



Classification of Expired Pharmaceuticals

FACT SHEET 37-041-0411

1. BACKGROUND: Pharmaceutical products are turned in to a reverse distributor from a dispensing facility (clinic, hospital, medical center, etc.) for many reasons: oversupply, recall, damaged shipment, or product expiration. Some returned pharmaceuticals have a monetary value and the pharmaceutical manufacturer may give credit to the facility. Some expired pharmaceuticals are classified as hazardous wastes (HW) under the Resource Conservation and Recovery Act (RCRA) when disposed or intended for disposal.

2. DISPOSAL: The regulatory issue surrounding expired pharmaceutical disposal is who classifies the item as hazardous or non-hazardous waste. The RCRA regulations in 40 CFR262.11 require a generator to determine whether an item is a waste, and if it is a waste, whether it needs to be classified as a HW or a non-hazardous waste. The issue for the military medical department is whether the dispensing facility or the reverse distributor (who might be able to give monetary credit for the value of the items) should make the HW determination. The answer to this question is not uniformly consistent throughout the U.S. The paragraphs below provide state-specific guidance.

3. REGULATORY OPINION: After communicating with all State environmental regulatory offices to obtain State specific guidance on this issue, the following states responded that military dispensing facilities (clinics, hospitals, medical center, etc.) are the waste generators and must make a waste determination of their expired pharmaceuticals:

Connecticut, Kentucky (with the exception for Ireland Hospital), Missouri, New Mexico, New York, Oklahoma, South Carolina, West Virginia.

This means that dispensing facilities located in these states **may not** return expired pharmaceuticals determined to be HW to a reverse distributor.

Expired pharmaceuticals that are determined **not** to be a HW can be returned to a reverse distributor. Dispensing facilities should contact medical logistics or USACHPPM at 1-800-276-MIDI or DSN 584-3651 for assistance in making waste determinations. Once it is determined that an expired pharmaceutical is a HW, it must be turned in through military channels for proper disposal. The installation Environmental Office or the Preventive Medicine Environmental Science Officer may also provide assistance in this matter.

4. ADDITIONAL INFORMATION: Military dispensing facilities in the states listed in Paragraph 3 should consider the value of returning products through reverse distributors **prior to** their expiration date (before they become a waste).

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