

Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6205.01 May 10, 2021

AD-CS

SUBJECT: Medical Logistics Guidance for the DoD Coronavirus Disease 2019 (COVID-19)

Vaccination Program

References: See Enclosure 1

- 1. <u>PURPOSE</u>. 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 (o), establishes the Defense Health Agency's (DHA's) procedures for ordering, receiving, and managing COVID-19 Vaccines inventory and ancillary kits for enduring COVID-19 support.
- 2. <u>APPLICABILITY</u>. DHA, DHA components (activities under the authority, direction, and control of DHA), Military Departments (MILDEPs), Military Medical Treatment Facilities (MTFs), all personnel to include: assigned or attached Active Duty and Reserve members, federal civilians, member of the Commissioned Corps of the Public Health Service, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA, to include DHA regional and field activities (remote locations), and subordinate organizations administered and managed by DHA, to include MTFs under the authority, direction, and control of the DHA.
- 3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (a) through (o) that MTFs and DHA Components will follow procedures outlined in this DHA-PI.
- 4. <u>CANCELLED DOCUMENTS</u>. This DHA-PI cancels and replaces DHA-PI 6205.01, "Medical Logistics Guidance for the DoD Coronavirus Disease 2019 (COVID-19) Vaccination Program," of February 5, 2021.
- 5. RESPONSIBILITIES. See Enclosure 2.

- 6. PROCEDURES. See Enclosure 3.
- 7. <u>PROPONENT AND WAIVERS</u>. The proponent of this publication is the Assistant Director (AD), Combat Support. 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 AD, Combat Support to determine if the waiver may be granted by the Director, DHA or their designee.
- 8. <u>RELEASABILITY</u>. Cleared for public release. This DHA-PI is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.
- 9. 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 Reference (c).

10. FORMS

- a. DD Form 1348-1A, Issue Release/Receipt Document is available at https://www.esd.whs.mil/Directives/forms/.
- b. DHA Form 177, Potentially Compromised Temperature Sensitive Medical Products Worksheet is available at https://info.health.mil/cos/admin/DHA_Forms_Management/DHA_Forms1/DHA%20177.pdf.

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

Enclosures

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

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) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
- (d) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017
- (e) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018
- (f) Defense Logistics Agency Regulation 4145.21, "Preparation of Medical Temperature Sensitive Products Requiring Cold Chain Management for Shipment," November 20, 2018
- (g) U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and Prevention, "Vaccine Storage and Handling Toolkit," January 2019
- (h) DHA-Guide "Vaccine Storage and Handling Guide," August 2018, as amended
- (i) DHA-Procedural Instruction 3700.01, "Director's Critical Information Requirements (DCIRs), Situation Report (SITREP)," October 4, 2019, as amended
- (j) U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and Prevention, "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations," September 16, 2020¹
- (k) U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and Prevention, "Supplemental COVID-19 Vaccine Redistribution Agreement," September 14, 2020
- (l) U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and Prevention, "Vaccine Storage and Handling Toolkit," January 2020²
- (m) USAMMA-DOC, "Vaccine Redistribution Standard Operating Procedures (SOP)," September 2019³
- (n) USAMMA-DOC, "Vaccine Ordering Portal Registration Standard Operating" Procedures⁴
- (o) USAMMA-DOC, "COVID-19 Vaccine Ordering Standard Operating" Procedures⁵

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¹ This reference can be found at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

² This reference can be found at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

³ This reference can be found at: https://www.usamma.army.mil/Pages/DOC-Home.aspx.

⁴ This reference can be found at: https://www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/Anthrax-and-Smallpox-Vaccine-Ordering/.

Vaccine/Anthrax-and-Smallpox-Vaccine-Ordering/.

This reference can be found at: https://a01.usamma.amedd.army.mil/mmip/MMQC/Messages/Detail/MMQC-21-1261.

ENCLOSURE 2

RESPONSIBILITIES

- 1. <u>DIRECTOR, DHA</u>. The Director, DHA, will assign the Chief, DHA Medical Logistics (MEDLOG) to implement this DHA-PI. DHA Director shall be responsible for coordination with MILDEPs and development of process for redistribution to MILDEPs.
- 2. <u>DHA</u>, <u>ADs</u>. The DHA, ADs must ensure military MTFs or DHA components implement and comply with this DHA-PI.
- 3. <u>DEPUTY ASSISTANT DIRECTOR, MEDLOG</u>. The Deputy Assistant Director, MEDLOG will perform oversight of the delivery of all MEDLOG business functions at DHA MTF or DHA Components in accordance with References (b) through (o).
- 4. <u>CHIEF, DHA MEDLOG</u>. Chief, DHA MEDLOG will ensure the procedures for this program are audit compliant.
- 5. <u>SECRETARIES OF THE MILDEPS</u>. The Secretaries of the MILDEPs must ensure MTFs under their command and control comply with the guidance in this publication.
- 6. <u>MTF DIRECTORS</u>. The MTF Directors must establish effective MEDLOG procedures to support and ensure adherence to ordering, receipting, and managing inventory of COVID-19 Vaccines guidelines included in this DHA-PI and must:
- a. Ensure Immunization and MEDLOG designate Points of Contacts (POCs) communicate the daily usage of COVID-19 Vaccines administered in order to track accurate movements and all inventory status changes of the vaccine in accordance with the DoD Coronavirus Disease 2019 Vaccination Plan.
- b. Ensure Temperature Monitoring Device systems are capable of monitoring storage locations 24 hours a day, 7 days a week, and notify the appropriate personnel when a failure is detected.
- c. Implement more stringent inspection and recording requirements than what is specified in this DHA-PI if appropriate.
- d. Ensure the Temperature Sensitive Medical Products (TSMP) Coordinator performs all tasks required in supporting this DHA-PI.

- e. If an MTF performs the redistribution functions, it will ensure COVID-19 Vaccine and ancillary kit(s) are handled in accordance with the manufacturer, Centers for Disease Control and Prevention (CDC), and U.S. Army Medical Materiel Agency Distributions Operations Center (USAMMA-DOC) or Defense Logistics Agency (DLA) guidance on COVID-19 Vaccine storage, shipping, and handling procedures.
- f. If an MTF receives redistributed COVID-19 Vaccine(s) and ancillary kit(s), ensure they are handled in accordance with the manufacturer, CDC, and USAMMA-DOC or DLA guidance on COVID-19 Vaccine storage, shipping, and handling procedures.
- 7. <u>CHIEF, MTF MEDLOG</u>. The Chief, MTF MEDLOG is responsible for all MEDLOG operations in the MTF or satellite MTF, and DHA Component to the extent authorized by the MTF Director. The Chief MTF, MEDLOG will act as the single POC for orchestrating effective and efficient supply chain support for MTFs or DHA Components. Additionally, the Chief MTF, MEDLOG must:
 - a. Ensure all storage units are labeled properly.
 - b. Ensure storage units are physically monitored per the guidelines of this DHA-PI.
 - c. Ensure proper documentation of storage unit temperatures.
- d. Ensure the MTF adds COVID-19 Vaccines and ancillary kits to the standardized assemblage in the Defense Medical Logistics Standard Support (DMLSS) Assemblage Management (AM) Module.
- e. Designate a MEDLOG POC to maintain the COVID-19 Vaccine on-hand balances within the COVID-19 Customer Owned Assemblage based on daily updates from the Immunization POC.
 - f. If a MTF performs redistribution functions, ensure:
- (1) All material required for handling and redistributing COVID-19 Vaccine(s) and ancillary kits are onsite prior to receiving the materials.
- (2) COVID-19 Vaccine(s) and ancillary kit(s) are handled in accordance with the manufacturer, CDC, and USAMMA-DOC/DLA guidance on storage, shipping, and handling procedures.
- 8. <u>ACCOUNTABLE MEDICAL SUPPLY OFFICER</u>. The Accountable Medical Supply Officer must:
- a. Maintain the required storage temperatures, for materiel in medical logistics and have a calibrated working recording thermometer.

- b. Follow CDC guidance: Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units. If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines. Potentially contaminated items (e.g., blood, urine, and stool) should be properly contained and stored below vaccines to avoid contamination from drips or leaks. For further guidance go to https://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html.
- c. Ensure to contact USAMMA DOC at <u>usarmy.detrick.medcom-usamma.mbx.doc@mail.mil</u> for Continental United States (CONUS) sites on product quality discrepancies/shortages within the COVID-19 ancillary kits. Outside Continental United States (OCONUS) and Fleet customers should contact DLA at <u>dla.trpsptccc@dla.mil</u> directly. Complete a Product Quality Deficiency Report for non-vaccines discrepancies and route to normal processing channels prior to or after contacting the appropriate POC.
- d. Ensure personnel handling COVID-19 Vaccines and ancillary kits comply with all handling instructions from the manufacturer and federal guidelines.
 - e. Ensure all applicable guidance provided within this DHA-PI are followed.
- 9. <u>TSMP COORDINATOR</u>. The TSMP Coordinator has overall responsibility for monitoring the TSMP program at the MTF. The TSMP Coordinator must:
- a. Ensure each freezer is labeled as "Freezer Ultralow -80° Celsius (C)" or "Freezer -20°C" and refrigerators labeled as "Refrigerator 2-8°C" and labeled for "COVID-19 Vaccine storage" on the outside of the unit.
- b. Ensure COVID-19 Vaccine and ancillary kits' storage unit temperatures are documented on the Temperature Log for each unit.
- c. Ensure physical checks are performed at the beginning and end of each duty day for proper operation and temperature ranges of COVID-19 Vaccines storage units in accordance with manufactures' guidance.
- d. Ensure manufacturers' required temperature parameters are strictly adhered to when transporting to outlying clinics.
- e. Ensure all MTF or DHA component departments are following appropriate manufacturer, CDC, USAMMA-DOC, DLA and DHA guidance for COVID-19 Vaccines and ancillary kits.
- f. Unless specifically prohibited by other DHA guidance, COVID-19 Vaccine storage and ancillary kit units must be connected to an emergency or backup power source to ensure proper storage conditions are maintained during commercial power interruption. Outlying clinics are an exception to the backup power source requirement.

10. <u>OUTLYING CLINICS OFFICER IN CHARGE</u>. The Clinic Officer in Charge is responsible for ensuring proper COVID-19 Vaccines and ancillary kits handling processes, procedures, and storage are adhered to while used at off-site clinics and other remote locations (away from the main MTF) such as a Soldier Readiness Processing site. To reduce potential losses at these sites, minimize on-hand material and return remaining TSMP to a properly monitored and alarmed storage area at the end of each duty day.

ENCLOSURE 3

PROCEDURES

1. MTF COVID-19 PROCESS

- a. The quantity of COVID-19 Vaccine and ancillary kits requested is based on the requirements for the MTF's population at risk.
- (1) CONUS MTF(s) will register for access to the USAMMA DOC Vaccine Ordering Portal at https://a01.usamma.amedd.army.mil/docvac/Account/Login in accordance with Reference (n). Once access is approved the Vaccine Ordering Site will submit order requests to USAMMA-DOC following applicable instructions within Reference (o).
- (2) OCONUS MTF(s) sites will continue their current COVID-19 Vaccine procedure by processing their orders through their respective Service Vaccine Representative as per DLA guidance.
- b. The MTF(s) will add the assemblage and process an In-Shipment Gain (SHG) for the COVID-19 Vaccine and ancillary kits in the DMLSS AM Module.
 - (1) Add the Customer Owned Assemblage in DMLSS AM Module.
- (a) Add the "COVID-19 Vaccine Response Program" (CVRP) Standard Assemblage for COVID-19 from the Select Assemblage table.
- (b) Associate to the appropriate Pharmacy or Clinic Customer and associated Expense Center to the CVRP Standard Assemblage. Upon completion, the COVID-19 Vaccine Catalog Record and ancillary kit record will be added to the MTF Catalog.
- (c) Add the Location and Sub Location to the Assemblage Record Data for the COVID-19 Vaccine and ancillary kits.
- (d) Perform an Item Allowance Change for the COVID-19 Vaccine and ancillary kits in the CVRP Standard Assemblage that matches the quantity of the materials in the order received by the MTF(s) MEDLOG Division. The MTF(s) MEDLOG Division will increase the allowance cumulatively in DMLSS AM to reflect the total quantity of vaccines and ancillary kits received at the MTF MEDLOG. As the second, third, or subsequent orders are received, the receipt quantity will be added to the current allowance quantity to equal the total product received to date. The allowance quantity will never decrease.
- (2) The MTF(s) MEDLOG Division will create additional individual CVRP Standard Assemblages to be added for MTF(s) with internal Customer Area Inventory Management customers utilizing COVID-19 vaccines and ancillary kits for vaccinations at outlying clinics or

activities where tracking is mandated and auditability is required. In the additional CVRP Standard Assemblages, MTF MEDLOG will update and standardize the following three fields to identify the outlying clinics or activities.

- (a) The geographic location or name of the outlying clinic will be added in parenthesis *after* the defaulted "COVID-19 VACCINE RESPONSE PROGRAM" in the 'Assemblage Description' field.
- (b) The 'Build Control Number' will be populated to match the geographic location or outlying clinic name.
- (c) The 'Warehouse Location' will also be populated to match the geographic location or outlying clinic name.
- (3) Gaining the COVID-19 Vaccine and ancillary kits to the CVRP Standard Assemblage in the DMLSS AM.
- (a) Handle the COVID-19 Vaccine and ancillary kits in accordance with the manufacturer's shipping and handling guidance and CDC's guidance on COVID-19 Vaccine storage and handling guidance (i.e., CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, CDC Vaccine Storage and Handling Toolkit, and CDC Supplemental COVID-19 Vaccine Redistribution Agreement).
- (b) Once any COVID-19 Vaccine and ancillary kit containers are opened and manufacturer guidance meticulously followed, Logistics will immediately contact DLA or contact USAMMA-DOC via (301) 619-4318/8002 or DSN 343-4318/8002 and provide:
 - 1. Lot number
 - 2. Quantity per lot
 - <u>3</u>. Expiration date
 - 4. Status of monitor
- (c) The MTF(s) MEDLOG Division will use the National Stock Number (NSN) which identifies the lowest unit of measure (LUM) which will be represented as each (EA) for vial and tracking of all variations of the COVID-19 Vaccines.
- <u>1</u>. Due to system logic, DMLSS Inventory Management is unable to track Quality Assurance (QA) information or provide unit of measure conversion data for non-stocked items of COVID 19 vaccines, therefore Assemblage Management will be utilized to perform this function.
- <u>2</u>. MTF(s) will track the COVID-19 Vaccines at the lowest units of measure, which are cataloged at the vial level with a unit of sale of EA.

Note: Due to the auditability requirement of tracking the vaccine by the LUM, the shipping document NSN/National Drug Code will differ from the DMLSS AM inventory accounting NSN.

- (d) MTF(s) must return the cold chain monitoring equipment to the manufacture per the shipment instructions.
- (e) Execute a DMLSS AM SHG transactions into the DMLSS AM CVRP Standard Assemblage for COVID-19 Vaccine(s) and ancillary kits. The MTF(s) MEDLOG Division will use the NSN which identify the LUM represented as EA for vial or kit and tracking of all variations of the COVID-19 Vaccines. The MTF MEDLOG Division will process a SHG for the correct COVID-19 ancillary kit, one ancillary kit for the appropriate corresponding number of COVID-19 Vaccine vials.
- (f) The MTF(s) MEDLOG Division will utilize the unit of measure "KT" for the ancillary kit associated with the appropriate COVID-19 vaccine.
- (g) National Drug Code numbers will not be used as Item Identifications for the COVID-19 Vaccines or COVID-19 ancillary kits in DMLSS AM.
- (h) Input all Quality Assurance information to include the Manufacture, Manufacture Date, Expiration Date, and Lot Number into the Assemblage Record Data for the COVID-19 Vaccine and ancillary kits in DMLSS AM.

Note: Upon receipt if any discrepancies are noted they will be reported to the Vaccine Service Representative and disposition determined.

- (i) If DLA or USAMMA-DOC determine the COVID-19 Vaccine or ancillary kit is unserviceable, the product will be restratified and placed in a Suspended status within the CVRP Standard Assemblage for COVID-19 in the DMLSS AM Module. USAMMA-DOC questions or concerns will be directed to usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil. DLA questions and concerns will be directed to DSCPColdchain@dla.mil or paacoldchainteam@dla.mil.
- (4) Decrementing the COVID-19 Vaccine and ancillary kits from the CVRP Standard Assemblage in the DMLSS AM Module:

Note: In Accordance with the Inventory Management requirements, on-hand balances in the CVRP Standard Assemblage will be reported and decremented daily for the quantities of COVID-19 Vaccine vials and ancillary kits administered that day.

(a) The Customer or POC associated to the CVRP Standard Assemblage will provide a daily update to Logistics by 1500 hours local time via e-mail of how much COVID-19 Vaccine and ancillary kits were administered in the Unit of Sale Quantity as opposed to the doses administered to include manufacturer and specific lot number(s).

- (b) Logistics POC will decrement the applicable on-hand quantity based upon the daily notification provided by the customer or POC associated to the COVID-19 Vaccine and ancillary kits from the appropriate assemblage in the unit of sale quantity via the Out-Shipment Loss (SHL) Transaction. Air Force MEDLOG will perform an Issue Non-Routine (INR).
- (c) The MTF MEDLOG Division will process a SHL daily for the decrement of on-hand balances of COVID-19 ancillary kits consumed in proportion with the applicable amount of vaccines consumed. Air Force MEDLOG will perform an INR.
- 3. <u>REDISTRIBUTING THE COVID-19 VACCINE</u>. Redistribute COVID-19 Vaccine and associated ancillary kits in the DMLSS AM Module CVRP Standard Assemblage in accordance with USAMMA-DOC CONUS guidance or DLA OCONUS guidance, manufacturer, and CDC guidance on COVID-19 Vaccine storage, shipping and handling (e.g., CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations).

Note: USAMMA-DOC or DLA are the Release Authorities, which will provide approval notification, guidance, and shipping materials to the MTF performing the redistribution.

- a. The MTF performing the redistribution will:
- (1) Receive Release Authority approval and guidance to redistribute COVID-19 Vaccine and associated ancillary kits to the supported MTF(s).
- (2) The Release Authority will provide the MTF performing the redistribution with the guidance and shipping materials, if needed, for each shipment.
- (3) Execute the Service appropriate transaction below for the COVID-19 Vaccine and ancillary kits, and print the DD Form 1348-1A, Issue Release/Receipt Document.
 - (a) Air Force will utilize the INR transaction.
 - (b) All others services will utilize the SHL transaction.
- (4) Provide advance shipping information to USAMMA-DOC/DLA and the supported MTF MEDLOG.
- (5) Ship or transport the COVID-19 Vaccine and ancillary kits, and the DD Form 1348-1A to the supported MTF with all Quality Control information adhering to USAMMA-DOC/DLA, manufacturer, and CDC requirements.
 - b. The supported MTF will:
- (1) Coordinate with USAMMA-DOC/DLA and the MTF performing the redistribution and provide:

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- (a) The Ship-To address and POC.
- (b) Commercial (e.g., FEDEX) shipping account.
- (2) Upon receipt of the COVID-19 Vaccine and ancillary kit, will execute a DMLSS AM SHG Transaction into the CVRP Standard Assemblage and follow all applicable guidance under paragraph 2 of this enclosure.
- (3) Input all Quality Control information for the COVID-19 Vaccine and ancillary kits into the DMLSS AM CVRP Standard Assemblage Records.

4. MANAGE POTENTIALLY COMPROMISED COVID-19 VACCINES AND ANCILLARY KITS POST-RECEIPT

- a. All MTF(s) or DHA components and supported activities will complete a Director's Critical Information Requirements per Reference (i) and submit any updates to DHA-AD CS-Med Log-BusinessOps.
- b. Ensure COVID-19 Vaccine and ancillary kits are maintained in a working storage unit at proper temperature.
- c. Physically label compromised COVID-19 Vaccine and/or ancillary kits as "DO NOT USE," and place in a separate container apart from other products in the storage unit.
- d. Complete DHA Form 177, Potentially Compromised Temperature Sensitive Medical Products Worksheet and submit completed worksheet and all supporting documentation to the appropriate source of supply, USAMMA-DOC or DLA Troop Support Medical.
- e. DO NOT destroy, discard, or use COVID-19 vaccines or ancillary kits until released by the USAMMA-DOC and/or DLA. Comply with all disposition instructions from USAMMA-DOC and/or DLA for compromised COVID-19 material. If the USAMMA-DOC or DLA disposition determination is that the COVID-19 Vaccine and/or ancillary kits is unserviceable and directs the MTF to destroy, the MTF will follow the Destruction Process.

5. <u>DESTRUCTION PROCESS</u>

a. Per the CDC COVID-19 Vaccination Program Playbook - Medical Treatment Facilities (MTFs) available at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf and vaccination sites should dispose of COVID-19 vaccine and diluent waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste.

- b. The MTF will follow local regulatory procedures for destruction of COVID-19 materials using DMLSS AM destruction process.
 - c. The MTF will create and maintain destruction document, DD Form 1348-1A.

GLOSSARY

ABBREVIATIONS AND ACRONYMS

AD Assistant Director

AM Assemblage Management

C Celsius

CDC Centers for Disease Control and Prevention

CONUS Continental United States
COVID-19 Coronavirus Disease 2019

CVRP COVID-19 Vaccine Response Program

DHA Defense Health Agency
DLA Defense Logistics Agency

DMLSS Defense Medical Logistics Standard Support

EA each

INR Issue Non-Routine

LUM Lowest Unit of Measure

MEDLOG Medical Logistics
MILDEP Military Department

MTF Military Medical Treatment Facility

NSN National Stock Number

OCONUS Outside Continental United States

POC Point of Contact

SHG In-Shipment Gain SHL Out-Shipment Loss

TSMP Temperature Sensitive Medical Products

USAMMA-DOC U.S. Army Medical Materiel Agency Distributions Operations Center