Defense Health Agency
PROCEDURAL INSTRUCTION

NUMBER 6025.31
December 20, 2019

Healthcare Operations/Pharmacy

SUBJECT: Military Medical Treatment Facility Pharmacy Operations

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 (r), establishes the Defense Health Agency's (DHA) procedures to:

   a. Implement standardized and efficient Military Medical Treatment Facility Pharmacy Operations.

   b. Maintain best practices for medication management.

   c. Comply with applicable laws and regulations.

2. APPLICABILITY. This DHA-PI applies to the Military Departments, DHA, and the MTFs.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (a) through (f), that the DHA maintain and operate Pharmacy Services within MTFs.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. RELEASABILITY. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: 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 Reference (c).

8. FORMS. DHA Form 111, Formulary Change Request can be found and downloaded at: https://info.health.mil/cos/admin/DHA_Forms_Management/SitePages/Home.aspx

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Enclosures
1. References
2. Responsibilities
3. Procedures

Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs," 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) DHA Pharmacy Operations Division Coordinated Concept of Operations," August 21, 2013[1]
(e) DHA-Procedural Instruction 6025.04, "Pain Management and Opioid Safety in the Military Health System (MHS)," June 8, 2018
(f) DHA-Procedural Instruction 6025.08, "Pharmacy Enterprise Activity (EA)," August 14, 2018
(g) United States Code, Title 10
(h) Executive Order 13139, "Improving Health Protection of Military Personnel Participating in Particular Military Operations," September 30, 1999
(i) United States Code, Title 21
(j) Office of Management and Budget, "Memorandum for the Heads of Executive Departments and Agencies and Independent Agencies," July 22, 2016 [2]
(k) The Joint Commission, "National Patient Safety Goals," 2018[3]
(l) United States Pharmacopoeia, Chapter 795 "Pharmaceutical Compounding – Nonsterile Preparations," March 30, 2018
(m) United States Pharmacopoeia, Chapter 797 "Pharmaceutical Compounding – Sterile Preparations," July 28, 2018
(n) United States Pharmacopoeia Chapter 800 "Hazardous Drugs – Handling in Healthcare Settings," July 1, 2018
(o) United States Consumer Product Safety Commission, "Poison Prevention Packaging Act: A Guide for Healthcare Professionals," October 14, 2008
(p) DoD Instruction 1000.13, "Identification (ID) Cards for Members of the Uniformed Services, Their Dependents, and Other Eligible Individuals," December 14, 2017
(q) DHA-Procedural Instruction 6025.25, "Military Health System (MHS) Drug Take Back (DTB) Program," February 20, 2018
(r) United States Code, Title 44, Section 3301
(s) DoD Instruction 6490.03, "Deployment Health," June 19, 2019

[1]This reference can be found by calling the DHA Pharmacy Operations mainline at: 703-681-2890.
[2]This reference can be found at:
https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/pra_flexibilities_memo_7_22_16_finalI.pdf
[3]This reference can be found at: https://www.jointcommission.org/assets/1/6/2019_HAP_NPSGs_final2.pdf

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will:

a. Be responsible for the administration and management of each MTF, including policy and procedure development, direction for budgetary, staffing, information technology, and other health care administrative functions required to support Pharmacy Operations.

b. Exercise authority and responsibility over MTF Pharmacy Operations.

c. Support and sustain necessary functions to ensure continuity within MTF Pharmacy Operations.

2. ASSISTANT DIRECTOR, HEALTHCARE ADMINISTRATION (HCA). The Assistant Director, Healthcare Administration will ensure the necessary functions are in place to support compliance with this DHA-PI.

3. DEPUTY ASSISTANT DIRECTOR, HEALTHCARE OPERATIONS. The Deputy Assistant Director, Healthcare Operations will:

a. Monitor compliance with this DHA-PI through the DHA Pharmacy Operations Division (POD).

b. Solicit recommendations for Military Health System (MHS)-wide improvements to MTF Pharmacy Operations and coordinate recommendations through the Enterprise Solutions Board.

4. CHIEF, DHA POD. The Chief, DHA POD will:

a. Identify and develop more specific processes and procedures as needed in accordance with this DHA-PI.

b. Provide management oversight of MTF Pharmacy Operations.

c. Provide overarching policy guidance, strategic direction, and develop criteria to establish metrics.

d. Exercise overall responsibility for compliance with applicable legal and regulatory standards, maintain quality assurance, and enforce DoD, MHS, and DHA policies and procedures.

e. Define standard Pharmacy Operations quality assurance performance metrics; report findings to MHS leadership through governance councils designated by the Director, DHA.

f. Collaborate with the Service's Pharmacy Consultants to provide direction and support through the DHA Pharmacy Workgroup.

5. DHA PHARMACY MARKET CONSULTANTS. The DHA Pharmacy Market Consultants will:

a. Provide DHA POD's market level administrative oversight of MTF Pharmacy Operations.

(1) In accordance with References (a) through (r), ensure market MTF compliance with applicable legal, regulatory, and professional standards, maintain quality assurance, and enforce DoD, MHS, and DHA policies and procedures.

(2) Seek guidance from DHA POD, MTF Management Branch Chief and notify MTF Commander/Director if concerns with compliance arise.

b. Monitor the performance of market MTF pharmacies, develop and define a plan for ensuring compliance with applicable legal and regulatory standards, quality assurance, along with DoD, MHS, and DHA policies and standardized procedures.

c. Report directly to the DHA POD, Chief, MTF Management Branch.

d. Advise Market Directors on all pharmacy actions within their market.

e. Maintain current knowledge regarding best practices for Pharmacy Operations, including operating in compliance with applicable laws and regulations, accreditation standards defined by the current accrediting body (e.g., The Joint Commission (TJC), and standards of care within the community.

f. Coordinate with MTF pharmacy leaders and staff along with DHA POD staff to develop/implement standardized best practices throughout all pharmacy operations.

6. COMMANDER/DIRECTOR, MTF. The Commander/Director, MTF, will:

a. Appoint members of the MTF Pharmacy and Therapeutics (P&T) Committee per paragraph 7c.

b. Exercise supervision over all phases of day-to-day Pharmacy Operations and medication management in accordance with DoD, MHS, and DHA policy, and initiatives in accordance with References (a) through (r). This includes:

(1) Ensuring direct pharmacy supervision is exercised by a pharmacist (military officer or civilian) licensed to practice pharmacy or a physician operating as officer-in-charge or other licensed independent practitioner is designated as the officer-in-charge when no pharmacist is available during normal operating hours of the pharmacy. Pharmacists must have graduated from a College of Pharmacy accredited by the Accreditation Council for Pharmacy Education or have a Foreign Pharmacy Graduate Examination Committee Certification and have an active unrestricted license to practice pharmacy in one of the 50 United States, District of Columbia, Puerto Rico, or a U.S. territory.

(2) Monitoring the compliance of the MTF pharmacy to established policies and procedures and applicable law and regulations in accordance with TJC and DHA standards and TJC National Patient Safety Goals®.

(3) Evaluating MTF pharmacy performance with respect to cost-effectiveness, patient safety, and the provision of appropriate and safe drug therapy.

(4) Identifying and pursuing opportunities for performance improvement and value-added activities aligned with higher level guidance and initiatives, to include: efforts to minimize or eliminate errors, increase access as appropriate, and enhancing patient satisfaction.

(5) Having the ultimate responsibility for the security of controlled substances and oversight over the controlled substance inventory program.

(6) Ensure that Chief, Pharmacy services and subordinate staff keep abreast of new developments in the field of pharmacy and serve as subject matter experts.

(7) Monitor and evaluate staffing levels, funding, and pharmacy scope of practice to ensure alignment with mission requirements.

7. MTF P&T Committee. The MTF P&T Committee will:

a. Meet as often as required, but no less frequently than four times per year. The MTF P&T Committee should be multidisciplinary to the extent practical, and must consist of, at a minimum, one pharmacist, one physician, and one nurse. The chair of the committee must be a licensed independent practitioner and the co-chair must be a pharmacist (i.e., Chief, MTF Pharmacy Services).

b. Develop and recommend policies and procedures relating to the selection, distribution, handling, use, and administration of drugs and diagnostic materials in accordance with DHA policy and procedures, Federal regulations, and accreditation standards.

c. Evaluate clinical, safety, and pharmacoeconomic data on medications or preparations requested for use in the MTF which have not been evaluated by the DoD P&T Committee. MTF P&T Committee may not evaluate or place on formulary those medications designated non-formulary (Tier 3) or not covered (Tier 4) by the DoD P&T Committee.

d. Refer to nationally recognized standard of care practices to develop policies facilitating the safe use of medications in the facility, including the initial and annual review and approval of pharmaceuticals stored outside of the pharmacy that are able to be administered without prospective pharmacy review (e.g., override lists and high-risk drugs).

e. Review initial medication forms (including electronic and preprinted paper version inpatient order sets) and must review all forms a minimum every 2 years. May not exceed biennial review.

f. Review and approve prescribing protocols for providers with limited prescribing privileges (e.g., optometrists, pharmacists, nurses, and Independent Duty Hospital Corpsmen), every 2 years.

g. Monitor the medication use evaluation program and make recommendations to optimize drug use to include Non-Formulary Drug Requests (NFDRs) for trends, approval rates, usage, cost, and clinical indications.

h. Recommend safety guidelines with directions for use in prescribing medicines, including developing a list of "DO NOT USE" abbreviations, acronyms, or symbols that must not be used in any written medication management-related document and developing a list of high alert and look-alike sound-alike medications unique to each MTF, as appropriate.

i. Coordinate with and appoint a representative to serve on the MTF Patient Safety Committee and other applicable MTF committees.

8. CHIEF, MTF PHARMACY SERVICES (or other approved title). The Chief, MTF Pharmacy Services (or other approved title), will:

a. The Chief will oversee all of pharmacy operations, to include inpatient and outpatient services in accordance with References (a) through (r), to ensure MTF Pharmacy compliance with applicable legal, regulatory, and professional standards, maintain quality assurance, and enforce DoD, MHS, and DHA policies and procedures. Oversee efforts of the MTF Pharmacy to recognize, identify, select, order, prepare, safeguard, evaluate, and dispense all pharmaceutical substances used in preventative, curative, and diagnostic medicine.

b. Maintain current knowledge regarding best practices for Pharmacy Operations, including operating in compliance with applicable laws and regulations, accreditation standards defined by the current accrediting body (e.g., TJC), and standards of care within the community.

c. Assess effectiveness of staffing levels, funding, and pharmacy scope of practice to ensure alignment with mission requirements and report issues to Commander/Director, MTF. Additionally, issues should be reported for awareness to the DHA Pharmacy Market Consultant assigned to that MTF's Market.

d. Ensure that MTF personnel conduct and document auditing and compliance activities.

e. Ensure documentation of competency assessment of pharmacy staff.

f. Be responsible for the coordination and development of MTF specific pharmacy policies, contingency plans, checklists, and procedures as required to augment DHA policies.

9. MTF PHARMACY STAFF. The MTF Pharmacy Staff will:

a. In accordance with References (a) through (r), adhere to the policies and practices of the DHA and MTF.

b. Maintain all necessary licenses, certifications, training and current knowledge of best practices for their role.

c. Provide consistent, effective, safe, high quality patient care by the most cost-effective means possible.

ENCLOSURE 3

PROCEDURES

1. PHARMACY SUPPLY AND SUPPORT

a. Pharmacy Logistics

(1) The MTF will follow standardized processes reviewed by DHA Pharmacy Market Consultant to prevent or deter diversion during the ordering, delivery, and receiving of medications.

(2) MTFs must utilize an inventory management ordering system (e.g., Defense Medical Logistics Standard Support), to manage credit memos and order pharmaceuticals in accordance with References (i) sections 1301.23 and 1301.25.

b. Formulary Management

(1) All MTFs will implement and adhere to formulary decisions of the DoD P&T Committee, including Prior Authorization (PA) criteria, quantity limits, and medical necessity criteria in accordance with Reference (g) section 1074g.

(2) MTFs are prohibited from adding medications to their local formulary listed as Non-formulary (e.g., Tier 3), by the DoD P&T Committee.

(3) When the Director, DHA removes medications from the benefit and places them in a not-covered status (e.g., Tier 4), MTFs may not carry or dispense those medications.

(4) MTF pharmacies will not fill non-formulary (DoD Tier 3) medications from non-MTF providers unless the patient has been referred to that provider by the MTF. MTF pharmacies are encouraged to educate patients not empaneled to the MTF about the requirement to use the Home Delivery Pharmacy instead of Retail Pharmacies for obtaining most non-formulary (Tier 3) medications.

(5) NFDR and PA requests processed by the local MTF will be initiated, written, and submitted by the prescribing provider for the patient. These NFDR and PA requests will include documentation of the review and approval by a pharmacist. The intent is the provider provides patient specific information that substantiates the clinical need required for a PA or a non-formulary medication and the specific reason(s) why a formulary option is clinically inappropriate. Documentation for NFDRs may be accomplished by using the applicable TRICARE Medical Necessity Request or an appropriate MTF approved form. Documentation for PA requests may be accomplished using the applicable TRICARE PA Request. NFDR and PA Requests will encompass criteria developed by the DoD P&T Committee and included in TRICARE PA or Medical Necessity Request criteria. A pharmacist must review and ensure criteria are met before local approval for dispensing. Criteria information can be found on the

following website at: https://health.mil/formulary. All MTF NFDR and PA form formats must be reviewed a minimum every 2 years and may not exceed biennial review.

(6) Changes to the DoD Uniform Formulary are requested using DHA Form 111 Formulary Change Request and submitted to the DHA POD, Formulary Management Branch via fax or e-mail. This information can be found on the following website at: https://health.mil/formulary.

(7) MTF Pharmacy Chiefs will ensure compliance with national pharmacy contracts and "Brand to Generic" conversions established by The Defense Logistics Agency in conjunction with the Chief, DHA, POD and the DoD P&T Committee. MTF directors will not permit prescribers or pharmacy industry initiatives to supplant or circumvent contract requirements. Only medications which have been approved by the Food and Drug Administration (FDA) are authorized for use in MTFs except for investigational use.

(8) Written policy for the procurement, utilization, and storage of Investigational Drugs must be developed in accordance with References (g) section 1107 and (i) section 312.3, applicable laws, regulations, and investigational research protocols.

(a) The principal investigator, research team, pharmacy leadership, and MTF leadership must ensure all requirements and regulations are met in maintaining and administering these products and all security requirements are maintained in accordance with References (g) sections 1107 and 1107a and (i) section 312.3, applicable law and regulations.

(b) References (h) and (g) sections 1107 and 1107a, must be followed with respect to obtaining consent from military members. These statutory provisions contain certain requirements that must be met before military members may be given a product authorized for either emergency use or investigational drug use as defined by Reference (i) section 312.3.

c. Inventory Management

(1) Chief, MTF Pharmacy Services will ensure the inventory stock levels of pharmaceuticals on-hand are neither excessive nor too low and based on historic utilization patterns, potential urgency of medication use, administrative costs, and known limitations of the supply system.

(2) When only a month and year of expiration are provided for a drug, the drug may be used through the end of that month.

(3) Facilities will minimize the potential for the dispensing of expired, recalled, adulterated, or suspected counterfeit drugs through effective inventory management.

(a) All expired, damaged, or contaminated medications will be inventoried, removed, and quarantined in an isolated area separate from bulk stock.

(b) The storage area and container for expired medications will be clearly marked and separated from serviceable medications. Each facility must have a written procedure for FDA or manufacturer drug recalls, market withdrawals, and safety alerts.

(4) Pharmacy staff will conduct pharmacy inventory expiration date checks at least monthly. Pharmaceutical items discovered during the inspection which expire within 90 days for outpatient dispensing or within 30 days for products used within the facility will be removed from inventory, isolated, and securely stored in an area away from unexpired pharmaceuticals. The Chief, MTF Pharmacy Services may make exceptions to this timeline for high cost and short supply medications. MTF staff assigned to patient care areas will conduct at least monthly inspections of any medications stored within their spaces and not housed in a pharmacy-owned automated dispensing cabinet and will remove and return to pharmacy all items which expire within 30 days.

(5) Pharmacy staff will perform monthly checks of all wards and clinics where medications are dispensed, administered, or stored, to verify medications are stored according to current established standards and applicable law and regulations.

(6) MTF staff assigned to patient care areas will conduct end of shift reconciliation of controlled substance medications and appropriately account for receipts, utilization, waste, and turn-ins. Discrepancies will immediately be reported to the supervisor of that patient care area, and if the discrepancy can't be reconciled it should immediately be reported to the Chief, MTF Pharmacy Services and to the appropriate MTF leadership. At a minimum, 100 percent physical inventory of all controlled substances will be conducted by each patient care area daily if using manual systems and weekly if using automated dispensing cabinets that provide a perpetual inventory.

(7) The MTF Director may require a monthly sampling and/or a risk-based approach for auditing non-controlled medication inventories until a perpetual inventory system is implemented. A risk-based approach focuses on identifying drugs with high cost, high volume, or high abuse potential. Results will be reported to the MTF P&T Committee.

(8) Drug samples must not be maintained at MTFs.

(9) Security measures will be put in place to adequately prevent unauthorized entry into the pharmacy. Such measures may include, but are not limited to, utilization and maintenance of a logbook for visitors entering and leaving, and appropriate pharmacy key accountability. The use of a surveillance camera system is advisable. Local policy will determine which categories of personnel may be permitted access to secure non-controlled drugs or to carry keys to secure areas.

(10) Automated pharmacy and medication systems should be utilized to the maximum extent practical.

(a) The MTF will ensure acquisitions for automation and/or technology solutions adhere to standardization goals for DHA, consistent with requirements of DHA-IPM 18-013 or

its successor. The site must validate purchases align with centralized contract purchases, and adherence to defined regional or DoD decisions for automation/ technology is met. All pharmacy automation and medication systems must interface with existing medical information systems and meet all facility regulations and standards. Whenever a conflict in requirements occurs, the pharmacy will use the more stringent requirement.

(b) Each MTF utilizing an automated system will have a written plan for its safe and effective use, including a plan to reduce the risk of patient medication harm and economic loss through medication misuse, pilferage, and drug diversion.

1. The Chief, Pharmacy Services will develop the plan in collaboration with all disciplines in the MTF affected by the system. The plan will include the monitoring, usage, surveillance, and documentation of medications accessed through automated systems.

2. Each MTF will have a written contingency plan for maintaining timely medication distribution, security, and documentation when system interruptions occur.

(c) Automated systems will be properly maintained, updated, and serviced according to service agreements. These agreements should be universal and standardized across the enterprise to the greatest extent possible.

d. Record Numbering and Filing

(1) All hardcopy prescriptions and orders filled by the pharmacy will be placed in files established and maintained by the pharmacy. Three or more series of numbers will be used; one series for Schedule II controlled substances, alcohol, and alcoholic liquors; one series for Schedules III, IV, and V controlled substances; and one series for all others. These records must be maintained for at least 2 years.

(2) Pharmacies may also develop plans to store all prescriptions into an electronic database in accordance with References (i) section 1304.04, (j), and (r) section 3301. The electronic application must be capable of printing out or transferring the records in a format readily understandable to a Drug Enforcement Agency (DEA) or other law enforcement agent. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

2. INPATIENT PHARMACY OPERATIONS

a. Sterile Product Preparation

(1) A pharmacist will supervise the preparation of intravenous admixtures by pharmacy staff and ensure the requirements of References (m) and (n), for the preparation of sterile products are met. MTF leadership will ensure non-pharmacy personnel preparing admixtures outside of the pharmacy are trained to follow correct aseptic technique and meet all accreditation and Federal standards.

(2) Pharmacy leadership will develop and maintain personnel training and evaluation in aseptic technique. Environmental quality and control monitoring are maintained to meet the requirements of References (m) and (n).

(3) Pharmacy leadership will ensure all staff who conduct sterile product preparation are trained on the handling, storage, and transport of sterile products in accordance with References (m), and (n).

b. Labeling of Medication

(1) Pharmacy is responsible for labeling medications except when a non-pharmacy staff member removes a medication from its labeled container and it is not immediately administered (e.g., nurses draw medications into syringes and then label them to prep for a procedure). At a minimum, the medication label must include the generic drug name, brand name (if combination drugs), drug unit concentration/strength, and the beyond use date.

(2) A standardized process must be developed locally to allow for efficient and complete relabeling for medications not dispensed in their original containers to wards and clinics.

c. Dispensing

(1) The primary means of inpatient drug distribution in fixed inpatient treatment facilities will be the unit-dose system or automated dispensing cabinet system, which must include pharmacist review of the provider's orders and monitoring inpatient medication needs.

(2) The MTF must have a policy for the process whenever providers authorize and order medications for bedside use or for self-administration.

(3) All medication orders must be reconciled when a patient transfers to a different level of care. Accreditation standards regarding National Patient Safety Goals in accordance with Reference (k) and medication reconciliation procedures must be followed. Except in emergency or emergent situations allowed in accreditation standards, medications will not be dispensed until a properly written or electronic order is received and recorded in the patient's medication profile.

(4) Pharmacists will review all inpatient orders. Oral or telephone orders will only be used in emergency or emergent situations allowed in accreditation standards and must be immediately transcribed to written form, either hard copy or electronic by a pharmacist and read back to the provider for verification and documented as oral or telephone.

(5) Pharmacists will retrospectively review all pharmaceutical orders occurring after normal duty hours to ensure the dispensed medications are annotated in the patient's medication profile.

d. Collection of Medications from Patients

(1) All medications brought into the hospital by patients will be given to a member of the

patient's family or escort to return to the patient's home for safekeeping. If the patient does not have an escort, nursing personnel must collect the medication, store, and secure in a pharmacy approved location.

(2) When the pharmacy does not stock the medication, the provider may authorize use by writing a valid inpatient order and indicating use of the patient's own medications ("patient may take own medication" following the order). These medications will be verified, stored, and dispensed by the pharmacy.

3. OUTPATIENT PHARMACY OPERATIONS

a. Labeling

(1) All labels will be prepared and affixed to each prescription according to applicable law and regulations.

(2) Auxiliary labels will be affixed according to the pharmacist's professional judgment and the current standard of pharmacy practice.

b. Prescriptions

(1) Prescriptions must be electronic order entry, handwritten in ink, indelible pencil, typewritten, or a printed form generated from a computerized program. Duplicate, carbon copy, photographic reproduction, preprinted, or rubber-stamped orders are not valid prescriptions for controlled substances. For all Schedules II–V controlled substance prescriptions, the prescriber's signature will be handwritten or comply with the DEA electronic prescribing requirements.

(2) Telephone or oral prescriptions will not be accepted, except in an emergency or under extraordinary situations, and only when received directly from an authorized prescriber. Telephone and oral prescriptions must be immediately transcribed to written form, either hard copy or electronic by a pharmacist and read back to the provider for verification. Documentation of the read back order is required. When electronic prescribing is unavailable, a licensed pharmacist has the authority to allow Schedules III-V controlled substance prescriptions to be faxed from a provider. Before a faxed prescription is accepted, all data integrity, patient privacy, security, and audit capabilities must be established. An accepted faxed prescription will be considered the original order.

(3) Prescriptions will be personalized. All medications for a patient must be entered into their specific electronic patient medication profile and/or a separate hardcopy prescription for each patient must be issued.

(4) All items provided to outpatients will be dispensed in accordance with Reference (i).

(5) The DoD Pharmacy Benefit Manager's adjudication system screens all patient outpatient medications against their current medication profile (MTF, TRICARE retail network, and home delivery), for drug interactions, drug overlaps, drug dosage, and patient compliance.

(6) MTF practitioners will not be directed to countersign or rewrite NFDRs for prescriptions written by non-MTF providers.

c. Dispensing

(1) MTF pharmacies must fill or provide the opportunity to have filled, all MTF formulary prescriptions and approved non-formulary requests written by its providers. Unapproved non-formulary requests may be filled using home delivery benefits or a retail pharmacy if covered by the patient's TRICARE benefit. MTF pharmacies will be responsible for filling prescriptions for those empaneled patients referred to the network.

(2) MTF pharmacies will ensure TRICARE Formulary PA and Medical Necessity requests have been reviewed prior to processing formulary and non-formulary medications for all beneficiaries.

(3) Pharmacy personnel will not fill prescriptions that are illegible, contraindicated, or if there are questions regarding dosage, interactions, allergies, or method of administration. Pharmacy personnel may clarify these prescriptions with the prescriber and fill the prescription only after patient safety concerns have been addressed and documented on the hardcopy or electronic prescription record.

(4) When a pharmacy receives a prescription refill request, but no further refills are authorized, and the patient is unable to readily obtain a new prescription, the pharmacist may use professional judgement, consistent with applicable federal and state law, to dispense a one-time limited gap fill of a maintenance medication. The amount should be reasonable to maintain the patient until the patient can contact the prescriber, but not greater than a 30-day supply. Other restrictions may apply including the emergency refill of controlled medications.

(5) All prescriptions originally filled at one MTF may be refilled at another MTF. MTFs with pharmacy data processing systems that do not access the same prescription records electronically, will notify the original facility of the transfer of remaining refills, thus voiding any remaining refills at the original MTF. An electronic record will be made of the prescription such as: Transferred to "(name of MTF)" with date of transfer. The pharmacy staff will transfer prescriptions to and from all pharmacies in a timely and responsive manner. Transfers are done between pharmacists and/or technicians according to applicable laws and regulations. Care should be taken to prevent therapy interruption or compromise Sole Prescriber/Provider agreements. Review your MTF's P&T guidance for information about the Sole Prescriber/Provider Program. The pharmacy will approve non-formulary medication transfers from other DoD facilities that have met TRICARE requirements.

(6) Refills for non-controlled maintenance medications may be processed when 75 percent or more of the prior prescription has been used. A pharmacist or pharmacy technician may authorize an early refill for non-controlled medications, under special circumstances (patient on travel out of the area, disasters, or contingency operations).

(7) A process designed to ensure eligibility of outpatients will be established. The pharmacy will follow MTF guidance when encountering a non-eligible patient. These procedures should cover, at minimum, the following items:

(a) Patients will be asked to present their Uniformed Services photo identification card or facsimile of the identification card upon receiving the prescription(s). In the absence of a Uniformed Services photo identification card, the MTF pharmacy will refer the individual to Patient Administration for an eligibility statement or locally develop procedures to verify patient's name, date of birth, and Defense Enrollment Eligibility Reporting System eligibility.

(b) Some persons may be eligible for care but not enrolled in the Defense Enrollment Eligibility Reporting System and/or may not be issued an identification card. The pharmacy will follow MTF guidance to verify eligibility for such patients.

(c) If an emergency exists, pharmacy personnel will dispense prescription(s) before verifying eligibility; however, pharmacy personnel must properly identify the patient using the two DoD-recognized patient identifiers (i.e., patient's name and date of birth), prior to dispensing. Questions concerning eligibility for Pharmacy Services at the MTF will be referred to Patient Administration.

(d) Photocopying military identification cards to facilitate medical care processing is an example of authorized photocopying of Uniformed Services photo identification cards (Enclosure 3, Section 2.a of Reference (p)). Facsimile includes a photocopy, digital picture, or electronic image. The pharmacy will follow MTF guidance when an identification card scanner fails to scan the identification card or a facsimile of the card.

(e) Patients may authorize adult third-parties to pick up their prescriptions. An individual acting as the patient's representative can pick up a prescription for the patient with proper patient authorization as determined locally.

(8) Pharmacists and trained pharmacy technicians will provide drug therapy information in as private a setting as possible to patients or legally authorized representatives.

(9) When applicable, active duty requiring resupply of maintenance medication while deployed will be enrolled in the TRICARE Deployment Prescription Program (DPP) and provided contact information for updating their mailing address once at the deployed site. Pharmacy personnel will review refill prescription requests for accuracy and forward completed DPP prescription request to the DPP for filling and mailing. Prior to deployment, the Services and other DoD components that deploy units or individuals will identify deployable personnel and ensure they are medically ready, including provision of appropriate force health protection prescription products, pursuant to DoDI 6490.03.

(10) When emergency contraceptives are prescribed, they must be documented in the medical record and the electronic health record medication profile to screen for overlaps and contraindications before dispensing. ED distribution of FDA-approved emergency contraceptive

medications should be under the supervision of a privileged medical provider or pharmacist in accordance with local MTF policy.

(11) Bulk Compounding: Pharmacy staff will compound pharmaceutical preparations using formulas from official compendia, other references or locally developed formulas only when a quality product can be ensured, and a commercial product is unavailable. Records of compounded products will be maintained. All non-sterile compounding will follow Chapter 795 of Reference (l), and FDA requirements. MTF pharmacies will follow the P&T Committee recommendations for compounding.

(12) After-hours dispensing:

(a) When the pharmacy is closed, drugs prescribed to complete an acute therapeutic regimen may be dispensed by a provider directly from the clinic or ED.

(b) Labels for prescription medications prepared by non-pharmacy personnel (clinic re-issue or after-hours clinic), will comply with applicable law and regulations.

(c) The prescriber must check all prescription medications before they are given to the patient.

(d) When the pharmacy is closed, clinic or ED staff must have access to an on-call pharmacy staff member.

(e) Providers dispensing medications outside of the pharmacy (i.e., after-hours clinics), will annotate the medication(s) dispensed in the patient's Medical, Dental, Emergency Care and Treatment records.

(13) Wait Time Definition: Total wait time consists of the initial time from when the ticket is printed at the check-in kiosk to when the ticket is first called to the dispensing window to notify a patient their prescription(s) are ready for counseling and pick-up.

4. CONTROLLED SUBSTANCES

a. Inventory Process

(1) Pharmacies will conduct a 100 percent inventory of the pharmacy working stock each duty day for medications placed in Schedule II of the DEA Controlled Substance Act of Reference (i) sections 1308.11-1308.15 in accordance with Reference (i) section 1304.11.

(2) Minor overages and shortages will be recorded through inventory adjustments to the inventory record. All other losses will additionally be reported to the pharmacy chief, inventory program lead, and DEA as appropriate. The pharmacy chief and/or the inventory program lead will trend all adjustments and losses and report findings through the Chain of Command. The MTF will develop a program that will inventory and conduct inspections on at least a quarterly

basis on controlled and other medications having a potential for diversion or abuse. The individuals assigned to inspect will not be directly responsible for the substances being inventoried.

(3) The inventory program lead, and pharmacy chief will separately conduct periodic reviews to detect controlled substances diversion or abuse, along with periodic inventory assessments at all locations.

(4) All pharmacies with an electronic data entry system and a controlled substance vault should use the electronic inventory provided in the vault functions of the data entry system. All pharmacies, without a data entry system, will keep a perpetual inventory on all controlled substances.

(5) All controlled substances should have maximum inventory stock supply limits set by a pharmacist.

(6) MTF P&T Committee may designate items subject to potential abuse or diversion as a locally controlled substance (i.e., drugs with high potential for diversion), in which case all controlled substance inventory requirements apply.

b. Accountability of Controlled Substances

(1) MTFs will develop procedures and reports to audit and monitor controlled substances and other locally controlled substances from receipt into inventory through dispensing to outpatients or administering to inpatients.

(2) An officer or civilian employee who has been designated by the MTF Leadership to purchase or procure controlled substances or preparations for official use, must be so designated on the MTF's registration filed with the Registration Branch, DEA, and Department of Justice.

(3) Custodial responsibility for controlled substances and those drugs designated as locally-controlled drugs by the MTF leadership, must be vested in the appropriate MTF entity (pharmacy officer, a civilian pharmacist, a commissioned officer, or senior member of a subordinate clinic), who is appointed in writing.

(4) Conduct a complete and accurate inventory of all controlled substances within the MTF every 2 years on 1 May (or the first duty day thereafter) of odd-numbered years.

c. Prescribing

(1) Each controlled substance prescription must be a separate document for documentation and filing purposes. The original of a controlled substance prescription written on a prescription in combination with other medications should be copied, with the original filed in the controlled substance file and the copy filed with the non-controlled prescriptions.

(2) All eligible, credentialed healthcare providers must obtain a DEA number in addition to their National Provider Identifier number.

(3) No authorized provider may prescribe or furnish a controlled substance for themselves or members of their immediate family.

(4) Providers must prescribe controlled substances only for patients under their direct care. Only under extraordinary circumstances will controlled substances be prescribed for a patient that was not personally evaluated by the prescriber at the time a controlled substance was prescribed.

(5) Prescribers will check complete controlled substance histories, to include state prescription drug monitoring programs (PDMPs) when appropriate, for informed decision making.

(6) Opioid prescribing quantities should follow the guidelines outlined in Reference (e). Medications to treat Attention Deficit Hyperactivity Disorder may be filled for quantities up to a 90-day supply with no refills. Schedules III-V non-opioid controlled substance prescriptions may be filled for quantities up to 90-day supply with refill(s); not to provide more than a 6-month supply over the life of the prescription.

(7) Schedule II controlled substance prescriptions, originally written electronically at one DoD MTF, may be electronically forwarded, filled and dispensed at another MTF if the pharmacy data processing systems access the same prescription records, and verification is made that the prescription was not dispensed and received by the patient (or his or her representative), at the originating MTF.

(8) Refills or renewals for Schedules III–V controlled substance prescriptions may be processed no earlier than when 75 percent or more of the prior prescription has been used or at pharmacist's discretion. A pharmacist can authorize early refills and renewals for controlled substances, after contacting the patient's provider and/or conducting a review of the patient profile to ascertain there is no concerning pattern of receiving early refills or enrollment in controlled substance therapy monitoring program.

d. Securing Drugs

(1) Controlled substances must be stored at a minimum in a securely locked cabinet of substantial construction. Automated dispensing equipment that collects, controls, and maintains all transaction information may be used. Storage is within restricted access areas of the MTF.

(2) The pharmacy chief determines which pharmacy staff will have access to controlled substances, to include consideration of prior history of theft or diversion. Access to controlled substance storage is above and separate from access to the restricted access area of the MTF.

e. Reporting Theft or Loss. The pharmacy chief will:

(1) Notify the Chain of Command, and as appropriate the DEA Field Division Office in their area, in writing, within 1 business day of the determination of theft or significant loss of any controlled substance; complete and submit DEA Form 106 on-line as required by the DEA.

(2) Report any unresolved controlled substance medication inventory discrepancies to the inventory program lead and appropriate higher authority.

f. Deterioration/Disposal

(1) The pharmacy chief will dispose of controlled substances using contracts for waste and for reverse distribution.

(2) Return of expired Schedules II–V controlled substances and locally controlled drugs will be accomplished through a contracted reverse distributor that is authorized to perform this function by the DEA.

(3) Products that are not returnable (such as products that have deteriorated and are not usable, are of questionable purity or potency, or have had their identity compromised), through the contracted reverse distributor must be inventoried for destruction, and when destroyed, removed from the inventory.

(4) Appropriate modification of electronic inventories must be conducted at the time deteriorated inventory is segregated from the regular inventory. A separate inventory of controlled substances awaiting destruction/return must be maintained.

(5) The MTF must not accept returns of medications dispensed to the ultimate user (the patient). MTF may refer patients to use an MTF or local DEA-compliant collection or mail back program.

g. Dispensing

(1) Pharmacists may dispense Schedules II-V controlled drugs from automated dispensing equipment that meets the approved requirements.

(2) The pharmacy will serve as the source from which wards/clinics and other departments within an MTF obtain controlled substances for use in connection with the treatment of patients.

(3) For outpatient prescriptions, a label with a clear, concise warning Federal law prohibits transfer of the controlled substance to any person other than the patient for whom it was prescribed must be affixed to the containers.

h. PDMP. Enrollment into the DoD PDMP is mandatory for pharmacists. A PDMP query is recommended:

(1) When a new or renewal opioid prescription is dispensed with the following

exceptions.

(a) Quantity dispensed is a 72-hour or less supply.

(b) Patient receiving oncological treatment or is terminal and discontinued curative treatment.

(2) When the pharmacist is suspicious of patient abuse, misuse, or diversion.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

DEA	Drug Enforcement Agency
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DPP	Deployment Prescription Program
ED	Emergency Department
FDA	Food and Drug Administration
MHS	Military Health System
MN	Medical Necessity
MTF	Military Medical Treatment Facility
NFDR	Non-Formulary Drug Request
PA	Prior Authorization
P&T	Pharmacy and Therapeutics
POD	Pharmacy Operations Division
PDMP	Prescription Drug Monitoring Program
TJC	The Joint Commission
USP	United States Pharmacopeia

PART II. DEFINITIONS

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

beneficiaries. Individuals who have been determined to be entitled to or eligible for pharmacy benefits and therefore authorized treatment in an MTF or under DoD auspices.

Chief, MTF Pharmacy Services. Individual responsible for managing MTF Pharmacy Services and Operations. Normally, this individual is a military pharmacy officer or government employee pharmacist.

controlled substance. Drug or chemical whose manufacture, possession, or use is regulated as a Schedules I-V substance by the DEA.

Formulary Medication. List of preferred medications that a committee of pharmacists and physicians deems to be the safest, most effective and most value added.

Inventory Program Lead. A staff member or team that is not involved in the prescribing, dispensing, or administering of medication who are assigned the responsibility to conduct inventories of controlled substances within the MTF and try and determine real or potential diversion of these substances. This team may be referred locally as Controlled Substance Inventory Board or disinterested party.

Investigational Drug**.** A new drug not approved by the FDA for general marketing and human use, intended solely for investigational use by experts qualified by training and experience to investigate the safety and effectiveness of drugs, or a drug approved by the FDA for use as outlined in the package insert whose indication, dose or route of administration differs significantly from its recommended use.

Licensed Independent Practitioner. Individual permitted by law and the organization to provide care and services without direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges.

P&T Committee. Group responsible for developing medication formularies and rules associated with those formularies.

PA. Requirement that the provider obtain approval before a specific medication is covered from a health insurance standpoint.

prescriber. A licensed medical care provider who has the authority to write prescriptions for medications.