to injury for the healthcare provider and would be against OSHA requirements for proper management of sharps. It is challenging to train generators to segregate partially versus fully depressed syringes. If a small amount of material remains in the syringe, generators might be tempted to sewer the remaining material in the syringe to avoid managing the syringe in a different manner. The easier it is to train generator staff on management of regulated medical waste and dangerous pharmaceutical waste, the better it will be ultimately managed. The risks for mismanagement or the complication associated with managing these materials far outweigh the risk for a sharps injury, therefore we do not support that ONLY fully depressed syringes be allowed to be placed into sharps containers.

Further, our members' experience suggests that when generators fail to comply with this requirement, the regulated medical waste processors are held accountable and subject to enforcement risks. As Ecology is aware, removing partially depressed syringes from a container of fully depressed syringes puts workers at even greater risk.

Packaging

We recommend excluding containers including single dose packaging, vials and other packaging that may be similarly empty of regulated pharmaceutical materials from the requirement that the packaging be destroyed. It is not realistic for the generator to "destroy" the containers prior to placing them in the trash. Defacing the containers would be non-invasive. However, we are concerned that defacing the packaging would not be considered adequate. Destroying containers could expose workers to additional hazards from trace residues becoming airborne or through direct contact, containers being sharp and injuring workers. We suggest including an exemption for the containers and revising the packaging destruction requirements so that workers are not exposed.

Further, it is not clear what problem this destruction requirement purports to solve. Is it Ecology's concern that there would be misuse of these containers after discarded, counterfeit, or diversion? Does Ecology have any data to support this requirement and these risks? As written, this requirement will create numerous problems and add significant costs for managing and processing these containers. The risks that Ecology is trying to mitigate will be out of proportion to the risks and expense created. Lastly, we believe addressing these risks is beyond Ecology's jurisdiction and charge to require container destruction. We strongly recommend that Ecology retain the current definition of "empty" for U-listed chemotherapy drugs and other dangerous wastes with respect to IV bags and tubing. Currently, the majority of facilities manage these all empty chemotherapy IVs and tubing as "trace chemotherapy" waste and segregate them into yellow bins that are incinerated at a regulated medical waste facility. Operationally, all chemotherapy and many other IV bags and tubing would need to be managed as hazardous waste as the proposed rule is written. This would significantly increase the cost of disposal. One way to insure this type of handling would be to offer the option of either managing empty IV bags and tubing for U-listed chemotherapy as hazardous waste or as trace chemotherapy waste destined for incineration at a regulated medical waste facility. We believe the current definition of empty for other potential IV hazardous waste is sufficient as these occur very infrequently if at all. We are also very concerned about the proposed requirements to manage all "trace contaminated" gowns, gloves, pad, etc. as hazardous waste. These also are managed as trace chemotherapy waste and incinerated at a regulated medical waste facility in most cases. We again encourage Ecology to offer this option as an alternative to hazardous waste management to reduce costs while maintaining environmental protection.

Solvent contaminated wipes

We request clarification on the code sections related to solvent contaminated wipes. These are used in healthcare settings for certain spill cleanups. We recommend that solvent contaminated wipe be exempted from the rule when generated at healthcare facilities due to small quantities generated.

Recordkeeping requirements

Ecology requires recordkeeping retention for a period of five years while EPA only requires three. We request that Ecology revise the recordkeeping retention to be consistent with EPA.

Storage

This proposed rule is nearly the same as the EPA regulations for the ability to accumulate pharmaceuticals on-site for one year or less without a permit. The difference is that the EPA also allowed for the generator to maintain the inventory electronically or by some other means but that option is missing from the Ecology regulations. We recommend consistency with EPA.

EPA letter

Attached please find a copy of the letter that was sent to EPA on the Pharmaceutical Rule. We request that Ecology review our comments and consider them accordingly when drafting the next version of the rule.

CONCLUSION

Based on the Fall 2016 Unified Agenda for Federal EPA, it appears that the rule may be further delayed as it shows the rulemaking to be under long-term Action with a Final proposed date of December 2017. This makes it unlikely that the rules will take effect in the current proposed form, so we would again encourage Ecology to await the final rule before releasing the proposed regulations again. The HWI appreciates your consideration of our comments. HWI members would appreciate the opportunity to discuss these comments further with the DEC to clarify any points for the department should they need them. Should you have any questions, please call me at 202-364-3724 or e-mail at agermain@wasterecycling.org.

Very truly yours,



Anne Germain, P.E., BCEE
Director of Waste & Recycling Technology

Attachment