



Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6025.25
February 20, 2018

CSD/J-3

SUBJECT: Military Health System (MHS) Drug Take Back (DTB) Program

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (g):

a. Describes procedures for MHS organizations to offer beneficiaries the option of returning their controlled and non-controlled prescriptions and over-the-counter medications for disposal through a DTB program. The DTB program will provide an environmentally safe method for beneficiaries to properly and safely remove unused and expired medications from circulation, including medications that can be used for suicide or suicide attempts and have the potential for misuse, diversion, or accidental poisoning.

b. Details the tasks and procedures necessary to ensure successful implementation of the MHS DTB program within military Medical Treatment Facilities (MTFs).

2. APPLICABILITY. This DHA-PI applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this DHA-PI as the “DoD Components”).

3. POLICY IMPLEMENTATION. It is the Defense Health Agency’s (DHA) instruction, pursuant to Reference (d), that a DTB program will be provided for beneficiaries to properly and safely dispose of their unused or expired controlled and non-controlled prescription and over-the-counter medications. The DTB program will be provided by Service MTFs, where allowed by Federal, State, and Local laws and regulations, in the Continental United States, Alaska, Hawaii, and Puerto Rico. In addition to providing beneficiaries with information on proper and safe disposal of unused and expired medications, the Services will establish and implement a DTB program at the MTFs in accordance with this procedure in order to meet all applicable Federal,

State, and Local laws and regulations (e.g., References (e) and (f)), State and Local environmental agencies, applicable transportation authorities (e.g., United States Postal Service, Department of Transportation, etc.). Beneficiaries may only use and mail back pre-paid/pre-labeled envelopes provided by the MTF for return to the contracted vendor from within the customs territory of the United States to ensure compliance with import laws. There will be no change to the MTFs located outside the legal jurisdiction of the United States. These MTFs will continue to operate under the applicable medication disposal regulations of the host nation.

4. RESPONSIBILITIES

a. DIRECTOR, DHA. The Director, DHA, will oversee the measures and metrics developed by DHA's Healthcare Operations Directorate to assess the utilization of the DTB program.

b. SURGEONS GENERAL OF THE MILITARY DEPARTMENTS. The Surgeons General of the Military Departments will:

(1) Ensure the DTB program meets all applicable Federal, State, Local laws, and regulations (e.g., environmental compliance or transportation) that may exceed those referenced in this DHA-PI.

(2) Train all providers (including Patient-Centered Medical Home providers) on DTB.

(3) Provide educational materials for beneficiaries at the MTFs and assess the utilization of the DTB program.

c. CHIEF, PHARMACY DIVISION. The Chief, Pharmacy Operations Division, will assess the effectiveness of the DTB program.


d. CHIEF, COMMUNICATIONS DIVISION. The Chief, Communications Division, will develop educational and promotional materials for the DTB program.

5. PROCEDURES. See Enclosure 2.

6. RELEASABILITY. **Cleared for public release.** This DHA-PI is available on the Internet from the DHA SharePoint site at: <http://www.health.mil/dhapublications>.

7. EFFECTIVE DATE. This DHA-PI:

- a. Is effective upon signature.
- b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with DHA-PI 5025.01 (Reference (c)).



R. C. BONO
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Director

Enclosures

1. References
2. Procedures

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System” August 21, 2015
- (d) DoD Instruction 6025.25, “Drug Take Back Program” April 26, 2016
- (e) Department of Justice, Drug Enforcement Administration (DEA), Final Rule on Disposal of Controlled Substances, September 9, 2014
- (f) The U.S. Environmental Protection Agency Memorandum, Household Hazardous Waste Exemption for Pharmaceuticals Collected via DEA Approved Take-back or Collection Programs, October 2, 2015
- (g) Title 21, Code of Federal Regulations, Section 1301.13(j), and Sections 1308.11–1308.15

ENCLOSURE 2

PROCEDURES

1. OVERVIEW. A DTB program will be offered to TRICARE beneficiaries to properly and safely dispose of their unwanted controlled and non-controlled prescription and over-the-counter medications. The DTB program will be provided by Service MTFs, where allowed by Federal, State, and Local laws and regulations, in the Continental United States, Alaska, Hawaii, and Puerto Rico. This enclosure details the tasks and procedures to be completed by MTFs to ensure a successful DTB program.

2. PRE-IMPLEMENTATION ACTIVITIES. Describes activities the MTFs should accomplish prior to establishing a DTB program.

a. Site Identification. In compliance with all Federal, State, and Local laws and regulations (e.g., References (e) and (f)), State and Local environmental agencies and applicable transportation authorities (e.g., United States Postal Service, Department of Transportation, etc.) identify sites that may use collection receptacles and/or sites which may use mail-back envelopes. MTFs are not required to have both collection receptacles and mail-back envelopes.

(1) The U.S. 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 (see Reference (f)). This determination exempts the collected contents from Federal regulation as potential hazardous waste, provided the contents and their containers are managed within the requirements for such an exemption. Although this exemption has been granted by the EPA, State, and Local environmental agencies often have regulatory primacy and may establish more restrictive requirements.

(2) Registrants establishing a DTB program must evaluate the potential restrictions and associated management requirements before implementing the local DTB program. Consultation with local environmental compliance and law enforcement staff is recommended.

b. Registration Modification. Each hospital/clinic with an on-site pharmacy currently registered with the Drug Enforcement Administration (DEA) and identified by the MTF to have a collection receptacle is required to modify their registration with the DEA to become a collector. Registration modification to conduct a mail-back program is only intended for entities receiving mail-back envelopes returned by patients and destroying them on-site. MTFs that provide mail-back envelopes to beneficiaries, but do not receive them back should not register as conducting a mail-back program. Registration modification is only necessary if the MTF intends to have a collection receptacle.

(1) To modify existing registration, the pharmacy will submit a written request to the Registration Unit, DEA, or submit online at www.DEAdiversion.usdoj.gov.

(2) The request will 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; and,

(c) A signature in accordance with Section 1301.13(j) of Reference (g).

c. Collection Methods. Collection receptacles are placed at eligible MTFs and/or envelopes made available to beneficiaries, when requested. If the mail-back envelope option is used, prior to providing the envelope, the beneficiary should be educated on proper medication disposal and prompt deposit of the envelope.

(1) Beneficiaries must place their own unwanted, unused, and expired medications into the collection receptacles themselves. Pharmacy employees/providers/clinics are not authorized to take medications from beneficiaries and deposit them into the collection receptacles. Similarly, with mail-back envelopes, beneficiaries must place their own medications into the envelopes, seal them, and deposit into a U.S. mailbox, or return to the indicated carrier per the envelopes' instruction (e.g., United Parcel Service). MTFs may choose to install multiple collection receptacles.

(2) Collection receptacles and mail-back envelopes are only for beneficiaries to dispose of personal unwanted, unused, and expired medications and cannot be used to dispose of pharmacies' drug inventory or other pharmaceutical wastes generated within the MTF.

(3) Collection receptacles and mail-back envelopes 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 comingling of these wastes may result in regulatory violations (e.g., DEA, EPA) and loss of regulatory exemption status for the DTB program.

d. Placement of Collection Receptacles. The placement of the collection receptacles at MTFs should be determined by the respective Service in accordance with the DEA's requirements (Reference (e)). The following are requirements set forth by the DEA Final Rule:

(1) Must be located in an area that is regularly monitored by employees;

(2) Cannot be where emergency or urgent care is provided; and,

(3) Cannot use the receptacles for the disposal of unused controlled substances in inventory.

(4) Collection Receptacle Requirements:

- (a) Securely placed and maintained;
- (b) Securely fastened within and to permanent structure;
- (c) Must have an opening for the deposit of controlled substances, but the substances cannot be retrievable; and,
- (d) The small opening of the outer container of the collection receptacle will be locked or made otherwise inaccessible to the public when an employee is not present, e.g., when the pharmacy is closed.

(5) Inner Liner Requirements:

- (a) Removable and sealable;
- (b) Waterproof, tamper evident, and tear resistant;
- (c) Contents cannot be visible;
- (d) Size of liner must be marked on the outside of the liner;
- (e) The liner must be serialized for tracking purposes;
- (f) Pharmacy must retain disposal log of serialized containers;
- (g) Only employees of the collector may have access to the liners;
- (h) Must be removed by two employees; and,
- (i) Contents cannot be counted, inventoried, or handled.

e. Security. The Services may choose to implement additional security measures beyond the abovementioned requirements and measures to ensure only beneficiaries utilize the DTB program and not the general public, as long as it is in compliance with all applicable Federal, State, and Local laws and regulations.

f. Funding. Implementation and maintenance costs are associated with the execution of the DTB program. The DTB program requires the purchase of collection receptacles, liners, and the disposal of returned drugs. This is a Service-level responsibility, and funding for the program will be provided by the respective Service.

g. Vendor. The MTFs should use the approved vendor indicated by their respective Service for disposal of unwanted, unused, and expired medication. This vendor will:

- (1) Have been appropriately vetted for compliance with regulations associated with the services provided (e.g., compliance with transportation and environmental regulations) by the

contracting official, with assistance as requested by appropriate subject matter experts, prior to contract award.

(2) Provide services, products, and support for DTB programs.

(3) Provide mail-back envelopes, collection receptacles, and the inner liners with the respective pre-labeled and marked shipping containers at request and on a frequency agreed upon by the MTF and the vendor.

h. Staff Training. Pharmacy staff should be trained and educated on all requirements for the management of collection receptacles and the usage of mail-back envelopes, the available DTB options at MTFs, and beneficiary education prior to providing them with a mail-back envelope.

3. IMPLEMENTATION OF DTB. MTF pharmacies with collection receptacles should allow beneficiaries to deposit their unused, unwanted, and expired medications into the receptacle for the purpose of disposal. Mail-back envelopes can be provided to beneficiaries after they are educated on the importance of medication disposal. In addition to promotional materials being placed throughout the MTFs, when possible, and when requested, pharmacy personnel should educate beneficiaries on alternative take back methods, specifically addressing how to dispose of unwanted, unused, and expired medications outside of the MTF DTB program. This will empower the beneficiary and provide them with an alternative to the MTFs.

Materials used to educate beneficiaries and promote the program will be developed by the DHA, in conjunction with the Services, to ensure a standard message. The DHA will assess the effectiveness of the DTB program using established metrics.

a. Communication Activities. The MTF pharmacies should provide patient and provider education after collection receptacles have been placed at the MTF pharmacies, but no later than 30 business days after installation occurs. Provider education materials will inform providers that the DTB program is meant for beneficiaries and not the general public.

(1) Communications with beneficiaries should focus on informing them that MTFs are now offering collection receptacles and/or mail-back envelopes at certain pharmacies for beneficiaries to return their unwanted, unused, and expired medication for the purpose of disposal. A “Coming Soon” announcement of this program to beneficiaries should occur prior to the implementation; however, details of the program should be shared with beneficiaries no later than 30 business days after the program starts and the collection receptacles are installed.

(2) Local outreach may include posting flyers in MTF pharmacies and websites alerting beneficiaries of the DTB program, using a graphic on monitors in pharmacy waiting areas, and/or throughout MTFs. The DTB information and templates will be developed and provided to the Services by the DHA along with some suggestions that may be used to distribute the information locally.

b. Communications Plan. The Communications Division will develop and implement a communications plan in concert with the DHA Pharmacy Division, the Services' Medical Public Affairs Offices, and the vendor(s) to notify beneficiaries about the MHS DTB program. The communications plan will focus on the initial launch to build awareness and have a continuing component to help drive participation in MHS DTB activities. In addition, educational information on medication disposal in compliance with existing DEA, U.S. Food and Drug Administration, and EPA regulations will be provided. Key audiences include all beneficiary populations, military and veteran service organizations, MTF providers, pharmacists and other staff, TRICARE network pharmacies and providers, and other interested stakeholders. Tactics to support the DTB program will be developed using industry best practices along with input from the Services' Medical Public Affairs Offices. Materials will be adjusted, maintained, and shared as appropriate.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

DEA	Drug Enforcement Administration
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DTB	Drug Take Back
EPA	U.S. Environmental Protection Agency
MHS	Military Health System
MTF	Medical Treatment Facility

PART II. DEFINITIONS

These terms and their definitions are for the purpose of this DHA-PI.

beneficiary. A person eligible for health care services under the DoD health care program (TRICARE).

collection method. An established procedure for the return of medications for the purpose of disposal.

controlled medications. Drugs and other substances that are considered controlled substances under the Controlled Substances Act. A complete list is provided in Sections 1308.11–1308.15 of Reference (g).

non-controlled medications. Pharmaceutical preparations that can only be obtained through a medical practitioner's prescription and dispensed by a pharmacist, but are not considered controlled substances under the Controlled Substances Act.

over-the-counter medications. Medications available without a prescription.

prescription. An instruction written by medical practitioner to pharmacist to dispense a pharmaceutical preparation.

Services. Refers to Army, Navy, and Air Force.

take back method. An established procedure for the return of medications for the purpose of disposal.