



State of Ohio Environmental Protection Agency

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October 12, 2000

Doug Staton  
EXP Pharmaceutical Waste Management, Inc.  
238 East Kelso Road  
Columbus, Ohio 43202

Dear Mr. Staton:

Thank you for your letter of July 31, 2000. You asked a number of questions regarding the proper disposition of non-dispensable/non-returnable discarded pharmaceuticals that meet the definition of a hazardous waste. Overall, the questions you ask are broad and request an explanation of the overall hazardous waste regulatory program as it applies to generators. Unfortunately, this cannot be accomplished in a letter so, please find enclosed our *Hazardous Waste Generator Handbook*. The handbook provides a detailed description of the hazardous waste program.

Below, I have restated some of your questions. Where possible I have tried to focus my responses to the disposition of non-dispensable/non-returnable pharmaceuticals once they are deemed wastes by the pharmacy. Our understanding is that the pharmacy does not have a reasonable expectation that these pharmaceuticals can be recycled.

When the pharmacy does not have a reasonable expectation that the pharmaceuticals can be recycled (i.e., the pharmaceuticals will be discarded) the pharmacy must consider the pharmaceuticals to be a waste. The pharmacy must evaluate these wastes in accordance with Ohio Administrative Code (OAC) rule 3745-52-11 to determine if the pharmaceutical is a hazardous wastes. If the pharmaceuticals are hazardous wastes then the pharmacy must manage them in accordance with the applicable hazardous waste regulations. According to Ohio Revised Code (ORC) § 3734.02 the pharmacy can only send hazardous waste to a facility which has a hazardous waste installation and operation permit for treatment, storage or disposal of hazardous wastes.

**How should the pharmacy determine whether the pharmaceutical is EPA-designated hazardous or nonhazardous waste?**

OAC rule 3745-52-11 mandates the method by which a waste generator determines whether his waste is a hazardous waste. In short, a pharmacy will need to determine if the discarded pharmaceutical meets the definition of a listed hazardous waste or exhibits one or more characteristics of a hazardous waste.

A listed hazardous waste is a discarded material that U.S. EPA has specifically identified to be a hazardous waste. These materials are named individually and described in the hazardous waste rules. To determine if a discarded pharmaceutical is a listed hazardous waste, one needs to review the list of chemicals provided in OAC rule 3745-51-33. If the discarded pharmaceutical contains only one active chemical ingredient (e.g., lindane shampoo) and that chemical appears on the list given in OAC rule 3745-51-33, then the waste is either a P or U listed hazardous waste. In the case of lindane shampoo, the discarded pharmaceutical would carry the hazardous waste code U129.

A discarded pharmaceutical, not defined as a listed hazardous waste, would be a characteristic hazardous waste if it exhibits one or more of the characteristics defined in OAC rules 3745-51-21 to 3745-51-24. The hazardous waste characteristics are ignitability, corrosivity, reactivity, and toxicity. To determine if a discarded pharmaceutical is a characteristic hazardous waste, the pharmacist must test the material as explained in the rules and/or use his knowledge regarding the ingredients in the discarded pharmaceutical. For example, some cough syrups contain a fair amount of alcohol. These wastes may meet the definition of an ignitable waste. Other wastes may exhibit the toxicity characteristic due to their barium content. Please find enclosed a draft guidance document regarding the use of generator knowledge in making waste determinations. Also, chapter five of the *Hazardous Waste Generator Handbook* explains how a generator should perform a hazardous waste determination.

### **How should each waste group be destroyed or otherwise properly removed from the hospital for destruction?**

There are two common options available to pharmacies with regard to treating discarded hazardous pharmaceuticals. The pharmacy may:

1. Segregate the discarded pharmaceuticals by waste code and have the waste treated in accordance with the specified treatment standard provided in the Land Disposal Restrictions (LDR) rules for that waste code. The LDR rules, 40 CFR part 268, dictate to what level a hazardous waste must be treated; or
2. Create a lab pack. A lab pack is a collection of different types of hazardous wastes (in small volume containers) that are placed in one large container for storage, transportation, and treatment. Per the LDR rules, lab packs must be treated by incineration.

Anytime hazardous wastes are removed (i.e., transported) from the site where they were generated, a hazardous waste transporter must be used. Also, the hazardous waste must be accompanied by a hazardous waste manifest during transportation.

***Furthermore, hazardous wastes can only be treated or stored at a facility that is permitted under Ohio EPA's or U.S. EPA's hazardous waste program.*** An incineration facility that is permitted by Ohio EPA to burn infectious waste cannot burn hazardous waste unless it also holds a hazardous waste permit. We have no such dual permitted commercial incineration facilities in Ohio. Also, no Ohio hospitals hold permits to burn hazardous wastes in their on-site incinerators.

**Do hospitals need to be concerned with how much P-listed and U-listed waste is generated per month and large quantity waste generator status?**

Yes. If a hospital pharmacy generates more than 2.2 pounds (1 kg) of an acute hazardous waste in a calendar month or 2200 pounds (1000 kg.) of any other hazardous waste, the hospital as a whole would be a large quantity hazardous waste generator for that calendar month. An acute hazardous waste carries the P- waste code or is followed by an (H) code in its listing. There are a number of requirements a large quantity generator must follow; please see chapter seven of the handbook for a summary of these requirements.

**How should a hospital determine the total weight values per month?**

A hospital must determine the amount of hazardous waste it generates, in a calendar month, by adding together the amounts of hazardous wastes and the amounts of acutely hazardous wastes generated by each department located on-site at the hospital. Hazardous wastes generated at satellite offices may not be included in the hospital's monthly hazardous waste generation rate. The hazardous waste rules are site-specific so, each hazardous waste generator, by site, must account for the hazardous wastes he generates at his own facility.

**What additional licensing and reporting requirements are there?**

A hazardous waste generator must obtain a hazardous waste identification number if he generates more than 220 pounds (100 kg) (2.2 pounds of acute hazardous waste) of hazardous waste in a calendar month. This identification number is obtained from Ohio EPA. A large quantity generator must submit an annual hazardous waste report. This must be done even if the generator is defined as a large quantity generator for only one month during the calendar year. When generators send hazardous wastes off-site for treatment, they need to complete an LDR notification form. This form is usually provided by the treatment company with whom the generator contracts with to treat and dispose of his hazardous waste. A copy of this form is to be maintained by the generator.

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If you have any further questions, please do not hesitate to contact me at (614)644-2927.

Sincerely,

Karen L. Hale, Environmental Specialist 3  
Technical Support  
Division of Hazardous Waste Management

cc:  
Alison Shockley, DSIWM  
Andy Kubulak, TSU, DHWM  
Linda Neumann, CAS, DHWM

*July 31, 2000*

*Ms. Alison Shockley  
Ohio Environmental Protection Agency  
PO Box 1049  
Columbus, OH 43216*

*Dear Ms. Shockley:*

*Thank you for our telephone conversations on July 24. As you requested, I have summarized my questions related to the proper waste stream within a hospital for expired pharmaceuticals and have also included some industry history.*

*My company is involved in what is known as the reverse distribution industry for expired pharmaceuticals. EXP, Inc., as well as perhaps 90 small companies across the country, contract with pharmacies (primarily impatient hospital pharmacies) to process pharmaceuticals that have passed their FDA expiration date. It is important to note that we are talking in most cases, about full or partial pharmaceuticals in their original manufacturer packaging i.e. unit dose, plastic and glass bottle, syringe, vial or ampule, although some has been repackaged according to proper pharmacy practice. We are not talking about empty pharmaceutical packages or any pharmaceuticals that have come in contact with humans, thereby designating those as infectious/biohazard. Nor are we ever talking about bulk chemicals used for pharmaceutical compounding. The purpose of reverse distribution is three-fold: To document the proper disposition of DEA controlled substances Schedule II through Schedule V, to return as much pharmaceutical product as possible back to the original manufacturers (thus gaining*

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*return credit or dollars for those products), and then to properly dispose of the non-returnable pharmaceuticals according to EPA RCRA list and other EPA requirements.*

*Questions arise when hospitals do not use a reverse distributor. It stands to reason that if reverse distributors must separate hazardous waste from non hazardous waste and use appropriately licensed incinerators, then hospitals should be doing likewise with their non-dispensable/non-returnable pharmaceuticals.*

*What are the proper procedures for hospital pharmacies to dispose of non-dispensable pharmaceuticals? There is an ongoing discussion at the Ohio Society of Health System Pharmacists' web site. Take into account that hospital pharmacies often encounter broken vials and other damaged product which need a waste outlet. These broken or partial products often find themselves placed in "red bags" or other red biohazard/infectious waste containers, and there seems to be support by the Ohio State Board of Pharmacy for this practice. It therefore is not a huge jump in logic for pharmacies to assume that if some pharmaceutical product can go into a red container, then all non-dispensable/non-returnable pharmaceuticals can be disposed of in the same fashion. These containers are then either incinerated on site using the hospital's incinerator, or removed by the hospital's waste contractor and handled according to the waste handler's procedures for these containers. I suspect the waste handlers have no idea that EPA hazardous materials may have been placed in these containers. I also believe that pharmacy personnel think they are correct/compliant in using this particular waste stream.*

*I am asking for clarification by the Ohio EPA and the Hazardous Waste Management Board regarding the proper disposition of non-dispensable/non-returnable pharmaceuticals, some of which contain P-listed and U-listed hazardous materials, by the hospitals once these are deemed waste. Once it is waste, how should the pharmacy determine whether it is EPA-designated hazardous or non-hazardous, and how should each waste group be destroyed or otherwise properly removed from the hospital for destruction? Do the hospitals need to be concerned with how much P-listed and U-listed waste is generated per month, and potential 'large quantity waste generator' status? And if so, how should they determine the total weight values per month? What additional licensing and reporting requirements are there? I think one point of confusion here may be the use of the term "hazardous" both by the EPA for P-listed and U-listed waste and by other waste handlers for biohazard/infectious waste. Some examples of possible penalties for noncompliance would also be helpful.*

*Thank you for your prompt attention to this matter. Should you have any questions or need for clarification, please contact me at 614-842-6444.*

*Sincerely,*

*Doug Staton*