RCRA-C Compliance

Information for Pharmacies and Others

Reverse Distribution/Reverse Logistics

Introduction

Pharmacies, hospitals, nursing homes, and other health care facilities are responsible for ensuring that the facility is in compliance with RCRA-C hazardous waste storage and handling requirements. The person responsible for facility compliance ("Compliance Officer" herein) must evaluate, among other things, whether appropriate hazardous waste determinations are being made. As described below, there are situations where pharmaceuticals that may appear to be solid/hazardous wastes are not if they qualify for legitimate "reverse distribution." When the concept is applied to non-pharmaceuticals, it is called, "reverse logistics." Reverse logistics, which can be applied to products as diverse as batteries and household cleansers, is not as well-defined or regulated as reverse distribution of pharmaceuticals, and it should NOT be assumed that whatever is allowed for pharmaceuticals is also allowed for other products. Reverse distribution of pharmaceuticals is well-established and are in part regulated by the U.S. Drug Enforcement Agency (DEA) and the New York State Department of Health Bureau of Narcotics Enforcement (BNE). Reverse logistics is not subject to such regulatory oversight, so there is less of a presumption of control.

Definitions

"Pharmaceutical" - means any chemical product, vaccine or anti-allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or anti-allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical product, vaccine or anti-allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or anti-allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or bio-hazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials. (see Federal Register, December 2, 2008, page 73542, column 1). Note: "Pharmaceutical" includes products that are prescribed by a doctor as well as those available over the counter.

"DEA registrant" - a person registered by DEA (the Federal Drug Enforcement Agency) to possess controlled substances of which they are not the end user. (see DEA's website).

"Reverse Distributor" - a company (generally a DEA registrant) which receives pharmaceuticals from a wholesale or retail seller or a healthcare facility (generally the sender is also a DEA registrant) for the purpose of returning unwanted, unusable, or outdated pharmaceuticals to the manufacturer or the manufacturer's agent; or where necessary, arranging for processing such substances for disposal. (see Federal Register, July 11, 2003, page 41228, column 2)

"Reverse logistics" - The process of planning, implementing, and controlling the efficient, cost effective flow of raw materials, in-process inventory, finished goods and related information from the point of consumption to the point of origin for the purpose of recapturing value or proper disposal. If no goods or materials are being sent "backward", the activity probably is not a reverse logistics activity. Reverse logistics also includes processing returned merchandise due to damage, seasonal inventory, restock, salvage, recalls, and excess inventory. It also includes recycling programs, hazardous material programs, obsolete equipment disposition, and asset recovery. (see Reverse Logistics Magazine, Winter/Spring 2006)

Pharmaceutical Waste

Some unused pharmaceuticals are hazardous wastes when discarded (e.g., Coumadin (warfarin, P001), nicotine (P075; inhalers, patches, gum), lindane (U129), resorcinol (U201), and others). They can be listed as non-acute hazardous waste (the U-list) or acute hazardous waste (the P-list). They can also be hazardous waste by exhibiting one or more of the characteristics: ignitability (e.g., alcohols), corrosivity (e.g., Compound W), reactivity (generally, medicinal nitroglycerine formulations do NOT exhibit this characteristic), or toxicity (e.g., some multivitamin and mineral tablets). Most discarded pharmaceuticals are not hazardous wastes, but many, if not all, can have adverse effects on the environment (see the DEC Public Website, e.g., http://www.dec.ny.gov/chemical/45083.html). It is therefore important for generators of pharmaceutical wastes to manage these materials properly.

Facilities that do not send their pharmaceuticals to a reverse distributor must make a hazardous waste determination and handle any hazardous waste in accordance with all applicable regulations. When pharmaceuticals are removed from inventory, it must be decided whether they can be redirected for use, returned to the manufacturer, or must be disposed of in accordance with all applicable requirements.

EPA Policy

EPA's policy, as stated in the 1981 letter to Merck Sharp and Dohme, supports DEC's assertion that pharmaceuticals do not have to be considered a waste until the decision to discard has been made, and that this decision can be made at a remote location. This letter is posted by EPA as RCRA Online Number 11012.

Reverse Distribution

If the pharmaceuticals leaving the facility continue to be handled as products (i.e., in original packaging and/or tracked by UPC code and maintained in an inventory control system) then they may not yet be considered a waste, and they could instead be sent to a "reverse distributor." These companies determine if the products are eligible for credit from the manufacturer, can be reused/recycled, or are to be returned to the manufacturer under a product stewardship program, or

are to be disposed. In order for the reverse distributor to comply with RCRA regulations, the pharmacy must understand that they are shipping a product to the reverse distributor who in turn chooses to dispose of it. The pharmacy cannot dispose of its pharmaceuticals or its other waste at a reverse distributor. If the facility makes a decision to discard a pharmaceutical, or it is clearly a waste (see below, under "Items Compliance Officers Should Review at…Materials not eligible for reverse distribution"'), it cannot be sent for reverse distribution, and the facility is required to make a hazardous waste determination and dispose of it in accordance with applicable regulations.

For pharmaceuticals, all reverse distributors listed by the NYSDOH can be considered legitimate reverse distributors for the purpose of this information. If the reverse distributor is not on this list, the legitimacy of that facility will need to be determined on a case-by-case basis, with assistance from the NYSDEC. If the originating facility and the reverse distributor are both DEA registrants, controlled substances can be included. Pharmaceuticals may be shipped via a common carrier or a transporter. Although manifesting is not required in these instances, it is strongly recommended that the originating facility and the reverse distributor keep records of all shipments as a best management practice.

Materials shipped to a reverse distributor are considered products and not wastes until they are processed by the reverse distributor. Once the shipment is opened, materials that are being assessed for credit are still considered products until processed. All other materials are considered a waste, and must be managed in accordance with applicable regulations, including requirements for accumulation, storage and disposal. Unopened shipments cannot be "stored in lieu of disposal" so they must be opened and processed in a timely manner (e.g. 3-5 days).

The reverse distributor determines whether the pharmaceutical is eligible for manufacturer's credit. Anything not returned to the manufacturer, recycled, sold or used must then be declared a waste, and a hazardous waste determination must be performed. Hazardous wastes are considered to be generated by the reverse distribution facility at the time of this determination, and must be managed in accordance with 6 NYCRR 370 through 374 and 376 if the reverse distributor is in New York State, or according to the regulatory standards in effect in the state in which the reverse distributor is located.

Allowable storage time for the hazardous wastes depends on the reverse distribution facility's generator status. Assuming that the reverse distributor accepts pharmaceuticals that would be acute hazardous wastes if discarded, they can easily become a Large Quantity Generator by generating at least one kilogram of this type of waste in a calendar month or by storing at least one kilogram (but note that, per DEC policy DSH-HW-03-17, the weight of a functioning container is not included in the total weight of hazardous waste, even for P-listed materials).

Recent and Anticipated EPA Proposals

On December 2, 2008, EPA published a proposed Universal Waste Rule for Pharmaceuticals. The preamble contains a discussion of reverse distribution (EPA's recent interpretation of the subject). EPA has not finalized the Universal Waste Rule for pharmaceuticals, but it is anticipated that EPA will be re-proposing new regulations to address the management of hazardous pharmaceutical wastes at healthcare facilities.

Items Compliance Officers Should Review at:

A. Pharmacies and Healthcare Facilities:

   a. Manufacturer and vendor policies change frequently; what may not be creditable product today, may be creditable the next time the item is processed. NYSDEC concludes that all pharmaceuticals are potentially returnable unless the originating facility has been informed otherwise.

      i. Materials not eligible for reverse distribution:

         1. If a material is clearly a waste, then it is not eligible for reverse distribution and is a solid waste. This would include most broken/spilled products. The generator must determine if it is a hazardous waste and manage it accordingly.

         2. Regulated medical waste cannot be sent for reverse distribution.

   b. Materials that have already been determined to be hazardous wastes by the originating facility must be identified, properly labeled, stored (maintaining appropriate timeframes and quantities for their generator category), transported (including manifests and using Part 364 permitted transporters), and ultimately disposed.

B. Reverse Distributors:

   a. Storage and handling of pharmaceuticals awaiting credit determination and/or transportation to the manufacturer, charity, etc., must reflect their product-like status.

      i. Materials must not be improperly stored or stored in lieu of disposal.

      ii. Incoming items must be promptly processed and recorded in an inventory control system used to account for all pharmaceuticals in the facility.

   b. Regulated medical waste must not be accepted by reverse distributors.

   c. Pharmaceuticals that have been determined to be hazardous waste must be managed according to the requirements applicable to the reverse distributor's generator category. This includes storage areas, labeling, storage times, training, etc.

C. Reverse Logistics Facilities and Facilities Using Reverse Logistics:

   Reverse distribution of non-pharmaceuticals is generally referred to as "reverse logistics." Reverse logistics is not as well established, defined, or controlled as reverse distribution. We expect guidance will evolve over time along with the development of this sector. At this time, we offer the following general guidelines when evaluating a reverse logistics operation. Companies engaged in reverse logistics should be aware of enforcement action taken by EPA.

   - All materials should be in an inventory controls system.
   - The material must not be stored in lieu of or in anticipation of disposal (quantity of material present and how long the material has been stored would be factors in determining this).
   - The material should generally still be in its original, unopened container. However, in some circumstances, material not meeting this description may still be considered a commercial chemical product (instead of a waste).