Classification of Waste Pharmaceuticals

1. BACKGROUND: Pharmaceutical waste is generated by a dispensing facility (clinics, hospitals, medical centers, etc.) for various reasons: oversupply, manufacturer recall, damaged shipment, or product expiration. Many returned pharmaceuticals have a monetary value and the pharmaceutical manufacturer will give monetary credit to a facility toward future purchases. Under the Resource Conservation and Recovery Act (RCRA), unless an unneeded item is reused or recycled, it is considered waste. Some waste pharmaceuticals are classified as hazardous waste (HW) under RCRA when disposed of or intended for disposal, and waste generators must evaluate this waste to determine whether it is a HW.

2. DISPOSAL: The regulatory issue surrounding pharmaceutical waste disposal is who determines if a waste pharmaceutical is hazardous or nonhazardous waste. The RCRA regulations in 40 CFR 262.11 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 nonhazardous waste. The issue for the military medical department is whether the reverse distributor can make the HW determination as part of the credit eligibility determination at their processing facility or does this need to occur at the medical facility prior to pick up. 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 State environmental regulatory agencies and reviewing State laws for specific requirements, the following states determined that military dispensing facilities are the waste generators and must make a waste determination of their waste pharmaceuticals:

California, Colorado, Connecticut, Kansas, Kentucky (with the exception for Ireland Hospital), Missouri, Oklahoma, South Carolina, and West Virginia.

This means that dispensing facilities located in these states may not return unneeded or waste pharmaceuticals determined to be HW, to a reverse distributor, regardless of expiration date.

The New Mexico Environment Department does not recognize the reverse distribution of expired HW pharmaceuticals. Once a product has expired, it is considered waste and must be disposed of in accordance with HW regulations. Hazardous waste pharmaceuticals may, however, be returned to a reverse distributor prior to their expiration date (e.g., not expired when turned over to the reverse distributor).1

Waste pharmaceuticals that are determined not to be a HW can be returned to a reverse distributor. Once it is determined that a waste pharmaceutical is a HW, it must be turned in through military channels for proper disposal.

Dispensing facilities should contact medical logistics or the Public Health Center’s Waste Management Branch at 410-436-3651 or DSN 584-3651 for assistance in making waste determinations. The Installation Environmental Office or the Preventive Medicine Environmental Science and Engineering Officer may also provide assistance in this matter.

References:
1 New Mexico Environment Department, Fact Sheet for Hazardous Waste Pharmaceuticals, version 5/14/2014.