

## Defense Health Agency

### **ADMINISTRATIVE INSTRUCTION**

**NUMBER** 6430.08 March 10, 2022

DAD-MEDLOG

SUBJECT: Controlled Medical Items Management for Medical Logistics Areas

References: See Enclosure 1.

- 1. <u>PURPOSE</u>. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (f); Part 1301 of Reference (g); and References (h) through (m), establishes DHA procedures to provide policy and procedures necessary for the effective management of controlled medical items within DHA's Medical Logistics (MEDLOG) departments.
- 2. <u>APPLICABILITY</u>. This DHA-AI applies to DHA, DHA Components (activities under the authority, direction, and control of DHA), and all personnel: assigned or attached active duty or Reserve members, Commissioned Corps, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA and DHA Components.
- 3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (a) through Section (§) 1301.72b of Reference (g), that DHA Components and military medical treatment facilities (MTFs) will follow the procedures outlined in this DHA-AI for the management of controlled medical items.
- 4. <u>RESPONSIBILITIES</u>. See Enclosure 2.
- 5. PROCEDURES. See Enclosure 3.
- 6. <u>PROPONENT AND WAIVERS</u>. The proponent of this publication is the Deputy Assistant Director (DAD), MEDLOG. When Activities are unable to comply with this publication the

activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the DAD-MEDLOG to determine if the waiver may be granted by the Director, DHA or their designee.

7. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-AI is available on the Internet from the Health.mil site at: <a href="https://health.mil/Reference-Center/Policies">https://health.mil/Reference-Center/Policies</a> and is also available to authorized users from the DHA SharePoint site at: <a href="https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx">https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx</a>.

#### 8. <u>EFFECTIVE DATE</u>. This DHA-AI:

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

#### 9. FORMS

- a. The Standard Form (SF) 700, Security Container Information is available at: www.gsaglobalsupply.gsa.gov.
- b. The SF 702, Security Container Check Sheet is available at: https://www.gsa.gov/forms-library/security-container-check-sheet.
- c. DD Form 1348-1A, Issue Release/Receipt Document is available at: <a href="https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd13481a.pdf">https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd13481a.pdf</a>.
- d. <u>The following DHA forms are available from:</u>
  <a href="https://info.health.mil/cos/admin/DHA\_Forms\_Management/Lists/DHA%20Forms%20Management/AllItems.aspx">https://info.health.mil/cos/admin/DHA\_Forms\_Management/Lists/DHA%20Forms%20Management/AllItems.aspx</a>.
  - (1) DHA Form 125, Stock Accounting Record
  - (2) DHA Form 154, Notice of Delegation of Authority

- e. The following Drug Enforcement Administration (DEA) Forms are available from: <a href="https://www.deadiversion.usdoj.gov/online">https://www.deadiversion.usdoj.gov/online</a> forms apps.html.
  - (1) DEA Form 106, Report of Theft or Loss of Controlled Substances
  - (2) DEA Form 222, Official Order Form

/S/ RONALD J. PLACE LTG, MC, USA Director

#### Enclosures

- 1. References
- 2. Responsibilities
- 3. Procedures

Glossary

#### ENCLOSURE 1

#### REFERENCES

- (a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
- (b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (c) United States Code, Title 10, Section 1073c
- (d) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
- (e) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017
- (f) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018
- (g) Code of Federal Regulations, Title 21<sup>1</sup>
- (h) DEA Schedule of Controlled Substances<sup>2</sup>
- (i) DoD Instruction 6025.25, "Drug Take Back Program," April 26, 2016
- (j) DHA Procedural Instruction 6490.03, "Deployment Health Procedures," December 17, 2019
- (k) DHA-Procedural Instruction 6025.31, "Military Medical Treatment Facility Pharmacy Operations," December 20, 2019
- (l) DHA-Procedural Instruction 3700.01, "Director's Critical Information Requirements (DCIR), Situation Report (SITREP)," October 04, 2019
- (m) Privacy Act of 1974 (justice.gov)

<sup>&</sup>lt;sup>1</sup> 21 CFR Part 1301 is available at: https://www.ecfr.gov/current/title-21/chapter-II

<sup>&</sup>lt;sup>2</sup> DEA Controlled Substance Schedules available at: https://www.deadiversion.usdoj.gov/schedules/index.html

<sup>&</sup>lt;sup>3</sup> DEA Theft Loss Reporting available at: https://www.deadiversion.usdoj.gov/21cfr reports/theft/index.html

<sup>&</sup>lt;sup>4</sup> 21 CFR Part 1304 is available at: https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR9944e94ba5f1eb0/section-1304

#### **ENCLOSURE 2**

#### RESPONSIBILITIES

- 1. <u>DIRECTOR, DHA</u>. The Director, DHA must ensure the Deputy Assistance Director (DAD), DHA MEDLOG will implement this DHA-AI in accordance with Reference (e).
- 2. <u>DHA, ASSISTANT DIRECTORS</u>. The DHA, Assistant Directors must:
  - a. Ensure MTFs or DHA components implement and comply with this DHA-AI.
- b. Ensure MTFs under their command and control comply with the procedures contained in this publication.
- 3. <u>DAD-MEDLOG</u>. The DAD-MEDLOG will perform oversight of the delivery of all MEDLOG business functions at DHA MTF or DHA components in accordance with References (b) through (f).
- 4. MARKET, SMALL MARKET, AND STAND-ALONE MTF ORGANIZATION DIRECTORS. Market, Small Market, and Stand-Alone MTF Organization Directors must ensure compliance with this publication.
- 5. <u>MTF DIRECTOR</u>. The MTF Director will establish effective medical logistics processes necessary, in accordance with this instruction, to safeguard and manage controlled medical items ordered, received, stored, or issued by MEDLOG. Additionally, the MTF Director will:
- a. Appoint in writing a Disinterested Inventory Officer (DIO) team in the pay grade of Enlisted (E)-7/GS-09 or above to perform a monthly inventory and audit of controlled medical items stored in the activity's logistics warehouse (i.e., vault, cage, safe) belonging to MEDLOG. MEDLOG personnel may not be assigned duties as a DIO. There is no minimum or maximum number of members appointed as members of the DIO team; it is dictated by local mission needs.
- b. Ensure all areas storing controlled medical items MEDLOG are inventoried monthly by the DIO.
- c. Review and approves the final DIO report and directs and ensures corrective actions are taken as needed to clear any discrepancies.
- d. Ensure MTF MEDLOG contacts the appropriate investigative authority regarding loss or theft of controlled medical items. Upon discovery of a theft or loss of controlled medical items,

ensure the DEA registrant reports the loss in writing to the area DEA field office on DEA<sup>3</sup> Form 106, Report of Theft or Loss of Controlled Substances, either electronically or manually within one business day. Refer to Enclosure 3, paragraph 10 on the handling of loss or theft of controlled medical items.

- 6. <u>CHIEF, MTF MEDLOG</u>. The Chief, MEDLOG, as part of the MTF's MEDLOG Office, is responsible for all medical logistics operations in the facility. The Chief, MEDLOG must:
- a. Ensure MEDLOG does not issue controlled medical items to internal medical/dental customers on wards or in clinics.
- b. Appoint in writing an Accountable Medical Supply Officer (AMSO) and MEDLOG Controlled Medical Item Custodian/Alternate.
- c. Verify AMSO and Controlled Medical Item Custodians/Alternates having access to controlled medical items have a completed employee screening in accordance with §1301.90 of Reference (g) with the local installation Provost Marshall office, Base Security Forces Squadron, or other appropriate investigative authority having jurisdiction.
- d. Ensure all controlled medical items stored in the MEDLOG areas are accounted for and secured in accordance with DHA Physical Security policies and §1301.72 of Reference (g) and (m).

#### 7. MTF AMSO. The MTF AMSO will:

- a. Manage medical supplies for the MTF and ensure controlled medical items are secured and stored in accordance to the manufacturers' guidance and federal laws and applicable regulations.
- b. Serve as the MEDLOG DEA Registrant POC and manage the MEDLOG POA assigning authorized MEDLOG Controlled Medical Item Custodian/Alternate. Refer to Enclosure 3, paragraph 4 for DEA registration and POA procedures.
- (1) On an annual basis, validate the following are current: the section's DEA license and Controlled Substance Ordering System (CSOS) certificate, and the POA of individuals authorized to execute and sign the DEA Form 222, Official Order Form, either electronically or manually, in the absence of the DEA registrant.
- (2) On an annual basis, or sooner upon personnel changes, validate all names are accurate on the POA and the electronic NORA system.
- c. Ensure DIO team has access to controlled medical items storage areas in MEDLOG in support of the monthly inventories the DIO team is required to complete. Inventories will be completed at a minimum on a monthly basis for Chemical, Biological, Radiological, and Nuclear

(CBRN) items. Conduct a 100 percent inventory of all controlled medical items stored in MEDLOG areas every two years. In accordance with the Reference (g) the biennial inventory<sup>4</sup> will involve two disinterested individuals in the rank of E-7/GS-09 or above, and each witness will legibly print and sign the inventory form with their full name, rank, title, date and time of inventory, and signature. The biennial inventory will be labeled "DEA Biennial Inventory."

- d. Notify the MTF Director of any loss or theft of a controlled medical item. Refer to Enclosure 3, paragraph 9.
- e. Ensure Intrusion Detection Systems (IDS) and duress switches are tested and documented quarterly. Installation Physical Security policies may require more frequent testing of IDS and duress systems.
- f. Follow Reference (g) and local physical security policies for controlled storage area access to include maintaining proper key control, badge access, and maintaining access rosters. Safeguard and control access to vault and caged storage areas of controlled medical items, and ensure physical security standards are in accordance with installation Physical and Personnel Security requirements. Maintain proper key control and badge access to only personnel authorized access to the controlled storage area in accordance to local Personnel Security policies and ensure access rosters are updated and posted inside the controlled storage area.

# 8. <u>MEDLOG CONTROLLED MEDICAL ITEM CUSTODIAN/ALTERNATE</u>. The MEDLOG Controlled Medical Item Custodian/Alternate must:

- a. Manage and ensure controlled medical supplies for the MTF are secured and stored in accordance with the manufacturers' guidance and federal laws.
- b. Secure controlled medical items immediately upon receipt and immediately post all gains and losses transactions in the Defense Medical Logistics Standard Support (DMLSS).
- c. Ensure controlled medical items stored in MEDLOG area are 100 percent inventoried monthly during the DIO program. The inventory will be conducted using the controlled item inventory list generated from the DMLSS Business Intelligence (BI) "Control Item Inventory" report.
- d. Conduct a 100 percent inventory of all controlled medical items stored in the MEDLOG area every two years on 1 May (or the first duty day thereafter) of odd-numbered years per Reference (k). The biennial inventory will involve two disinterested individuals in the rank of E-7/GS-09 or above, and each witness will legibly print and sign the inventory form with their full name, rank, title, date and time of inventory, and signature. The biennial inventory will be labeled "DEA Biennial Inventory."
- e. Provide the DIO a list of all activities in the MTF that ordered controlled medical items from the previous month to include controlled items in CBRN assemblages. Refer to Enclosure 3, paragraph 1 for a list of controlled medical items.

- f. Ensure controlled medical items are maintained in storage areas that meet local Physical Security requirement and §1301.72 of Reference (g). Maintain current security container designations and records to include SF 700, Security Container Information, SF 702, Security Container Check sheet, and updated access rosters posted inside the storage area and kept from public view. Access rosters shall be updated upon personnel changes.
- g. Issue controlled medical items directly to authorized recipients, preferably at the security storage site. The custodian must obtain a full signature of the recipient and complete the DHA Form 125, "Stock Accounting Record" at the storage site immediately after a transaction.
- h. Investigate shortages and unusual requisitions or expenditures immediately, and report any unresolved discrepancy to the AMSO for corrective action in accordance with the procedures in Enclosure 3, paragraph 5.
- i. Coordinate with local Physical Security for the quarterly testing of the IDS and duress system. Installation Physical Security policies may require more frequent testing.
- j. Complete employee screening IAW §1301.90 of Reference (g) from the local Provost Marshal, Base Security Forces Squadron, or other appropriate investigative authority having jurisdiction and ensure warehouse personnel and other personnel having access to controlled items have completed screening.
  - k. Safeguard and control access to vault and caged storage areas of controlled medical items.
- 1. Ensure the POA is readily retrievable with the executed DEA Form 222. Executed DEA Form 222 shall be filed numerically and tracked.
- m. Ensure unexecuted DEA Form 222 and CSOS digital certificates are safeguarded as controlled medical items. Unexecuted DEA Form 222 shall be kept in a secured, locked area, and tracked in a log to ensure a full accounting of the forms received.
- n. Immediately report any lost or stolen unexecuted DEA Form 222 or the compromise of CSOS digital signatures to the AMSO in accordance with Enclosure 3, paragraph 9.

#### 9. DIO. The DIO must:

- a. Be appointed by the MTF Director to conduct 100 percent inventory of controlled medical items stored in MEDLOG areas.
  - b. Hold the rank of E-7/GS-09 or above.
  - c. Not work in the MTF Pharmacy or MTF MEDLOG sections.

d. Complete the Disinterested Inventory between the 1<sup>st</sup> and 10<sup>th</sup> working day of the month, and submit a final report to the MTF Director NLT the 15<sup>th</sup> working day of the month in accordance with Enclosure 3, paragraph 8. Submits in writing to the MTF Director any requested extensions.

#### ENCLOSURE 3

#### **PROCEDURES**

- 1. <u>GENERAL</u>. This DHA-AI provides policy and guidance for controlling and safeguarding controlled medical items stored in MEDLOG.
- a. Controlled medical items are coded in the DMLSS with the appropriate Controlled Inventory Item Codes (CIICs) in the Inventory Management Module/Catalog.
- b. The following categories will be considered controlled medical items for the purpose of this publication:
- (1) Controlled medical items designated by the DEA as a Schedule I and II are categorized as a CIIC "R," and DEA Schedule III, IV, or V medications are categorized as a CIIC "Q" controlled medical item. Schedules are set by the DEA in accordance with Reference (h).
- (2) Precious metals containing substances such as gold, gold alloy, silver, silver alloy, and platinum are categorized as a CIIC "R." Dental amalgam caps used for direct chairside restorations are not controlled medical items and not considered precious metals for this policy.
- (3) Non-Denatured 100 percent and 95 percent Ethyl Alcohol used in medical treatment laboratories will be controlled and are categorized as a CIIC "R" item.
  - (4) Unexecuted DEA Form 222s and CSOS Certificates.
- (5) The MTF Director may assign other items as Director-Designated Controlled Medical items due to their high dollar value, likelihood of pilferage, or potential for abuse, and these will be managed as a controlled medical item.

#### 2. STORAGE OF CONTROLLED MEDICAL ITEMS

- a. The Controlled Medical Item Custodian will ensure that controlled medical items are maintained in storage areas that meet the criteria mandated by §1301.71 of Reference (g).
  - b. MEDLOG vaults are to be secured in accordance with Reference (g).
- c. For secure storage areas equipped with an IDS or Duress alarm system, the AMSO will ensure the system is tested quarterly, unless local installation physical security requires more frequent testing. Results will be maintained on an Alarm/Intrusion Detection Record and retained for two years in accordance with WHS OSD Records and Declassification Programs, File Number: 217-10.2 which can be found at

https://www.esd.whs.mil/Portals/54/Documents/RPDD/RDS/200 Series Management and Ope rations (Updated Apr 21).pdf. Testing will be coordinated with the local Physical Security office to ensure the system is operational and contacts the appropriate law enforcement personnel.

- d. Only the MEDLOG Controlled Medical Item Custodian/Alternate and the AMSO will have combinations, keys, security codes, or access badges to Controlled Medical Item storage areas. MEDLOG with minimal manning may maintain an emergency key or written combination in a signed and sealed envelope stored in a secure safe only accessible by the MTF Director or their designated representative. Sealed envelopes will be accounted for in accordance with local Key Control policies. Sealed envelopes that have been compromised or tampered with will immediately be reported to the MTF Director.
- e. Local physical security policies may allow for stricter physical security measures based upon risk assessments.

#### 3. PERSONNEL ACCESS TO CONTROLLED MEDICAL ITEMS

- a. Access to controlled medical items and controlled medical items is limited to those individuals who have been granted authorization by the MTF Director, and have an official need for that access within the scope of their duties.
- b. Personnel whose action results in a loss of confidence by their supervisory chain will not be granted unescorted access to controlled medical items.
- c. Access to controlled medical items will be denied to any individual undergoing investigation, treatment, rehabilitation, judicial or non-judicial processes, or administrative action as a result of actual or suspected drug abuse, or as a result of suspected illegal activity involving controlled medications. Access may be reinstated when suspicions or allegations against the person are determined to be unfounded by the relevant law enforcement agency investigating the alleged misconduct, or the commander of suspects who are military, or the MTF Director of suspects who are civilian employees, or when rehabilitation is determined to be successful by a Department of Defense (DoD) substance abuse rehabilitation program or an accredited non-DoD substance abuse rehabilitation program.
- d. All areas storing controlled medical items must post an access roster inside the storage area, and the access roster must be kept from public view. The names and duty positions of those personnel authorized unaccompanied access to the medication storage areas will be depicted on the access roster. Access rosters will be updated upon personnel changes.
- e. The MEDLOG Controlled Medical Items Custodians/Alternates and AMSO having access to controlled medical items must complete an employee screening. MTF Personnel Security services may impose stricter requirements.

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#### 4. DEA REGISTRATION AND PROCUREMENT

- a. MTFs in the 50 United States and Territories will register with DEA for the procuring, ordering, storing, and collecting of controlled medical items in accordance with §1301.72 of Reference (g).
- b. The individual who signed the current DEA registration may grant POA to individuals designated as Approving Officials for the procurement of controlled medical items in accordance with §1305.05 of Reference (g).
- c. Procurement of CIIC "Q" and "R" items from commercial sources requires the use of a DEA Form 222 for Schedule I and II Controlled Substances. Officials signing the order form must be the individual who signed the current DEA registration application or individuals designated on a POA. Unexecuted/blank DEA Form 222s are controlled medical items in accordance with §1305.17 of Reference (g) and will be maintained in a locked secured area. In the 50 United States and Territories, ordering officials may use the NORA system to electronically submit the DEA Form 222. Request DEA issued digital certificates from the CSOS at: <a href="http://www.deaecom.gov/">http://www.deaecom.gov/</a> in advance of migrating from the current paper-based system to CSOS and NORA. Download CSOS Registration Manual at: <a href="https://www.deaecom.gov/submanual.html">https://www.deaecom.gov/submanual.html</a> to aid in the registration process. For controlled medical item orders through an approved DoD Pharmacy Distributor or Drug Manufacturer that does not accept electronic DEA Form 222s, DMLSS manual offline non-submit orders may be used with a hard copy DEA Form 222.
- (1) All executed DEA Form 222s, invoices, supporting documents (Delivery Lists, and Signature Cards), and POAs must be maintained locally for two years to include any unaccepted or defective forms in accordance with §1305.17 of Reference (g). Documentation must be filed numerically by the DEA Form 222 number in order to account for and track all forms.
- (2) Ensure unexecuted DEA Form 222s and CSOS digital certificates are safeguarded as controlled medical items. Unexecuted DEA Form 222s shall be kept in a secured, locked area, and filed/tracked to ensure a full accounting of the forms received.
- (3) Immediately report any lost or stolen unexecuted DEA Form 222s or the compromise of CSOS digital signatures to the MTF Director for appropriate actions. Refer to Enclosure 3 paragraph 9 for guidance on reporting theft or significant loss of controlled medical items.

#### 5. RECEIPT AND DISCREPANCY RECEIPT OF CONTROLLED MEDICAL ITEMS

a. The MEDLOG Controlled Medical Item Custodian/Alternate will secure controlled items immediately upon receipt, and receipt in DMLSS/NORA. The NORA system will require reviewing and approval of pending orders. For Schedule I and II Controlled Substance medications, annotate "No. of Packages Received" and "Date Received" for each line item on Copy 3 of the DEA Form 222 and file in accordance with Enclosure 3 paragraph 4.

- b. When a discrepancy exists in the receipt of controlled medical items or a product is received broken or damaged, follow these procedures:
- (1) Suspend the shipment in DMLSS (Internal Transfer Section), segregate the materiel in the designated secure storage area, label as suspended, and initiate an investigation into the potential cause of the discrepancy.
  - (2) Obtain a witness to the discrepancy.
- (3) Immediately contact the Distributor and investigate the cause of the discrepancy. For loss or theft during shipment from the Distributor/PV, the MTF will immediately contact the Distributor (i.e., PV) and the Distributor will report the loss to the DEA.
- (4) MEDLOG is responsible to report and resolve shipment discrepancies in accordance with DLA Statement of Work guidance. Failure to report discrepancies may result in financial liability to the MTF.
- (5) If the investigation of the shortage indicates the items may have been removed in an unauthorized manner at the MTF, immediately initiate the procedures for lost or stolen controlled medical items in Enclosure 3 paragraph 9 through the supervisory chain and MTF Director.
- (6) When all notifications, certifications, and investigative documentation have been completed, release the materiel from suspension stratification and complete the receiving action for the actual quantity of items received.

#### 6. RETURN OF CONTROLLED MEDICAL ITEMS

- a. MTF MEDLOG will not accept patient returns.
- b. For recalled controlled medical items, MTF MEDLOG sections will follow Medical Materiel Quality Control guidance.
- c. MTF MEDLOG activities in the 50 United States and Territories registered with the DEA will utilize the DLA Reverse Distributor program when disposing of expired or damaged pharmaceutical controlled medical items. Overseas MTFs not registered with the DEA will utilize the DIO program to dispose of controlled medical items.
- (1) Contaminated, counterfeit, adulterated, or illegal substances will not be returned through the DLA Reverse Distributor system. Ensure product was not opened or damaged.
- (2) Medications previously dispensed to or used on a patient that may have been contaminated with biological fluids will not be returned through the DLA Reverse Distributor program but will be wasted in accordance with local pharmacy and environmental medical waste policies.

- d. Returned Schedule II (CII) controlled medical items medications will be returned to the DLA Reverse Distributor via a DEA Form 222 or the electronic equivalent form supplied by the DLA Reverse Distributor. The DEA Form 222 will be completed with the following information:
- (1) Each CII medication will have its own line. Enter the Number of Packages, Size of Package, Item Name (Drug name to include the drug name, drug strength/concentration/volume size, and dosage formulation), NDC, Packages Shipped, and Date Shipped.
- (2) The names, addresses, and DEA registration numbers of the MTF MEDLOG service and DLA Reverse Distributor involved in the transfer of the controlled substance. The MTF will use the name and address listed on the DEA Registration. NOTE: The last line completed must be documented on the form.
- (3) The MTF will retain Copy 1 of the DEA Form 222 and send Copy 2 to the DEA in accordance with §1304.04 of Reference (g).
- (4) The DLA Reverse Distributor will scan the Schedule III-V (CIII-V) Controlled medical items and provide the MEDLOG Controlled Medical Item Custodian/Alternate a copy of the return invoice with the medication name, strength/concentration, dosage form, quantity returned, and date transferred listed on the invoice. The DLA Reverse Distributor will document returns for controlled versus non-controlled medications separately.
- e. MTF MEDLOG activities may receive credits through the DLA Pharmaceutical Prime Vendor (PV) account of unopened, undamaged products, which the MTF activity shall use for the procurement of pharmaceuticals.

#### 7. DESTRUCTION

- a. This section only applies to overseas MTF MEDLOG services, which are not registered with the DEA. The MTFs in the 50 United States and Territories registered with the DEA will utilize the DoD's Reverse Distributor program as outlined in paragraph 7 of this Enclosure. Overseas MTFs, which are not registered with the DEA, will utilize the DIO as the MTF Destruction Officer.
- b. The DIO is responsible for ensuring that all controlled medical items requiring destruction are destroyed in such a manner that renders them unusable and will not pose a risk to the public through an unintended exposure or the potential for diversion/abuse.
- c. Reasons for the destruction of controlled medical items may include expired, broken, crushed, stability compromised, or recalled medications. When notified by a clinical area that medications used on patients may have been contaminated, the controlled medical item will not be destroyed through the DIO process but will be wasted in accordance with local pharmacy and environmental medical waste policies. Patient Care Areas may not destroy controlled medical items; medications stored in these areas shall be returned to the pharmacy for disposition.

- d. Destruction of controlled medical items will be documented on a DMLSS Destruction Report with the following:
- (1) Each item destroyed will be listed with Item description, Stock Number, unit of issue, quantity, supply action, unit of sale, total cost, date posted, and by whom.
- (2) Three people must be present to witness the destruction to include the DIO, the MTF MEDLOG Controlled Item Custodian/Alternate, and a disinterested witness in the rank of E-7/GS-09 or above. Each person will legibly print and sign the DMLSS Destruction Report with their full name, grade, date and time of destruction, and signature.
- (3) The DIO will ensure the following statement is written or typed on the DD Form 1348-1A, Issue Release/Receipt Document "On DD-MM-YYYY and Time, I witnessed the destruction of the drugs that were destroyed by the following method \_\_\_\_\_\_, and witnessed the drugs were deducted from the inventory system."
- e. Upon completion of the destruction of the controlled medical items, the DIO will witness that all destroyed medications were properly deducted from the inventory system (Inventory Loss into DMLSS) performed by the MTF MEDLOG Controlled Medical Item Custodian/Alternate. See Reference (g) Part 1317, Subparts A through C.

#### 8. INVENTORY OF CONTROLLED MEDICAL ITEMS IN MTF MEDLOG

- a. The DIO will conduct a 100 percent inventory of all controlled medical items stored in MEDLOG areas to include Medical Countermeasures-CBRN assemblages.
- b. MTF MEDLOG personnel who are involved with ordering, storing, receiving, and issuing controlled medical items will not be appointed as the DIO.
- c. On the day of the inventory, the MTF MEDLOG Controlled Item Custodian will provide the DIO a list of all controlled medical items stored in the MEDLOG area. MTF MEDLOG will escort the DIO for the duration of the controlled medical items inventory within the MEDLOG area. The controlled item inventory list can be generated using the DMLSS BI "Control Item Inventory" report. The inventory will be conducted using a blind-count of the quantity on hand and comparing the on-hand count to the DMLSS inventory record balance on the BI Control Item Inventory Report or the manual perpetual inventory form. During the inventory, DIO will annotate on the inventory form the following:
- (1) If no discrepancies exist, the DIO will document on the BI Report that the inventory was found to be correct on the line "DIO Inventoried and Found Correct" along with the current date/time of inventory, legible full name/rank of the DIO, and DIO signature. The MEDLOG Controlled Item Custodian/Alternate will co-sign the inventory report with full name, rank, and signature.

- (2) If the on-hand amount does not match the amount listed on the form, the DIO will provide the section an opportunity to research the discrepancy. If the discrepancy cannot be resolved, the DIO will document on the next available line on the form, bottom of the automated accounting system the following statement "DIO Inventoried and Discrepancies Noted" along with the date/time of the inventory, legible full name/rank of the DIO, and DIO signature. The MEDLOG Controlled Item Custodian/Alternate will co-sign the inventory report with full name, rank and signature.
- (3) All unresolved discrepancies found during the inventory will be included in the final DIO report and immediately reported to the AMSO. The AMSO will provide the DIO with a copy of a signed memorandum acknowledging the discrepancy along with any supporting documents. The original signed memorandum and original supporting documents will be maintained by the MEDLOG section.
- (4) All adjustments made to the inventory to correct any discrepancies found during the DIO inventory will be closed out before the next DIO inventory.
- d. For any minor administrative adjustments made to the DMLSS inventory during the month, the MEDLOG Controlled Item Custodian/Alternate will provide the DIO a copy of a memorandum describing the administrative adjustment along with a copy of any supporting documents describing the administrative adjustments made to the inventory. The memorandum will be signed by the AMSO with a description of the item adjusted, the administration error, actions taken, person who discovered the error, other personnel involved, and all supporting documentations of the error. Local directorates may further require signature from the MTF Director on the memorandum. The original signed memorandum and original supporting documents will be maintained by the MEDLOG section.
- e. The MTF MEDLOG Controlled Medical Item Custodian/Alternate will produce a DMLSS list of controlled medical items ordered since the previous DIO inventory (for controlled medical items ordered through MEDLOG, not any that were ordered directly by other customers, such as Pharmacy Services). This report can be retrieved from the DMLSS BI "Controlled Transaction History" report with a prompt for the date range of Established Due In/Receipt and provide line-item detail with customer information. For areas that are authorized to order controlled medical items, the DIO will verify 100 percent of the controlled medical items orders were received in DMLSS/NORA and verify the quantities were added to the section's perpetual inventory form or electronic automated accounting system. The DIO will not use shipping container invoices as a substitute to verify if an order was received.

#### 9. REPORTING LOSS OR THEFT OF CONTROLLED MEDICAL ITEMS

a. The AMSO, through the MTF Chief, MEDLOG, must immediately notify, in writing, the MTF Director of any suspicion of loss or theft of controlled medical items. Refer to the glossary, Part II: Definitions, for the list of controlled medical items (i.e., controlled substance medications, precious metals, unexecuted DEA Form 222s).

- b. The MTF Director must ensure any loss or theft of a controlled medical item is reported using a DCIR to the DHA Assistant Director for Healthcare Administration and report to the local military Law Enforcement investigative service.
- c. For MTF MEDLOG activities located in one of the 50 United States or Territories, the MEDLOG DEA Registrant will report all losses or theft of controlled medical items, any loss or theft of unexecuted DEA Form 222, or a compromised CSOS digital signatures within one business day to the local DEA Diversion Field Office using a DEA Form 106 either electronically or manually. If a DEA Form 222 is lost, include the serial number of each DEA Form 222 that is lost or stolen, or if an entire book is lost or stolen and the serial numbers cannot be ascertained, report the date or approximate date of issuance. The registrant can submit the DEA Form 106 online at: <a href="https://www.deadiversion.usdoj.gov/online\_forms\_apps.html">https://www.deadiversion.usdoj.gov/online\_forms\_apps.html</a>.
- d. For loss or theft during shipment from the Distributor/PV, the MTF will immediately contact the Distributor (i.e., PV) and the Distributor will report the loss to the DEA. Refer to paragraph 5, Enclosure 3 on discrepancy receipts for controlled medical items.
- e. Report losses to the unit MTF Report of Survey Monitor, Financial Liability Investigation of Property Loss Coordinator, or other equivalent POC for reporting theft or loss to initiate the appropriate actions (e.g., Unable to Locate).
- 10. <u>RECORDS MANAGEMENT</u>. Records for controlled medical items will be maintained in the local area for a period of two years in adherence to the local Records Management policy, the Privacy Act and the Health Insurance Portability and Accountability Act and in accordance with §1304.04 of Reference (g). Controlled medical item records must be available for inspection by the DEA and include:
- a. DEA registrants will maintain separate files for Schedule I and II (CIIC "R") and Schedule III-V (CIIC "Q") controlled drug records.
- b. Hard copies of the DMLSS Delivery List, BI Report "LOG-Owned Assemblage Management" or "Controlled Item Inventory Report," and perpetual inventory forms/reports used to perform inventories.
- c. Issue transactions such as DMLSS Delivery Lists used to account for all issue transactions of CIIC "Q" and "R" items. Issue transactions will include the drug name (concentration/strength), dosage form, volume/quantity issued, and signatures of the both the MEDLOG Controlled Medical Item Custodian/Alternate and activity representative with their full name, rank, and date printed legibly on the DD Form 1348-1a.
- d. Documentation of the DEA-mandated biennial inventories of all Controlled Item Inventory Code "Q" and "R" items. DIO inventories must be available for inspection by the DEA.

- e. All executed DEA Form 222s, shipping invoices, and POAs must be maintained locally in accordance with §1305.17 of Reference (g). Executed DEA Form 222s will be filed numerically with the shipping invoice in order to account and track for all forms, and POAs shall be maintained with the executed DEA Form 222s and available for inspection.
- f. All executed, unaccepted, or defective DEA Form 222s will be accounted for, filed numerically, and secured in a locked container.
- g. MTFs will maintain all documents associated with receipt, inventories, returns, or DIO disposal of controlled medical items for two years for inspection and copying by the DEA and in accordance § 1304.04 of Reference (g). Documentation will include:
  - (1) Initial and adjusted inventory reports in DMLSS.
- (2) Vendor inventory of medications returned, DEA Form 222s if applicable for Schedule II Controlled Substances.
  - (3) Commercial return reports and destruction reports.
  - (4) DIO destruction forms such as DMLSS Destruction Report.
- h. Documentation of testing of the IDS and duress alarm system will be retained in the local area.

#### **GLOSSARY**

#### PART I. ABBREVIATIONS AND ACRONYMS

AMSO Accountable Medical Supply Officer

BI Business Intelligence

CBRN Chemical, Biological, Radiological, and Nuclear

CIIC Controlled Inventory Item Code

CSOS Controlled Substance Ordering System

DAD Deputy Assistant Director

DEA Drug Enforcement Administration

DHA-AI Defense Health Agency-Administrative Instruction

DIO Disinterested Inventory Officer
DLA Defense Logistics Agency

DMLSS Defense Medical Logistics Standard Support

E Enlisted

GS General Schedule

IDS Intrusion Detection Systems

MEDLOG Medical Logistics

MFR Memorandum For Record

MTF Military Medical Treatment Facility

NDC National Drug Code

NORA Narcotics Order, Review, and Approval

POA Power of Attorney POC Point of Contact

PTF Pharmacy and Therapeutics Function

PV Prime Vendor

SF Standard Form

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#### PART II. DEFINITIONS

Force Health Protection Prescription Products. Defined in Reference (j).

<u>Controlled Medical Item</u>. Controlled medical items include DEA Schedule I-V Controlled Substance medications (CI-V), precious metals, ≥95 percent non-denatured ethyl alcohol, DEA Form 222 and CSOS certificates, or other locally approved Command Designated Controlled Medical Items as approved by the MTF Commander/Director.

<u>Controlled Substance Medication</u>. A DEA Schedule I-V Controlled Substances as defined at the DEA Diversion Control Division website:

https://www.deadiversion.usdoj.gov/schedules/index.html

<u>Precious Metals</u>. Gold, gold alloy, silver, silver alloy, and platinum used in Dental procedures are precious metals and are categorized as a DoD CIIC "R." Dental amalgam caps used for direct chairside restorations are not considered precious metals.

<u>DHA MEDLOG EA</u>. The DHA MEDLOG Enterprise Agency includes the management of Class VIII medical materiel as defined in Reference (g), assemblage management, medical maintenance, and lifecycle management of medical and dental materiel.

<u>DHA MEDLOG</u>. An organization title for the subdivision of activities performing medical logistics under the authority, direction and control of the DHA. Examples include stand-alone combat support medical logistics teams, MTFs, and research and development organizations.

<u>DEA Registrant</u>. The individual who signed, or is authorized to sign, the latest application for the DEA Registration renewal. This is typically the same person authorized to grant POA to other individuals employed by the organization. An MTF service registered with the DEA may include the Pharmacy or MEDLOG service.

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