



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

DHA-IPM 16-001
June 13, 2016

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS)
DIRECTOR OF THE JOINT STAFF
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH SERVICES POLICY AND OVERSIGHT)

SUBJECT: Interim Procedures Memorandum 16-001, Military Health System (MHS) Drug Take Back (DTB) Program

References: See Attachment 1

Purpose. This Defense Health Agency Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b) and in accordance with the guidance of References (c) through (g):

- 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 a method for beneficiaries to properly and safely remove unused and expired medications from circulation that can be used for suicide or suicide attempts and have the potential for misuse, diversion or accidental poisoning. This DHA-IPM details the tasks and procedures necessary to ensure successful implementation of the MHS DTB program within military medical treatment facilities (MTFs).
- This IPM is effective immediately. It will be incorporated into the future DHA Procedural Instruction 6025.25. This DHA-IPM will expire effective 12 months from the date of issue.

Applicability. This DHA-IPM 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 DoD Office of the Inspector General, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.

Policy Implementation. In accordance with Reference (d), 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 applicable Federal, State, and local laws and

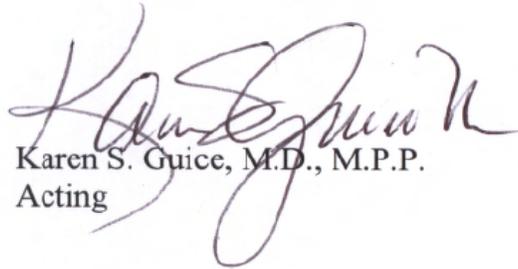
regulations, in the continental United States, Alaska, Hawaii, and Puerto Rico. In addition to providing beneficiaries with information on proper and safe disposal of unused and expired medications, the Services will establish and implement a DTB program at the MTFs in accordance with this procedure 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 of the continental United States (OCONUS). OCONUS MTFs will continue to operate under the applicable medication disposal regulations of the host nation.

Responsibilities.

- Director, DHA:
 - Oversee the development of measures and metrics by the DHA's Healthcare Operations Directorate for the DTB program;
 - Assess the utilization of the DTB program;
 - Oversee the development and implementation of a communications plan by DHA's Strategic Communications Division to inform all beneficiaries of the new program and its benefits; and
 - Develop a customizable promotional/educational materials package for the MTFs.
- The Surgeons General of the Military Departments:
 - Prior to implementation, review plans to ensure the DTB program meets all Federal, State, and local laws and regulations (e.g., environmental, compliance, or transportation) that may exceed those referenced in this DHA-IPM;
 - Train all providers (including Patient Centered Medical Home providers) on DTB, and provide educational materials for beneficiaries at the MTFs; and
 - Assess the utilization of the DTB program.

Procedures. See Attachment 2

Releasability. **Cleared for public release.** This DHA-IPM is available on the Internet from the DHA Web site at <http://www.health.mil/dhapublications>.



Karen S. Guice, M.D., M.P.P.
Acting

Attachments:

As stated

cc:

Surgeon General of the Army

Surgeon General of the Navy

Surgeon General of the Air Force

Medical Officer of the Marine Corps

Joint Staff Surgeon

Director of Health, Safety and Work-Life, U.S. Coast Guard

Surgeon General of the National Guard Bureau

Director, National Capital Region Medical Directorate

ATTACHMENT 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
- (f) The U.S. Environmental Protection Agency (EPA), Household Hazardous Waste Exemption for Pharmaceuticals Collected via DEA Approved Take Back or Collection Programs Memorandum, October 2, 2015
- (g) Title 21, Code of Federal Regulations, Section 1301.13(j), and Sections 1308.11–1308.15

ATTACHMENT 2

MHS DTB PROCEDURAL GUIDANCE

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 applicable Federal, State, and Local laws and regulations, in the Continental United States, Alaska, Hawaii, and Puerto Rico. This attachment details the tasks and procedures to be completed by MTFs to ensure successful implementation of the DTB program.

2. TIMELINE

a. Pre-implementation activities should begin within 90 days after the issuance of the DHA-IPM on the MHS DTB Program.

b. Two weeks prior to implementation, the MTFs should make a “Coming Soon” announcement to beneficiaries regarding the new DTB program at the MTFs and immediately prior to implementation, share complete details for use of the DTB program with beneficiaries.

c. Implementation should begin once mail-back envelopes are received or collection boxes are installed. DTB events, which are optional, should be coordinated with federal law enforcement and the proper command(s) and must meet all applicable Federal, State, and Local 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.).

d. One year after implementation, the DHA will assess the effectiveness of the DTB program using established metrics.

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

a. Assessment and Survey. If not completed prior to the issuance of the IPM, the Services should survey the military pharmacy leadership and personnel in the field to solicit pharmacy operational input on the demand for this service, and determine how to best serve beneficiaries, the community, and the commands supported.

b. Site Identification. In compliance with 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.), 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 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 staff is recommended.

c. Registration Modification. Each hospital/clinic with an on-site pharmacy currently registered with the DEA and identified by the MTF to have a collection receptacle should modify their registration with the DEA to become a collector.

(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 shall contain: (i) The registrant's name, address, and registration number as printed on the certificate of registration; (ii) The method(s) of collection the registrant intends to conduct (collection receptacle and/or mail-back program); and, (iii) A signature in accordance with Section 1301.13(j) of Reference (g).

d. 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 must be educated on proper medication disposal and prompt deposit of the envelope. During the first year of the DTB program, the Services may opt to sponsor federal law enforcement hosted DTB events.

(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., UPS). MTFs may choose to install multiple collection receptacles and sponsor federal law enforcement hosted DTB events.

(2) Collection receptacles, mail-back envelopes, or DTB events 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, mail-back envelopes, 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 comingling of these wastes may

result in regulatory violations (e.g., DEA, EPA) and loss of regulatory exemption status for the DTB program.

e. 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)).

(1) The following are requirements set forth by the DEA Final Rule:

- (a) Must be located in an area that is regularly monitored by employees;
- (b) Cannot be where emergency or urgent care is provided; and
- (c) Cannot use the receptacles for the disposal of unused controlled substances in inventory.

(2) Collection Receptacle Requirements:

- (a) Securely placed and maintained;
- (b) Securely fastened 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 shall be locked or made otherwise inaccessible to the public when an employee is not present, e.g. when the pharmacy is closed.

(3) 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. The Services may choose to implement additional security measures beyond the above mentioned 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 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 will use the approved vendor indicated by their respective Service for disposal of unwanted, unused, and expired medication. This vendor will 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. The vendor will provide services, products, and support for DTB programs. The vendor will provide mail-back envelopes, liners for events, collection receptacles, and the inner liners at request and on a frequency agreed upon by the MTF and the vendor.

h. Staff Training. Pharmacy staff will 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.

4. 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. If deemed beneficial, MTFs should sponsor federal law enforcement hosted DTB events.

In addition to promotional materials being placed throughout the MTFs, when possible, and when requested, pharmacy personnel will 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 to ensure a standard message.

a. Communication Activities. The MTF pharmacies should begin patient and provider education after collection receptacles have been placed at the MTF pharmacies, but no later than 30 business days after installation occurs. Education on DTB events should occur 30 days prior to the anticipation of the first DTB event. Providers will be made aware that the DTB program is meant for beneficiaries only 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. There will be promotion of DTB events prior to the event date. 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. DHA Strategic Communications will develop and implement a communications plan in concert with the DHA Pharmacy Operations 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

CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DHA	Defense Health Agency
DHA-IPM	Defense Health Agency-Interim Procedures Memorandum
DTB	Drug Take Back
EPA	U.S. Environmental Protection Agency
MHS	Military Health System
MTF	medical treatment facility
OCONUS	Outside of the Continental United States

PART II. DEFINITIONS

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

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 (CSA). 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 CSA.

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