

Kansas Department of Health and Environment
Bureau of Waste Management Policy 2012-P2

**Regulation of Pharmaceuticals from
Non-Exempt Generators of Hazardous Waste**

Purpose

This policy clarifies the Kansas Department of Health and Environment's (KDHE's) position on the regulation of pharmaceuticals from hazardous waste generators that are not exempt from the Resource Conservation and Recovery Act (RCRA) requirements. This includes Large Quantity Generators (LQGs), Small Quantity Generators (SQGs), and Kansas Small Quantity Generators (KSQGs) of hazardous waste, or in other words, any generator of 55 pounds or more per month of non-acute hazardous waste, or 2.2 pounds of acute (P-listed) hazardous waste.

This document does not replace technical guidance documents or other KDHE policies related to exempt generators of hazardous waste, including households, long-term care facilities, businesses not generating hazardous waste, or Conditionally Exempt Small Quantity Generators (CESQGs) of hazardous waste (who do not accumulate more than 55-pounds of hazardous waste on-site).

This policy does not address controlled substances that are regulated by the U.S. Drug Enforcement Administration.

Background

Pharmaceuticals are being developed rapidly and data shows they are impacting the environment before they can be adequately regulated under RCRA. The U.S. Environmental Protection Agency (EPA) has released multiple guidance documents regarding the regulation of different pharmaceuticals and pharmaceutical-related waste (i.e., containers). Much of this guidance conflicts with other EPA guidance and with guidance given by individual states. This has led to confusion among generators in Kansas about how to properly manage these wastes.

KDHE's goal is to efficiently protect human health and the environment and to encourage the use of Best Management Practices (BMPs) for all pharmaceuticals generated in Kansas, not just those that have the potential to be regulated under RCRA.

Action

Unused or undistributed pharmaceuticals (including pills, liquids, etc.) meeting the definition of a hazardous waste under K.A.R. 28-31-261 and 28-31-261a must be managed as hazardous waste by LQGs, SQGs, and KSQGs.

Wastes, including those discussed below, that exhibit a characteristic of hazardous waste (i.e., ignitability, reactivity, corrosivity, and/or toxicity) **must** be managed as hazardous waste.

If the waste is not a characteristic hazardous waste and the BMPs described in this document are followed, KDHE does not consider the following pharmaceutical-related wastes to meet the definition of listed hazardous wastes.

1. Used nicotine gum and patches

KDHE agrees with EPA's position that used nicotine gum and patches are not a commercial chemical product and therefore do not meet the definitions of 40 CFR 261.33 (P-listings). Therefore they are not a hazardous waste.

2. Epinephrine and syringes (including used epi-pens) with residual epinephrine

EPA guidance suggests that generators must check each container and each manufacturer for the chemical used in the medical applications to determine if it has an epinephrine salt base (non-hazardous) or an adrenalin base (P-listed hazardous waste). KDHE finds this guidance cumbersome and difficult to follow in most medical settings. Therefore, it is KDHE's position that, if the Best Management Practices (BMPs) listed in this document are followed, these wastes will not be considered a listed hazardous waste regardless of the base.

3. Nitroglycerine and containers with residual nitroglycerine

KDHE agrees with EPA's position that medicinal nitroglycerine does not meet the definitions of 40 CFR 261.33 because it is not reactive. Therefore these wastes are not hazardous waste.

4. Bubble packs and other containers previously holding pharmaceuticals on the P-list

EPA created guidance in a memorandum dated November 4, 2011, suggesting several ways that containers formerly holding P-listed pharmaceuticals can avoid regulation under RCRA. This guidance continues to place extra burdens on affected generators for exceedingly small amounts of potentially hazardous waste. KDHE will allow generators to choose to follow EPA's guidance of November 4, 2011, or alternatively manage this waste under the BMPs listed in this document. In order to manage these containers under the BMPs all pharmaceuticals (e.g., pills and liquids) must have been removed by conventional and practical means. If the containers are managed following the BMPs listed in this document, KDHE does not consider them a hazardous waste.

Again, if any of these wastes exhibits a characteristic of hazardous waste (i.e., ignitability, reactivity, corrosivity, and/or toxicity), then it remains a hazardous waste in Kansas.

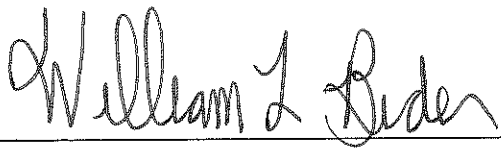
Best Management Practices (BMPs)

Waste items listed as numbers 1 through 4 in the previous section must be managed as follows in order for the KDHE interpretations of this document to be valid. Failure to follow these BMPs could result in the waste being subject to full regulation under RCRA.

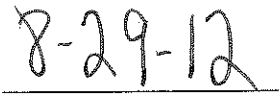
1. The generator must make a determination of whether or not each waste stream meets any of the characteristics described in 40 CFR 261 Subpart C. Either knowledge of the waste (or the process generating the waste) or analytical testing in a KDHE-certified lab may be used to determine if the waste is a characteristic hazardous waste. Documentation of each determination must be maintained on site for three years from the time the waste stops being

generated. Wastes that exhibit a characteristic of hazardous waste must be managed as hazardous waste.

2. The waste must be appropriately managed in an environmentally protective manner inside and outside the facility until it is removed for disposal. This can include managing the waste with other medical waste in medical waste containers (or sharps containers if the waste includes a sharp).
3. The waste must be disposed of at one of the following types of facilities (listed in order of KDHE preference):
 - a. **Medical Waste Incinerator.** The pharmaceutical-related wastes may be incinerated with other medical waste leaving the facility, but must comprise less than 10% of the total medical waste leaving the facility. The generator must ensure that the medical waste incinerator being used for destruction has all appropriate local, state, and federal permits.
 - b. **Pathological-only Waste Incinerator.** For facilities (mainly hospitals and clinics) operating pathological-only waste incinerators under applicable state and federal incinerator rules, these pharmaceutical wastes may be included as a portion of the no more than 10% (by weight) non-pathological wastes limitation. Any amounts exceeding the 10% limitation will cause the facility to violate the exemption, and subject the facility to the full range of the applicable Hospital/Medical/Infectious Waste incinerator regulations.
 - c. **Municipal Solid Waste Landfill.** The pharmaceutical-related wastes may be disposed of at a municipal solid waste landfill as a special waste, and may be included with other medical waste going to the landfill.
 - d. **Recycling Facility.** None of the waste (including containers) may be recycled unless the generator can demonstrate and document that the recycling will not cause pharmaceuticals or residual pharmaceuticals to enter the environment.



William L. Bider
Director, Bureau of Waste Management



Date