

APPENDIX G

PHARMACEUTICAL HW MANAGEMENT SOP

THIS PAGE INTENTIONALLY LEFT BLANK

G.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish processes for the proper management of Hazardous Pharmaceutical Waste (HPW) at Naval Construction Battalion Center (NCBC) Gulfport.

G.2 Reference

The Navy Bureau of Medicine and Surgery (BUMED) Pharmaceutical Waste Management Guidelines provide policy and guidelines for military treatment facilities generating HPW to ensure the implementation of 40 Code of Federal Regulations 260-279, United States Environmental Protection Agency Hazardous Waste Management Regulations. The guidelines also provide best management practices (BMPs) for non-HPW.

G.3 Definitions

Resource Conservation and Recovery Act (RCRA) Hazardous Waste (HW): Waste pharmaceuticals that meet the definition of a HW and must be segregated and managed as HW. These include nine antineoplastic agents.

Non-RCRA Antineoplastic HW: The BUMED Environmental Programs Directorate directs medical facilities to manage all antineoplastic agents as HW regardless of whether or not they are technically listed as RCRA antineoplastic HW due to their inherent toxicity. Non-RCRA antineoplastic HW includes all antineoplastic agents used for the treatment of cancer that are not regulated by RCRA.

BMP HW: Pharmaceuticals that meet the criteria in these guidelines should be evaluated for possible management as RCRA HW as a best management practice. NCBC Gulfport Clinic will make that decision with guidance from Naval Hospital (NAVHOSP) Pensacola.

BMP Non-HPW: All other pharmaceutical waste not included in one of the above three definitions. As a BMP, consider managing all pharmaceuticals not managed as HW through incineration at a regulated medical waste or municipal incinerator permitted to accept non-HPW. NCBC Gulfport Clinic will make that decision with guidance from NAVHOSP Pensacola.

Definition of Pharmaceutical Reverse Distribution. Pharmaceutical reverse distribution is the process of returning outdated, expired pharmaceuticals in the original manufacturer's packaging to a third-party company (reverse distributor) for the purpose of obtaining credit for the expired pharmaceuticals from the manufacturer.

G.4 Responsibilities

G.4.1 NCBC Gulfport HW Program Manager (HWPM)

The NCBC Gulfport HWPM shall provide guidance for compliance with this HWMP for HPW Management.

G.4.2 NCBC Gulfport Pharmacist

The NCBC Gulfport Medical Clinic Pharmacist shall manage HPW in accordance with this SOP and the guidance from NAVHOSP Pensacola. Other responsibilities include the following:

- a. Be appointed in writing as the Pharmaceutical Waste Officer;
- b. Receive training for HPW;
- c. Identify and label all received drugs that are potentially HPW including antineoplastic pharmaceuticals;
- d. Provide training to pharmacy personnel regarding HPW.

G.5 Training

Personnel handling Pharmaceutical Waste shall receive HPW-specific training per the BUMED Pharmaceutical Waste Management Guidelines. Training subjects shall include profiling, labeling, transporting, and disposing HPW.

G.6 General Pharmaceutical Waste Management

The Pharmaceutical Waste Management Guidelines contain specific requirements for managing HPW. The NAVHOSP Pensacola Commanding Officer is responsible for compliance at NCBC Gulfport Medical Clinic. The HPW typically handled at NCBC Gulfport Medical Clinic is listed in Table G-1. Additional guidance for HPW may be available from NAVHOSP Pensacola Environmental Office.

Table G-1: NCBC Gulfport Hazardous Pharmaceutical Waste

Waste Code	Pharmaceutical
P042	Epinephrine
P075	Nicotine, & salts
P081	Nitroglycerine (R)
P001	Warfarine & salts (>0.3%)
U205	Selenium sulfide

G.6.1 Pharmaceutical Reverse Distributor

The NCBC Gulfport Medical Clinic Pharmacy uses the pharmaceutical reverse distributor to return outdated product to the manufacturer or its designated agent. Credit for the return is issued to the pharmacy.

G.6.1.1 Limitation of Pharmaceutical Reverse Distribution

The pharmaceutical reverse distributor may not be used for waste disposal of pharmaceuticals that have been deemed to be waste or waste-like. Opened vials, unused IVs solutions, repackaged tablets and capsules, and other obviously “waste-like” items must be managed as waste and not sent through reverse distribution. HPW must be managed by the originator/generator, and the regulatory requirements must be maintained.

G.6.1.2 Exception for Controlled Substances

Controlled substances are regulated by the Drug Enforcement Agency (DEA). Schedule II through V controlled substances may be disposed through the reverse distributors. Some HW transporters and Transfer, Storage, and disposal Facilities have also obtained DEA registration as reverse distributors and provide appropriate disposal options for hazardous controlled substances.

Expired products in the original manufacturer’s packaging that are controlled substances should routinely be returned for possible credit through traditional reverse distributors, again as a transfer between registrants.

G.6.2 HPW Storage

The NCBC Gulfport Medical Clinic Pharmacy shall store HPW in a structurally sound containers in good condition and compatible with the HPW (generally a 1-gallon plastic container). Containers shall be closed except when adding or removing the HPW.

G.6.3 Labeling

The HPW container shall be labeled with the words “Hazardous Waste” or with a HW label (see Figure G-1). Shelves containing pharmaceuticals that would become HPW if dropped or spilled shall also be labeled per the BUMED guidance.

G.6.4 Pick Ups

The NCBC Gulfport Medical Clinic Pharmacist shall contact the NCBC Gulfport HWPM (228-323-1654) or the HW Handler (228-323-9877) to arrange for the removal of HPW.

G.7 Spills and Releases

In the event of a release/spill of HPW to the environment, dial “911” immediately from any phone, and state that the spill is at NCBC Gulfport. Afterwards, report the release to the NCBC Gulfport HWPM (228-323-1654).

The image shows a yellow rectangular label with a red border featuring a diamond pattern. The text on the label is as follows:

HAZARDOUS WASTE

FEDERAL LAWS PROHIBIT IMPROPER DISPOSAL

**IF FOUND, CONTACT THE NEAREST POLICE OR
PUBLIC SAFETY AUTHORITY OR THE
U.S. ENVIRONMENTAL PROTECTION AGENCY**

GENERATOR INFORMATION:

NAME: _____

ADDRESS: _____

CITY _____ STATE _____ ZIP _____

EPA ID NO. _____ EPA WASTE NO. _____

ACCUMULATION START DATE _____ MANIFEST TRACKING NO. _____

[_____]
[_____]
[_____]

D.O.T. PROPER SHIPPING NAME AND UN OR NA NO. WITH PREFIX

HANDLE WITH CARE!

Figure G-1: Sample Hazardous Waste Label (Yellow)