

# **PharmEcology Services, WMSS**

Please refer to uploaded file. Thank you.

TO:

**Rob Rieck**

Rulemaking Lead

[hwtrrulemaking@ecy.wa.gov](mailto:hwtrrulemaking@ecy.wa.gov)

360-407-6751

FROM: Charlotte A. Smith, R. Ph., M. S., Senior Regulatory Advisor, PharmEcology Services, WMSS; Kathleen Skibinski, R. Ph., M.S., Manager, Regulatory and Compliance, PharmEcology Services, WMSS

DATE: May 20, 2020

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

Our comments are in the spirit of assuring complete understanding and consistency between the Washington State Dept. of Ecology and the regulated healthcare community with respect to the adoption of EPA's Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine and is based on the webinar presented on this topic by the Washington State Dept. of Ecology on May 5<sup>th</sup>, 2020.

1. With respect to slide 14 in the presentation, will you please re-iterate the position with respect to Washington State-only dangerous waste? Will healthcare facilities be able to continue sending Washington State-only dangerous waste to incinerators that meet the requirements noted in the Conditional Exclusion or must these wastes be sent to a RCRA permitted incinerator when Washington State adopts the EPA's Subpart P and is there an additional exclusion for law enforcement? Is the differentiation between the controlled combustion requirements for law enforcement and the types of incinerators noted in slide 35?
2. With respect to the delisting of OTC nicotine gums, patches, and lozenges from the P075 hazardous waste category on slide 15, we believe it's important to note that prescription nicotine replacement therapies are still regulated under P075. We don't believe that was mentioned during the webinar.
3. Also, with respect to slide 15, since the EPA's exemption of P075 OTC nicotine is a separate listing under 40 CFR 261.33, we do not see that as including nicotine cigarettes or vaping devices as pharmaceuticals, nor are they approved by FDA as such. We encourage the Dept. of Ecology not to include these under the new regulations as hazardous waste pharmaceuticals under section -555.
4. On slide 24, we encourage the Dept. of Ecology to make it clear that while the terms "satellite accumulation" and "storage accumulation" may no longer apply, that healthcare facilities may store hazardous waste pharmaceuticals in what has previously been considered to be satellite storage areas e.g. the pharmacy and nursing units, and may move these to a central location for storage, e.g. where other hazardous wastes are

being stored, as long as the one year total storage time has been documented and not exceeded. Perhaps consider editing slide 26 to “no SAA required” for clarity.

5. With respect to slide 25, it has been noted federally that the term PHARMS does not fit on the electronic hazardous waste manifest and EPA has now also authorized the term PHRM.<sup>1</sup> We would encourage the Dept. of Ecology to also include this adjustment.
6. In EPA’s Final Rule, potentially creditable hazardous waste pharmaceuticals are clearly defined as being in the original manufacturer packaging, undispensed, and unexpired or less than one year past expiration. There is no mention in Subpart P of the requirement to constantly check reverse distribution records to determine specific credit determinations and then adjust returns accordingly. Since manufacturers’ policies are subject to change without notice, we strongly encourage the Dept. of Ecology to adopt EPA’s definitions of potentially creditable hazardous waste pharmaceuticals as stated in the federal regulations and as delineated on slide 40 without additional restrictions as were discussed during the webinar.
7. To our knowledge, “trace chemotherapy” waste was not mentioned in the webinar and due to the exclusion of empty P-listed vials, ampules, syringes, and IV bags under the new rule, we would assume that any of these empty containers that held arsenic trioxide could now be managed as trace chemotherapy and regulated medical waste and would not need to be segregated. Please confirm this to be an accurate interpretation.

Thank you very much for your time and consideration of these comments and questions. We appreciate the time and effort that Washington State has consistently demonstrated over the years to encourage the healthcare facilities in your state to manage waste pharmaceuticals in an environmentally friendly manner. We are grateful to both EPA and the Department of Ecology that there will now be more consistency and practicality in the management of both hazardous waste pharmaceuticals and all pharmaceutical waste.

Please contact us with any comments or questions at the following:

Charlotte Smith, [csmith32@wm.com](mailto:csmith32@wm.com), 713-725-6363

Kathleen Skibinski, [kskibin1@wm.com](mailto:kskibin1@wm.com), (608) 698-0616

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<sup>1</sup> Manifesting Non-Creditable Hazardous Waste Pharmaceuticals -New Four Character Code. Letter from Barnes Johnson, Director, OCRC, EPA. December 19, 2019. <https://rcrapublic.epa.gov/files/14919.pdf>