



DEPARTMENT OF THE NAVY  
BUREAU OF MEDICINE AND SURGERY  
7700 ARLINGTON BOULEVARD  
FALLS CHURCH, VA 22042

IN REPLY REFER TO  
BUMEDINST 6570.4  
BUMED-M3/B2  
9 Mar 2017

BUMED INSTRUCTION 6570.4

From: Chief, Bureau of Medicine and Surgery

Subj: IMPLEMENTATION AND MANAGEMENT OF PRESCRIPTION DRUG TAKE  
BACK PROGRAM

Ref: (a) Presidential Executive Action, DoD-VA Joint Fact Sheet, August 26, 2014  
(b) DODIG-2014-040  
(c) DoD Instruction 6025.25 of 26 April 2016  
(d) Department of Justice, Drug Enforcement Administration, Final Rule on Disposal of  
Controlled Substances, September 9, 2014  
(e) United States Environmental Protection Agency, Household Hazardous Waste  
Exemption for Pharmaceuticals Collected via DEA Approved Take Back or  
Collection Programs Memo, October 2, 2015 (RCRA Online #14853)

1. Purpose. To provide policy and guidance on the implementation of medical treatment facilities (MTF) Prescription Drug Take Back (DTB) Programs per references (a) through (c).

2. Scope. This instruction applies to all Navy MTFs with an on-site pharmacy located in the United States or a U.S. Customs Territory. MTFs Outside the Continental United States and not in a U.S. Territory are not required to implement a DTB Program and must follow applicable laws and regulations of host nations.

3. Background

a. Reference (d) established the regulations allowing for new collection options for Department of Defense MTFs. The Drug Enforcement Administration (DEA) regulations allow those MTFs with an on-site pharmacy holding a DEA registration with added collector status to collect controlled substances listed in Schedules II-V of reference (d) from patients. The collection can be done on-site into installed collection receptacle(s) for controlled, non-controlled, and over-the-counter medications. Also under the regulations, MTFs can partner with law enforcement to hold a collection take back event. Further, MTFs can partner with a collector that conducts mail-back programs to offer military beneficiaries mail-back collection containers (i.e., envelopes or small volume boxes).

b. The Environmental Protection Agency (EPA) has determined that the pharmaceuticals collected through beneficiary DTB programs qualify for classification as household hazardous waste for the purposes of disposal. This determination exempts the collected contents from Federal regulation as potential hazardous waste provided the contents and their containers are managed within the requirements of the household hazardous exemption. Although this

exemption has been granted by EPA, state and local environmental agencies often have regulatory primacy and may establish more restrictive requirements. MTFs establishing a DTB program must evaluate the potential restrictions and associated management requirements before implementing the local DTB program.

c. MTFs are not authorized to conduct a self-mail back program because they do not have the requisite on-site destruction capability (i.e., a permitted incinerator). MTFs instead can disseminate an empty patient mail back collection container, purchased by the MTF from a Defense Logistics Agency (DLA) approved collection vendor, to a patient if the patient is located inside the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico). The patient is then responsible for mailing the full container directly to a DLA approved collection vendor for destruction. Patient mail-back collection containers must only be mailed from within the customs territory of the United States to ensure compliance with import laws.

4. Policy. Navy Medicine MTF commanding officers and officers-in-charge with an on-site pharmacy in the United States or a U.S. Customs Territory will implement, or participate in, a prescription DTB program, which may include one or more of the following components: take back events, installed collection receptacle(s), and/or patient mail-back containers.

5. Responsibilities

a. Navy Medicine East and West Commanders, must provide oversight in the execution of the DTB program to ensure compliance with applicable laws and regulations governing the program.

b. Medical Inspector General (M001IG) must assess the DTB Program as part of the Bureau of Medicine and Surgery's Command Inspection Program.

c. MTF commanding officers must execute the DTB program, ensuring their commands are in compliance with applicable laws and regulations governing the program.

d. Navy Medicine MTF Environmental Program Manager (EPM) must:

(1) Ensure environmental compliance with Federal, state, local laws and regulations, and applicable Navy instructions for implementation and maintenance of the prescription DTB program.

(2) Monitor changes with regard to environmental compliance in Federal, state, local laws and regulations, and applicable Navy instructions for implementation and maintenance of the prescription DTB program.

(3) Ensure environmental funds approved for disposal of hazardous and medical waste generated within the MTF are not utilized for MTF prescription DTB programs, take back events, installed collection receptacles, inner liners, patient mail-back containers, or services to dispose of the drugs collected.

(4) Ensure drugs collected as part of a take back program do not comingle with existing MTF-generated medical waste, nor dispose of them using existing MTF medical waste disposal contracts.

e. Navy Medicine MTF Facility Managers must coordinate with pharmacy personnel and EPM to install the drug take back collection receptacles per reference (e), to include proper signage. Collection receptacles must be procured from a DLA approved collection vendor.

(1) Installed collection receptacle(s) must be placed in the interior of the physical premises at the MTFs DEA-registered location. They cannot be placed exterior to the MTF.

(2) Installed collection receptacle(s) must be located in an area of the MTF regularly monitored by MTF employees, and cannot be located in the proximity of any area where emergency or urgent care is provided. Constant video surveillance of the collection receptacle, if available, is recommended.

(3) Installed collection receptacle(s) must be securely fastened to a permanent structure to prevent removal.

(4) Installed collection receptacle(s) must have an opening for the deposit of controlled substances, but the substances cannot be retrievable.

(5) Installed collection receptacle(s) must be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed).

(6) MTF may choose to implement additional security measures beyond the above mentioned requirements and measures to ensure only eligible beneficiaries utilize the drug take back program and not the general public, as long as it is in compliance with all Federal, state, and local laws and regulations.

f. Navy Medicine MTF Security Officer/Physical Security Officer must:

(1) Coordinate with the local Provost Marshall or Installation Security Officer to ensure presence of a military law enforcement member to support drug take back events, if such events are planned by the MTF. The presence of an installed collection receptacle at the take back event site does not absolve the need for law enforcement presence at the event.

(2) Provide a staff member to serve as a witness during the removal and installation of collection receptacle inner liner.

g. Navy Medicine MTF Public Affairs Officer must provide educational materials and communicate reminders to eligible beneficiaries regarding proper medication disposal. Communication with beneficiaries should focus on informing them that the MTF is now offering collection receptacles and/or patient mail-back containers at certain pharmacies for the purpose of returning their unwanted, unused, and expired medication for disposal. The Food and Drug Administration guidance for safely disposing unused drugs may be used as a resource, available at: <http://www.fda.gov/forconsumers/consumerupdates/ucm101653.htm>.

h. Navy Medicine MTF Pharmacies must:

(1) Determine appropriate DTB service options (i.e., collection receptacles and/or mail-back containers) to offer to beneficiaries. MTF may provide both options but are not required to do so.

(2) Coordinate with EPM, facility, and security personnel to ensure compliance with DEA and EPA regulations and applicable Federal, state, and local laws for the service option(s) provided.

(3) Modify registration with the DEA to become a collector, if collection receptacles service option is offered. To modify existing registration, the pharmacy will submit a written request to the Registration Unit, DEA, or submit online at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov). The request must contain:

(a) the registrant's name, address, and registration number as printed on the certificate of registration;

(b) the method(s) of collection the registrant intends to conduct (e.g., collection receptacle); and,

(c) the registrant's signature. DEA registration as a collector is subject to renewal, which must be maintained while an installed collection receptacle is in use. If the MTF removes or discontinues use of its installed collection receptacle, then the MTF must notify the DEA.

(4) Train and educate all pharmacy staff on all requirements for the management of collection receptacles and the usage of patient mail back containers, DTB options at the MTF, and beneficiary education prior to providing them with a mail-back container.

(5) Coordinate with the MTF Security Manager to ensure a staff member from security is available to serve as a witness during the removal and installation of the collection receptacle inner liner by a pharmacy staff member.

(6) Ensure installable collection receptacles, inner liners, patient mail-back containers, and destruction services are purchased from DLA approved collection vendors and meets the minimum specifications in references (d) and (e).

(7) Ensure collection receptacles, patient mail-back containers, or DTB events are only for beneficiaries to dispose of personal unwanted, unused, and expired medications. The DTB events may not be used to dispose of wastes generated by the MTF or MTF pharmacy.

(8) Provide educational materials and clear signage to beneficiaries to ensure collection receptacles, patient mail-back containers, or DTB events may not be used for the collection of sharps (e.g., needles or syringes), aerosols, inhalers, illegal drugs, chemotherapy or radioactive substances, or other hazardous substances (e.g., batteries). Restrictions for use of the containers must be clearly communicated to beneficiaries as commingling of these wastes may result in regulatory violations (e.g., DEA, EPA) and loss of regulatory exemption status for the DTB program.

(9) Ensure timely replacement of the inner liner when full, or at the minimum 3 months from the date of installed, whichever is sooner.

(10) Ensure handling of collection receptacle and inner liner meets DEA and Department of Transportation requirements.

(a) Ensure key control to the collection receptacle will be maintained at all times by pharmacy staff.

(b) Ensure both the installation and the removal of an inner liner of an installed collection receptacle are performed by at least two MTF employees. The two MTF employees must consist of one each from pharmacy and security departments.

(c) Ensure once removed, an inner liner of an installed collection receptacle is immediately sealed by two MTF employees and cannot be later re-opened, x-rayed, analyzed, or otherwise penetrated by MTF personnel.

(d) Ensure deposits made by ultimate users into an installed collection receptacle are not removed from the container and cannot be counted, sorted, or otherwise individually handled by MTF personnel.

(e) Ensure ultimate users cannot transfer pharmaceutical controlled substances to MTF personnel for MTF personnel to then deposit into the installed collection receptacle.

(f) Ensure deposits made by ultimate users into an installed collection receptacle are not commingled with the MTFs generated medical or pharmaceutical waste. MTF personnel cannot dispose of any controlled substances in inventory or stock into the installed collection receptacle.

(g) Ensure temporarily stored filled and sealed inner liners from an installed collection receptacle are stored only at their primary DEA-registered location in either a securely locked, substantially constructed cabinet, or in a securely locked room with controlled access. MTFs cannot relocate filled and sealed inner liners to an off-site location for storage.

(h) Ensure filled and sealed inner liners removed from an installed collection receptacle are picked up at the MTFs DEA-registered location by either a DLA approved collection vendor, or by a common or contract carrier picking up on behalf of a DLA approved collection vendor. Two MTF employees must witness the transfer of the sealed inner liners to a DLA approved collection vendor.

(11) Ensure maintenance of all records and inventories and file the reports required of collectors.

(a) Record and date each unused inner liner for an installed collection receptacle with its unique identification number and its size (e.g., 18-gallon, 38-gallon, etc.).

(b) Record and date each inner liner for an installed collection receptacle with the address of the location where each inner liner is installed, the unique identification number and size of each installed inner liner, the registration number of the collector, and the names and signatures of the two MTF employees that witnessed each installation.

(c) Record and date each inner liner for an installed collection receptacle that is removed and sealed from the collection receptacle with the address of the location from which each inner liner is removed, the unique identification number and size of each inner liner, the registration number of the collector, and the names and signatures of the two MTF employees that witnessed each removal.

(d) Record and date each sealed inner liner removed from an installed collection receptacle that is transferred to storage, the unique identification number and size of each sealed inner liner stored, and the names and signatures of the two MTF employees that transferred each sealed inner liner to storage.

(e) Record and date each sealed inner liner removed from an installed collection receptacle that is transferred to the vendor for destruction, the address and registration number of the vendor to whom each sealed inner liner was transferred, the unique identification number and the size of each sealed inner liner transferred, and the names and signatures of the two MTF employees that transferred each sealed inner liner to the vendor. If a common or contract carrier is used to ship the sealed inner liner to the vendor, then also include the name of the carrier, name or employee identification number of the carrier's employee taking possession, and the tracking number assigned by the carrier to the shipment.

6. Records Management. Records created as a result of this instruction, regardless of media and format, must be managed per SECNAV M-5210.1 of January 2012.

7. Review and Effective Date. Per OPNAVINST 5215.17A, the Bureau of Medicine and Surgery will review this instruction annually on the anniversary of its effective date to ensure applicability, currency, and consistency with Federal, Department of Defense, Secretary of the Navy, and statutory authority using OPNAV 5215/40, Review of Instruction. This instruction will automatically expire 5 years after the effective date unless reissued or canceled prior to 5-year anniversary date, or an extension has been granted.
8. Information Management Control. The reports required in paragraph 11 are exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7j.



C. FORREST FAISON III

Releasability and distribution:

This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site at: <http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx>