

December 22, 2015

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**RE: Management Standards for Hazardous Waste Pharmaceuticals, Docket ID No.
EPA-HQ-RCRA-2007-0932**

Dear Mr. Stanislaus and Mr. Johnson:

Innovatix appreciates the ongoing efforts of the Environmental Protection Agency (EPA) to address hazardous waste pharmaceuticals (HWPs) and is grateful for the opportunity to submit comments on the HWP management standards. Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 30,000 non-acute care providers, including 650 long-term care pharmacies, 2,910 infusion providers and 6,396 skilled nursing facilities.

Prior to submitting these comments, Innovatix held Advisory Group meetings with members and Innovatix staff pharmacists to better understand the impact of the proposed rule. Innovatix has also participated in several stakeholder meetings to gain additional understanding of how the proposed rule will affect the broader long-term care and infusion community. While Innovatix generally supports the broad concepts in the proposal and efforts to reconcile environmental protections with healthcare operational issues, based on insight from our provider members and partner organizations, Innovatix is concerned about the possible impact of the following four provisions: identification and disposal of HWPs, controlled substances inactivation and disposal, the disposal of empty containers that once contained HWPs, and disposal costs.

Identification and Disposal of HWPs [page 58017]

In 2013, the EPA launched the "Hazardous Waste Pharmaceuticals Wiki" as a resource about hazardous waste to assist stakeholders in making accurate hazardous waste determinations for waste pharmaceuticals and to increase compliance with the EPA's existing regulations. The 2015 proposed rule references the Wiki website and affirms it as a viable resource for stakeholders. While we believe the website provides a helpful starting point for providers to assist in their important decisions regarding pharmaceutical waste, it

is not as comprehensive nor is it updated as frequently as it should be. Further, though the EPA developed the website, a prominent disclaimer that “the views expressed on this site do not reflect Agency policy or action or the official views of EPA or the federal government” is included. Our members strongly believe that the Wiki should be endorsed and maintained by the EPA to ensure that it serves as a valid resource for the provider community. In turn, healthcare facilities should be responsible for ensuring that the drugs included on the website are disposed of properly. Healthcare facilities and providers would benefit greatly if the website contained all HWP, toxics, ignitables, and other information that these entities need to be aware of. Additionally, it should be modified to become more user-friendly, and in doing so, eliminate any guess work by providers in determining if a substance is an HWP and how it should be disposed of. We recognize that such improvements would be a significant undertaking, but having comprehensive, up-to-date, and understandable requirements would facilitate compliance.

Recommendation: The EPA should assume responsibility for the HWP Wiki website, and the website should include all of the HWPs that a healthcare facility may encounter and instructions on how to properly dispose of them.

Controlled Substances Inactivation and Disposal [page 58049]

The EPA requested comments on its understanding that the Drug Enforcement Administration (DEA) tracking and shipping requirements are sufficient to act in lieu of the Resource Conservation and Recovery Act hazardous waste manifest and hazardous waste transporter requirements. Innovatix raises concerns with this understanding, since most long-term care facilities (LTCFs) do not maintain a collection receptacle for the disposal of controlled substances and do not need to be licensed by the DEA. For these facilities, controlled substances cannot be sent directly to an incinerator. In the absence of sewerage, LTCFs need a safe and straightforward method to dispose of unwanted controlled substances. We propose that the use of Cactus Sink, Rx Destroyer, Deterra Drug Deactivation System, or similar products that chemically digest or absorb these substances should be included as methods to dispose of unwanted controlled substances. Further, we recommend that the inactivated substances would then be disposed of as non-hazardous waste pharmaceuticals.

Recommendation:

The EPA should support alternatives to incineration for LTCFs that need to dispose of unwanted controlled substances.

The Disposal of Empty Containers that Once Contained HWPs [page 58055]

The EPA is appropriately relaxing the requirements for empty containers that once contained HWPs. However, the proposal to require crushing or shredding of some empty containers before disposal is not an appropriate course of action in response to concerns

about the potential for diversion. Residues in containers that are discarded in the municipal waste stream are not a high-risk for diversion. The proposed process will require additional training and unnecessary staff time. Furthermore, the disposal of empty containers in this fashion may lead to unintended consequences. For example, the destruction of waste in the proposed manner may aerosolize or contaminate personnel or equipment, and/or may result in injury. Instead, Innovatix recommends the intact disposal of all empty containers.

Recommendation: Innovatix recommends that the EPA eliminate the requirement to destroy empty containers that once contained HWPs before disposal of said containers.

Disposal Costs [page 58021 and page 58075]

The proposed rule inappropriately includes dietary supplements, HWP residues, personnel protective equipment, and clean-up materials in the HWP definition. Classifying these items as HWPs is excessive and will significantly increase disposal costs for our members. Facilities will incur additional expenses to identify these products, to train staff, and to ensure compliance with the definition. Innovatix believes that the financial resources required to comply with this expansive disposal mandate would be better spent on the provision of direct patient care. The EPA must consider the additional significant financial implications if it insists that facilities comply with this more robust—though minimally impactful—waste stream.

Recommendation: Innovatix recommends that the EPA evaluate and possibly eliminate the requirements for some [existing and proposed] HWPs, due to their minimal environmental impact and associated high disposal costs.

Thank you in advance for considering our recommendations. If you have any questions or wish to discuss further, I urge your staff to reach out to Shara Siegel, Director of Government Affairs, at ssiegel@innovatix.com.

Sincerely,



John P. Sganga, FACHE
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