

FS No. 051-1224

Management of Controlled Substances Pharmaceutical Wastage

The following is based on federal criteria. State or local regulations may be more stringent.

1. BACKGROUND. Questions often arise regarding the proper disposal of U.S. Drug Enforcement Agency (DEA) controlled substances in a clinical setting. There are two categories of DEA controlled substance pharmaceuticals that require disposal: (1) inventory/stock pharmaceuticals, and (2) pharmaceutical wastage. DEA controlled substance inventory (stock) that is out-of-date, damaged, or otherwise unusable or unwanted must be transferred to a DEA authorized registrant, usually the Reverse Distributor through the DoD Pharmaceutical Returns contract.

This fact sheet only addresses the disposal of controlled substance pharmaceutical wastage. Controlled substance pharmaceutical wastage is defined as the remaining or leftover portion of a pharmaceutical after it has been administered to a patient. Controlled substance wastage includes dispensed pills, patches, tablets, and IV solutions. In the past, staff often disposed of these unused amounts by wasting them onto a gauze or flushing them into the sanitary sewer. With increased scrutiny on pharmaceuticals in drinking waters, these practices are no longer recommended and are prohibited in some states and municipalities. **NOTE:** Pharmaceutical wastage that is also an EPA Resource Conservation and Recovery Act (RCRA) hazardous waste must be managed according to Federal, state, and local regulations. Do not commingle these wastes in a controlled substance pharmaceutical wastage container. Keep them separate.

The DEA advocates that pharmaceutical wastage be disposed via a method that precludes diversion (i.e., ensuring that it cannot be used by anyone other than the patient). Commercial companies have developed products intended to address the DEA recommendation for diversion. These products are containers or pouches that are pre-loaded with a binding agent, typically activated charcoal or an expectorant such as ipecac, into which pharmaceutical wastage is discarded.

2. CONCERNS. Prior to purchasing any wastage container, consult with your installation Department of Public Works Environmental Office to determine whether the used containers can be placed in general trash. Most product instructions indicate that these used containers can be discarded into general trash. However, local county regulations may prohibit pharmaceuticals from being landfilled. While the resulting mixture prevents diversion, it is still considered a pharmaceutical and, therefore, may be prohibited from being discarded into the general trash (landfill). Additionally, Defense Logistics Agency Disposition Services still considers this waste stream to be a controlled substance and, therefore, is not authorized to accept pharmaceutical wastage containers for disposal. Further, commercial wastage containers have been shown to have various measures of effectiveness (i.e., binding agent not breaking down). Therefore, it is essential that these devices are reviewed for effectiveness and useability, and that manufacturer's instructions are followed.

This Fact Sheet supersedes APHC FS No. 37-073-0719.

Defense Centers for Public Health—Aberdeen, Environmental Health Sciences Division
8300 Ricketts Point Road, Aberdeen Proving Ground, MD 21010
410-417-1377

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The mention of any non-federal entity and/or its products is for informational purposes only, and is not to be construed or interpreted, in any manner, as federal endorsement of that non-federal entity or its products.

3. DISPOSAL. Any waste stream should be characterized, according to 40 CFR 261, prior to disposal. Consult with your installation Department of Public Works Environmental Office to determine whether the used containers can be placed in general trash.

Stericycle and RxDestroyer offer Pharmaceutical Wastage containers mail-back services. RxDestroyer partners with Rx Waste Systems to offer a nationwide mail-back program for pharmaceutical wastage. Prepaid mail-back boxes can hold up to 55 lb of RxDestroyer bottles. Smaller boxes are also available. Prior to shipment, the RxDestroyer bottles must be solidified with a hardener. The hardener is included when you purchase the RXDestroyer bottles. When using any of the devices listed below, or any other pharmaceutical wastage device, follow the manufacture use, shipment, and disposal instructions. Email confirmation and/or Certificates of Destruction should be requested and retained for your recordkeeping purposes.

There are a few companies that offer services that provide manufacturer products and/or mail-back programs to address DEA’s definition of diversion. The following products and services are provided for informational purposes only. The DCPH-A does not endorse or recommend any commercial products, processes, or services listed below.

Company	Website	Product Description	Mail Back Program
RxDestroyer	https://www.rxdestroyer.com	RxDestroyer All Purpose Liquid 16oz–30-gal container sizes	Yes – disposal thru Rx Waste Systems
Deterra® drug deactivation system	https://deterrasystem.com	Deterra pouch 2 oz–2.5 gal	No
Stryker Cactus Smart Sink®	https://www.stryker.com/content/stryker/us/en/surgical/products/cactus-controlled-substance-waste-management-system/cactus.html	Hold approx. 1.7 liters of solid waste or 3.0 liters of liquid waste	No
Stericycle CsRx Controlled Substance Wastage Program	https://www.stericycle.com/en-us/solutions/regulated-waste-disposal/controlled-substance	CsRx® Controlled Substance Wastage Container	Yes – disposal thru Stericycle

References.

Code of Federal Regulations, “Disposal,” Title 21, Part 1317.

Code of Federal Regulations, “Hazardous Waste Management System: General,” Title 40, Part 260.

Code of Federal Regulations, “Identification and Listing of Hazardous Waste,” Title 40, Part 261.

Code of Federal Regulations, “Standards Applicable to Generators of Hazardous Waste,” Title 40, Part 262.