Classification of Waste Pharmaceuticals

1. BACKGROUND: Pharmaceuticals are turned in to a reverse distributor from a dispensing facility (clinic, hospital, medical center, etc.) for many 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 a waste. Some waste pharmaceuticals are classified as hazardous waste (HW) under RCRA when disposed or intended for disposal and waste generators have to evaluate this waste to determine whether it is a HW.

2. DISPOSAL: The regulatory issue surrounding pharmaceutical waste disposal is who determines is a waste pharmaceutical is hazardous or non-hazardous 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 non-hazardous waste. The issue for the military medical department is whether the dispensing facility or the reverse distributor 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 State environmental regulatory agencies and reviewing State laws for specific requirements, the following states determined that military dispensing facilities (clinics, hospitals, medical center, etc.) 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, New Mexico, New York, Oklahoma, South Carolina, 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.

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 Command's Waste Management Program 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.

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