Change 163
Manual of the Medical Department
U.S. Navy
NAVMED P-117

5 Mar 2018

To: Holders of the Manual of the Medical Department

1. This Change. Completely revises Chapter 21, Pharmacy Operation and Drug Control.

2. Summary of Changes. This change:

a. Removes references to State law that may not be applicable to a Federal medical treatment facility.

b. Adds electronic order entry as a means of prescription entering from the civilian sector.

c. Reflects updated Drug Enforcement Administration language.

d. Expands time and quantity limitations for filling and refilling controlled substance prescriptions.

e. Provides clearer guidelines around inventory controls for soon-to-expire items.

3. Action

a. Remove Chapter 21 and replace with the revised Chapter 21.

b. Record Change 163 in the Record of Page Changes.

C. FORREST FAISON III
Chief, Bureau of Medicine and Surgery

Chapter 21

Pharmacy Operation and Drug Control

Chapter 21
CONTENTS

Section I
Pharmacy Administration

21-1 Facilities (Regulatory)

(1) Naval medical treatment facilities (MTF) dispensing drugs range from large hospitals to support stations aboard the ships of the fleet and ashore. The overall mission of each facility, in addition to regulatory and accreditation authority, will determine the type and quantity of pharmacy personnel assigned and the drugs to be stocked. Established national pharmacy practice standards will be utilized as guidelines for pharmacy operations.

21-2 Personnel (Regulatory)

(1) Pharmacists must have graduated from an Accreditation Council for Pharmacy Education (ACPE) certified College of Pharmacy or have a Foreign Pharmacy Graduate Examination Committee certificate and have an active license in one of the 50 United States, the District of Columbia, or Puerto Rico. The civilian standard of care requires a pharmacy to operate only under the direct supervision of a licensed pharmacist. A licensed pharmacist will provide professional oversight of all pharmacy services at all fixed MTFs (Budget Submitting Office (BSO) 18) in the United States and overseas where a pharmacy is operated. The intent of this section is to ensure the Navy is consistent with civilian and accepted standards of practice.

(2) The number of pharmacists and technicians assigned to a facility is determined by the Activity Manpower Document. The Bureau of Navy Medicine and Surgery (BUMED) pharmacy staffing standard can be utilized to calculate additional pharmacy resources required to meet increasing workload or scope of services. The standard is based on several workload factors including: number of prescriptions dispensed and scope of services provided. The hours of operation also need to be part of the staffing decision. If the complexity of services provided at the clinic is high, then the standard of care calls for a pharmacist to be available to supervise the pharmacy operation, offer provider and patient consultation, and review all prescriptions prior to dispensing.

(3) At fixed MTFs where workload or complexity does not necessitate a full-time pharmacist, pharmacies may be operated by:

(a) Using the outpatient telepharmacy option (such as a licensed pharmacist at a central pharmacy site checks outpatient prescriptions prior to dispensing to the patient at a telepharmacy site through the use of video conferencing technology. This technology must be able to support two-way communication between the pharmacist and the patient). This solution is meant for low-volume, low-complexity pharmacies where less than 50 prescriptions per day require verification. In addition, the technology is meant for emergencies or when temporary coverage is needed for prescription verification.

(b) Utilizing active duty (AD) or prior AD pharmacy technicians (such as Navy Enlisted Classification (NEC) 8482 or equivalent) operating under the Department of Defense (DoD)/The Joint Commission protocol (Protocol for Compliance by DoD Pharmacy Services with Joint Commission Standard Regarding Review of All Prescriptions or Medication Orders, 12 July 2010).

(c) Having privileged providers available to prospectively review prescriptions prior to dispensing.

(d) Utilizing remote pharmacist via inpatient telepharmacy option to support inpatient pharmacy operations to ensure adherence to The Joint Commission medication management standards of prospectively checking medication orders.

(e) Utilizing a healthcare provider determined to be qualified by the MTF to review medication orders for allergies or potential sensitivities, drug and food interactions, current or potential impact as indicated by laboratory values, appropriate indication/dosage/frequency/route, therapeutic duplication, and other contraindications. The healthcare provider(s) reviewing the medication orders in the pharmacist's absence must be trained and assessed for orders review competencies. The pharmacist will conduct a retrospective review of all medication orders as soon as a pharmacist is available.

21-3 Responsibilities (Regulatory)

(1) The commanding officer (CO) is responsible for the operation of the pharmacy. The pharmacy must be operated per Federal law, Service regulations, and accepted standards of practice, such as those defined by The Joint Commission and other professional organizations. Supervision is normally exercised through a commissioned pharmacy officer. When a commissioned officer (pharmacist) is not assigned to an MTF, a civilian pharmacist or a Medical or Dental Corps officer will be assigned supervisory responsibilities. The CO and/or officer in charge (OIC) responsible for a BSO 18 MTF, without a pharmacist assigned (such as branch clinic), must ensure that pharmacy operations are reviewed by a pharmacist through site visits and inspections. For mobile MTFs without a pharmacist (such as non-BSO 18 activity), the CO may assign responsibility to an enlisted pharmacy technician (NEC 8482), a Medical Corps officer, physician assistant, nurse practitioner, certified nurse midwife, certified nurse anesthetist, privileged nurse provider, or an independent duty corpsman (IDC). A BSO 18 CO or OIC of an MTF in the immediate area of an operational unit may assign a pharmacy officer to assist the commander and pharmacy staff of the operational pharmacy in a manner similar to that for a branch clinic, if support is requested by the commander of the operational unit.

(2) The CO must:

(a) Establish policies to ensure rational prescribing, ensure quantities of drugs prescribed are not excessive, and ensure drug dispensing is based on the established DoD and local medication formulary that matches the scope of care at the MTF.

(b) Ensure that the staffing levels, funding, and pharmacy scope of practice are aligned to meet the mission of the MTF.

(c) Ensure that the pharmacy department head and subordinate staff keep abreast of new developments in the field of pharmacy and serve as subject matter experts.

(d) Ensure safe medication use in compliance with pharmacy regulatory and accreditation standards.

(e) Ensure safeguards are adequate to mitigate or prevent drug diversion. See article 21-24, for guidance on methods to prevent drug diversion.

(f) Delineate pharmacy department responsibilities to include, but not limited to:

1. Provide drug information and policy assistance to authorized individuals in the proper writing of prescriptions. In particular, provide reference to pharmacology and toxicology, dosage forms and strengths, precautions, side effects and adverse drug reactions, pharmacokinetics, parenteral nutrition support, availability of ingredients, size of standard packages, equivalent agents, therapeutic and physical incompatibilities, therapeutic equivalents, storage requirements, drug stability, dosage calculations, and any information that would assist the user. Additionally, support providers with information and recommendations regarding pharmaceutical elegance and palatability, use of agents and quantities for maximum effectiveness and economy, refill authorizations, and any matter involving the use or misuse of medications.

2. Assist and advise personnel of ward/clinics or departments within the MTF whose duties involve stocking pharmaceutical items by conducting inspections at least monthly, or more often if required. Provide inspections of all areas where pharmaceuticals are dispensed, administered, or stored. The inspections should include a review of adequacy of identification, sufficiency of storage, safeguards, and evaluation of condition and potency of stocked items based on normal expiration dates, observations or such other criteria as are accepted as good practice by the pharmacy profession.

3. Maintain current drug information resources, and routinely disseminate drug information to medical provider staff and patients.

4. Provide information concerning advances in the field of pharmacy and pharmacy-related matters.

5. Maintain and publicize, either electronically or hard copy, an MTF formulary for use in the facility and by its patients and external customers (such as civilian network providers, other local MTFs, and so forth). MTFs must have the DoD Basic Core Formulary (BCF) as the basis for their individual MTF formulary. A pharmacy newsletter may be used to publish timely information on pharmaceuticals and preparations available for use, along with other prescribing policies and items of interest to the professional staff.

6. For MTFs conducting research with investigational drugs:

a. Provide proper and separate storage, safeguarding, labeling, and dispensing of investigational drugs.

b. Maintain investigational drug files. Transfer these files to nearest Federal Records Centers within 5 years and destroy in 10 years.

c. Publish essential information concerning investigational drugs to personnel who administer such drugs or care for patients receiving such drugs.

d. Maintain a reference file copy in the pharmacy of the current protocols for all investigational drugs utilized in the MTF.

7. Where required to support inpatient care: Operate a pharmacy sterile products program to include the preparation and delivery of pharmaceutical sterile products in compliance with the United States Pharmacopeia standards; maintain laminar flow hood, biological safety cabinet (BSC) quality control requirements which must include: cleaning of the equipment used on each shift, and periodic certification of the BSC for operational efficiency by a qualified inspector at least twice yearly, or when the BSC is moved or repaired; changing high-efficiency particulate air (HEPA) filters when air flow is restricted (as indicated by the continuous monitor) or when the filters are contaminated by an accidental spill; maintaining written records of these actions; and centralizing all sterile compounding procedures within the pharmacy department or its satellites.

8. Provide a safe and cost effective unit-dose system as the preferred method for packaging pharmaceuticals for distribution to hospital patients at fixed MTFs. Key elements of a unit-dose system are:

a. Medications are contained in and administered from single-unit or unit-dose packages.

b. Medications are dispensed in ready-to-administer form to the maximum extent possible.

c. For most medications, not more than a 24-hour supply of doses is provided to or available at the patient care area at any time, unless an automated dispensing cabinet system is in place.

d. Patient medication profiles are concurrently maintained by the pharmacy for each patient.

e. Floor stock medication use is minimized.

9. Ensure maximum use of electronic prescription order entry utilizing the current DoD enterprise system to enhance patient safety. This system also includes adequate safeguards to maintain the confidentiality of patient records. Data on controlled substances must be readily retrievable in printed form from the system.

Note: Auxiliary procedures must be in place to continue pharmacy functions during equipment downtime. Such auxiliary procedures must ensure all appropriate data is retained for online data entry as soon as possible when the computer system is available. During facility downtime, commands are expected to provide an appropriate level of care, as determined by command capacity, patient population, and the pharmacist's clinical and professional judgment. Operating outpatient pharmacies without clinical decision support provided by an enterprise data entry system does not provide standard of care for drug interaction and allergy screening and should be evaluated for risk to benefit versus patient convenience.

10. Ensure prescriptions are filled only for eligible beneficiaries via a valid identification (ID) check or a Defense Enrollment Eligibility Reporting System (DEERS) eligibility check in an enterprise data entry system.

11. Assure, as part of the command's quality improvement program, the quality and appropriateness of patient care services provided by the pharmacy department are monitored and evaluated by using a planned and systematic process to identify and resolve problems.

12. Assure the scope of pharmaceutical services is consistent with the mission of the command, and the medication needs of the patients it serves. This will include promoting a relationship with the Fleet and Marine Forces within the responsible catchment area to determine and assist with pre-deployment and post-deployment medication needs. This may include, but not be limited to:

a. An assessment of therapeutic disease state management of shipboard and field personnel.

b. Obtain access to deployable forces current medication information.

c. Ensure appropriate types and quantities of medication are available and stored following current standards and regulations.

13. Ensure security measures are adequate to prevent unauthorized entry into the pharmacy. Such measures may include, but are not be limited to, utilization and maintenance of a logbook for visitors entering and leaving, and appropriate pharmacy key accountability by the key custodian with a sign out log. Surveillance cameras system is required in pharmacy spaces where controlled medications are stored and dispensed. Maintain a record of door locks and alarm code changes, to include date and by whom.

14. Ensure the facility provides pharmaceutical care consistent with Service regulations, medical staffing, and standards of practice defined by The Joint Commission and other professional pharmacy organizations.

15. Ensure management and disposal of pharmaceutical wastes will be conducted per applicable Federal, State, and local regulations. Additionally, applicable DoD policies and Navy instructions on pharmaceutical waste should be followed.

16. Generally, if a specific pharmaceutical is not on a government contract, the MTF must purchase the item that offers the best value for the government. Most often, this means buying a generic product. Authorized generics are those rated A/B in the U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

Exceptions: A trade name medication may be dispensed when medically indicated, supported by current literature, and documented in the patient's medical record.

17. Pharmacies must honor government contracts, if established, when purchasing pharmaceuticals. Additional blanket purchase agreements between the MTF and a pharmaceutical company cannot be made when a DoD contract is already in place. When necessary, to maintain efficient operations and in the best interest of patient care, the purchase of non-contracted items is allowed.

18. MTFs must utilize an inventory management ordering system (such as Defense Medical Logistics Standard Support (DMLSS)) to manage their credit memos and order pharmaceuticals from their Prime Vendor credit account. All credits must be spent within 120 days of posting, or, if within 120 days of the end of the fiscal year, before the fiscal year closes. Navy Pharmacy is not allowed to use credits across fiscal years. Credits that are not spent within the required timeframe or before the end of the fiscal year (30 September) will be returned to the U.S. Department of the Treasury.

(3) Pharmacy and Therapeutics (P&T) Committee:

(a) Each parent MTF, with a pharmacy department, must establish a P&T Committee to advise the CO on the selection and use of drugs in the facility. The P&T Committee is a function of the medical staff and will meet at least quarterly and its duties are governed by BUMEDINST 6010.17 series, Naval Medical Staff Bylaws. The committee will be co-chaired by a pharmacist and provider and will consist of an interdisciplinary team with representatives from the medical, nursing, risk management, and pharmacy communities. Other disciplines (such as administrative and logistics communities) may be appointed as needed. The local P&T Committee must ensure compliance with the TRICARE Uniform Formulary policies and DoD P&T Committee formulary management determinations.

(b) Functions of the P&T Committee:

1. Develops and recommends policies and procedures relating to the selection, distribution, handling, use and administration of drugs, and diagnostic materials.

2. Evaluates clinical data on drugs or preparations requested for use in the MTF that have not been evaluated by the DoD P&T Committee. The MTF P&T Committee must maximize its use of the BCF and Extended Core Formulary DoD P&T Committee decisions to avoid duplication of efforts.

3. Minimizes unnecessary duplication of drugs, drug combinations, or therapeutic equivalents.

4. Reviews and evaluates all reported adverse drug events (such as adverse drug reactions, medication errors) and completes trend analyses in coordination with risk management.

5. Recommends policies to ensure the safe use of drugs in the facility, including the initial and annual review of pharmaceuticals approved for clinic and ward stock and medications in automated dispensing cabinets that are able to be administered without prospective pharmacy review (such as override list and non-profiled automated dispensing cabinets).

6. Oversees drug usage evaluations and reviews.

7. Monitors the prescribing of controlled drugs by prescribers.

8. Recommends safety guidelines for use in prescribing medications. Complies with the most current Navy Medicine "Do Not Use List of Abbreviations."

9. Prospectively approves initial and revised forms and inpatient order sets (electronic and pre-printed paper versions) along with review every 2 years.

10. Complies with all National Patient Safety Goals, The Joint Commission medication management standards, and other guidelines as directed by BUMED.

11. Recommends policies to govern access to the facility by pharmaceutical manufacturer representatives to govern their conduct and activities while at the MTF.

12. Participates in risk management and quality improvement activities related to medication use per BUMEDINST 6010.13 series, Quality Assurance Program and BUMEDINST 6010.17 series, Naval Medical Staff Bylaws.

13. Recommends policies and procedures for evaluation and acquisition of non-formulary medications in compliance with DoD Uniform Formulary decisions. (See article 21-5(11)).

14. Reviews and approves formularies for providers with limited prescribing privilege (such as IDCs).

15. Approves injectable medications for outpatient dispensing as safe and appropriate. Pharmacy will restrict the dispensing of these injectable medications based on P&T decision. In rare instances, pharmacists may use professional judgment, in consultation with the provider, to make exceptions to this requirement.

21-4 Prescribers (Regulatory)

(1) Prescriptions from MTF and DoD-authorized providers for formulary drugs will be honored. Local MTF policy may allow the filling of an approved non-formulary medication written by authorized prescribers and must utilize a P&T Committee approved non-formulary review process. Authorized prescribers may include: Medical and Dental Corps officers, optometrists, physician assistants, pharmacists, physical therapists, podiatrists, advanced practice nurses (certified nurse anesthetists, nurse midwives, women's health nurse practitioners, family and pediatric nurse practitioners), veterinarians (when prescribing medications for military working animals), or civilian physicians employed by the Navy or the Military Health System. Authorized prescribers also include Navy IDC authorized in section IV of this chapter, and others authorized in writing by the CO (or delegated representative) to prescribe in their official capacities as defined by the MTF Professional Affairs office.

(2) Prescriptions written by civilian practitioners, other than those employed by the DoD, must be filled for authorized beneficiaries, providing the prescribed item is on the MTF formulary and a pharmacist prospectively verifies the prescription per current regulations. Local MTF policy may allow the filling of non-formulary medications written by civilian practitioners when a P&T Committee approved non-formulary review process is utilized. The act of filling a prescription written by a civilian practitioner does not imply knowledge of, or responsibility for, a patient's medical condition.

(3) Valid prescriptions will be filled following quantity restrictions and refill limitations.

(4) Medical Department personnel must not countersign nor rewrite non-MTF practitioners' prescriptions without the provider assuming care for the patient for the diagnosis supporting the specific medication need, which includes a full assessment of the patient.

(5) The policy of filling prescriptions written by civilian prescribers, and those written by MTF staff authorized prescribers, should coincide except for the following conditions:

(a) A distance factor or geographic boundary limitation will not be the reason for the denial of prescription services for outside of the continental United States (OCONUS) MTFs. Inside of the continental United States (CONUS), MTFs may only accept prescriptions from CONUS civilian providers.

(b) Civilian practitioner prescription service, as a whole, may not be withdrawn or curtailed without consent of BUMED via the MTF's respective regional command.

(6) IDCs must be authorized in writing by his or her assigned physician supervisor to prescribe or provide medications carried on the IDC specific MTF formulary or authorized medical allowance list (AMAL). Any restrictions or exceptions (controlled substances) must be plainly stated. A copy of the letter must be retained in the IDC Certification and Training Record with a copy provided to the pharmacy. OPNAVINST 6400.1 series, Training, Certification, Supervision Program, and Employment of IDC provides guidance for training, certifying, and supervising IDCs.

21-5 Outpatient Prescriptions (Regulatory)

(1) Authorized prescribers in the employ of, or serving in, the Navy as described in article 21-4 will use electronic-order-entry. DD Form 1289, DoD Prescription or NAVMED 6710/6, Poly Prescription will be used only during periods of electronic-order-entry system downtime. See special provisions for IDC personnel in article 21-50(11). Prescriptions from civilian practitioners and from the Department of Veteran's Affairs for dual-eligible patients are also accepted if the medication is a formulary or approved non-formulary item. Prescriptions are acceptable when written by authorized prescribers on prescription forms authorized by other Services. Retired military physicians, possessing a current license, may use the DD Form 1289 to write prescriptions for personal use, except for controlled substances (see article 21-22(6)).

(2) Prescriptions must be electronic order entry; handwritten in ink, indelible pencil, typewritten; or a printed form generated from a computerized program and must show the following:

(a) Patient's full name.

(b) Date prescription was written.

(c) Patient's date of birth and weight (if 12 years or younger). If the child's date of birth or weight is omitted**,** the pharmacy may record the child's date of birth or weight on the prescription.

(d) Full name of drug, form of drug, dosage size or strength written in the metric system, and quantity to be dispensed. Prescriptions should be written generically.

(e) Clear directions for use by the patient.

(f) Additional patient specific data/parameters (such as pregnancy/lactation status, weight, appropriate laboratory values) as required by regulation when appropriate.

(g) Valid legible signature of the prescriber. Electronic signatures on paper prescriptions brought in by the patient are accepted only for non-controlled substances. When enterprise data entry system prescriber-order-entry systems are used, the electronic signature is acceptable for all prescriptions.

(h) Refill authorization (as applicable).

(i) Additional requirements for controlled substances are found in article 21-27.

(j) However, if a patient chooses to have a prescription filled in a community pharmacy or through TRICARE Pharmacy Home Delivery, the physician may be required to write a traditional prescription and sign it as required by 21 CFR 1306.05(a) and (d), if electronic prescribing is not available. Prescriptions for controlled medications filled outside the MTF must also have the practitioner's Drug Enforcement Administration (DEA) number on the prescription.

(k) Other requirements per Federal law.

(3) 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 reduced to writing by a pharmacist and read back to the provider for verification. Per MTF policy and when allowed by DEA regulations, orders from providers may be faxed, and will be considered as the original order with approval of the MTF, provided data integrity, patient privacy, security, and audit capabilities and policies have been established.

(4) For electronic prescribing, a prescription is deemed valid if it is delivered from an external system having undergone a certification process consistent with DoD regulations to ensure data integrity, patient privacy, security, and full transaction audit capabilities. Each transaction must comply with the requirements in article 21-5(2) per local MTF policy and when allowed by DEA regulation.

(5) Prescriptions will be personalized. If more than one member of a family is prescribed the same medication, a separate prescription must be entered into each patient's electronic medication profile or a separate hard copy prescription for each patient must be issued.

(6) Prescriptions for animals, other than those owned by the Government, will not be filled.

(7) Outpatient prescription containers must be labeled properly and include:

(a) Name and telephone number of the MTF dispensing the prescription.

(b) Identifying prescription number.

(c) Patient's name.

(d) Date the prescription is originally filled and date refilled, if applicable.

(e) Clear, concise directions to the patient.

(f) Full name of drug, strength, and quantity dispensed. Pharmaceutical preparations will normally be identified and labeled with the generic name. However, trade or brand names may be used if the trade or brand name product actually is in the container. The use of the word "type" or "equivalent" is acceptable on the label (such as, Tenormin "type").

(g) Prescriber's name.

(h) Filler's and checker's initials (when not supported through automation or pharmacy information system).

(i) Number of refills remaining.

(j) Beyond-use date (such as reconstituted antibiotics with short date), if applicable.

(k) Proper auxiliary or cautionary labels as indicated.

(l) Other requirements per Federal law.

(8) MTF pharmacies must fill, or provide the opportunity to have filled, all MTF formulary and approved non-MTF formulary prescriptions written by its providers. Unapproved non-MTF formulary requests may be filled using mail order benefits or a retail pharmacy if covered by the patient's TRICARE benefit and listed on the Uniform Formulary Web site at: https://www.express-scripts.com/static/formularySearch/2.7/#/formularySearch/drugSearch?accessLink=FSTResults otherwise alternative medications should be prescribed. This does not preclude the patient from choosing to have prescriptions filled elsewhere. Under the Uniform Formulary guidance, certain medications require the completion of either a Medical Necessity form or a Prior Authorization form to be obtained by TRICARE patients with a formulary co-pay (see above Uniform Formulary Web site for additional information). MTF pharmacies will not fill prescription written by civilian, non-federal providers for any medication used exclusively for its anorexiant or weight loss effect. This includes AD members holding otherwise valid prescriptions.

(9) MTFs will not routinely dispense prescriptions by mail. TRICARE Pharmacy Home Delivery, a mail order benefit has been established as an option, and should be used by eligible beneficiaries. Pharmacy staff will refer patients who choose to use a mail order program to the TRICARE program for maintenance medications. Exceptions for individual patients, with prior approval by the pharmacy department head, may be authorized, but each situation should be evaluated on an individual basis. In all cases, an individual's eligibility and entitlement to prescription services will be determined before filling and mailing any prescriptions.

(10) MTFs pharmacies should direct patients with civilian prescriptions to use the mail order program or retail pharmacies to fill certain special medications not routinely provided by the MTF formulary. Note: Most over-the-counter (OTC) medication and non-FDA approved products are not covered under the TRICARE benefit.

(11) Prescriptions will be honored when written by an MTF or network referral provider acting in a consultant capacity. If the drug is not on the formulary, it will be processed according to the MTFs policies and procedures for evaluation and acquisition of non-formulary drugs. Local MTF policy may allow the filling of non-formulary medications from non-referral civilian providers when a P&T Committee approved non-formulary review process is utilized. See paragraph 1b under "General Policies" in the TRICARE Pharmacy Policy Guidance (Assistant Secretary of Defense for Health Affairs Policy Memo 95-011 of 26 Jul 1995).

(12) Outpatient prescription medications for oral use will normally be dispensed in child resistant containers, unless the patient or prescribing practitioner requests conventional (non-child resistant) closures. These requests for non-child proof containers must be authorized for each prescription by a notation in the enterprise data entry system (e.g., Composite Health Care System (CHCS), GENESIS) following the most current amendment to the Poison Prevention Packaging Act of 1970.

(13) MTF pharmacies will not provide medications intended for the purpose of home intravenous infusion. Patients should be referred to case management staff/health benefits advisory staff to coordinate home healthcare services. Pharmacies will not provide medications on an outpatient basis that are intended to be administered or inserted in a network provider's office; medications may be provided for use in any military healthcare setting or for use outside of a medical setting (the patient's home) when the pharmacist can determine that it can be safely administered by a patient or guardian.

(14) Injectable medications to be administered by home healthcare agencies will not be dispensed by the MTF pharmacy. Patients receiving home health pharmacy services should be referred to a case manager or health benefits advisor for coordination of care.

(15) Pharmacy will restrict the dispensing of injectable medications to those approved for outpatient dispensing by P&T Committee as safe and appropriate for self-administration. Pharmacists may use professional judgment, in consultation with the provider, to make exceptions to this requirement. MTF pharmacists must ensure patients receiving injectable medications for self-administration have been trained on proper storage, use, and disposal and will verify that package inserts contain guidance to the patient on self-administration.

(16) Acceptance of pharmaceutical samples from sales representatives for dispensing to patients is prohibited.

(17) Pharmacy personnel will not fill prescriptions that are illegible, incompatible, or if there is question of dosage, interaction, allergy, or method of administration. Pharmacy personnel may clarify these prescriptions with the prescriber, and fill the prescription after the patient safety concerns have been addressed.

(18) A system designed to protect patient privacy and assure accurate identification of patients at the time they receive prescribed medications must be established. Identification must involve the use of two identifiers, the patient's name on the DoD military ID card and birth date or DoD ID Number. The age at which a child may pick up his or her prescription from the pharmacy without being accompanied by a parent or guardian is 12 years old. A pharmacist may use professional judgment and experience with common practice to make reasonable inferences of the patient's best interest in allowing a person, other than the patient, to pick up the prescription. Individuals receiving medications for beneficiaries other than themselves or their minor children should provide reasonable proof of patient consent (such as an authorization letter and front and back photocopy of patient's ID, or letter of power of attorney) for the release of medical information and prescriptions. Expired IDs will be confiscated via local MTF policy.

(19) The parent MTF CO may authorize a limited number of OTC drugs to be dispensed from the pharmacy after a patient has seen a healthcare screener. Under no circumstances will a patient be authorized to select their own medications. A healthcare screener (Hospital Corpsman that has completed the sick call screener course or nurse) must either assess a patient's symptoms, select the appropriate item(s) on the approved list, and send the list with the patient to the pharmacy, or refer the patient for more definitive care. Pharmacy staff must not act as healthcare screeners. Guidelines for an OTC healthcare screener program include:

(a) Quantities dispensed are limited to one treatment regimen or a few days' supply for relief of a current condition.

(b) OTC items are limited to treatment of minor problems such as headaches, common cold, indigestion, or mild dermatitis.

(c) OTC items must be labeled per Federal regulations and provide adequate directions to the layman for safe and effective use and also provide warnings and cautions against misuse. OTC items must be dispensed in the manufacturer's original container.

(d) OTCs dispensed in these programs must be entered as a medication order.

(e) Products containing pseudoephedrine or other OTC medications with FDA restrictions must not be dispensed as an OTC. MTFs will only dispense pseudoephedrine-containing products as a prescription item.

(20) Report and record medication errors, including close calls or near-misses, via command's error reporting mechanism, and BUMED guidance. A close call or near-miss is defined as an event or situation that could have resulted in harm to a patient, if it had reached the patient. Further definitions and guidance are provided in the Navy Pharmacy Standard Operating Procedure, available at: https://www.milsuite.mil/book/groups/us-navy-pharmacy.

(21) 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 to dispense a one-time limited 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 30-day supply. The decision should be guided by:

(a) The medication is essential to maintain life or continue therapy of a chronic condition.

(b) The interruption of therapy might reasonably produce undesirable health effects or cause physical or mental discomfort.

(c) The prescription is not for a controlled substance drug. An exception: Controlled substance medications used for seizure control may be provided in a quantity not to exceed a 72-hour supply (Clonazepam and Phenobarbital).

(d) Documentation in the proper enterprise data entry system comment field (e.g., CHCS, GENESIS prescription comment field) will include that the fill was provided on a one-time basis.

(22) Automated pharmacy systems must provide online visual retrieval and hard copy printout of original prescription information and prescriptions currently authorized for refilling. Printouts must include, but are not limited to:

(a) Patient's full name.

(b) Prescribing practitioner's name.

(c) Name, strength, and dosage form of the pharmaceutical dispensed.

(d) Date the prescription was first dispensed.

(e) Date of dispensing for each refill.

(f) Quantity dispensed.

(g) Original prescription serial number.

(h) Number of refills dispensed to date.

(i) Name or initials of the person processing the order.

(j) A refill-by-refill audit trail for any controlled medication.

(23) Time and quantity limitations for filling and refilling prescriptions.

(a) Controlled medications. Time and quantity limitations for filling and refilling controlled substance prescriptions, see article 21-27(4) through 21-27(6).

(b) Non-controlled medications. A prescription for a non-controlled medication must be filled within 1 year of the date originally written. These prescriptions may be refilled, if authorized by the prescriber, up to 12 months from the date originally written. Prescription quantities will be filled as written up to a 100-day supply for maintenance medications at all MTFs. AD beneficiary prescriptions may be dispensed in larger quantities to meet readiness requirements. Since there are many reasons the prescriber may want to limit drug supplies to certain patients, MTF policies must retain enough flexibility for the provider to limit the quantity of medication dispensed to an individual patient.

Note: Whenever possible, women who use contraceptives on a long-term basis should be given a prescription for six packages with one refill.

(c) Non-controlled prescriptions marked with as-needed (pro re nata (PRN)) refills may be refilled up to 1 year from the date originally written.

(24) All prescriptions originally filled at one DoD MTF may be refilled at another as long as the pharmacy takes into account the type of medication and the method used for recording refills. MTFs with pharmacy data processing systems that do not access the same prescription records electronically, will notify the original facility of 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. Schedule II medication prescriptions, originally written electronically at one DoD MTF, may be 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.

(25) When requested by the patient, a pharmacist may transfer a prescription for a Schedule III, IV, or V controlled substance or, any non-controlled prescription, to another pharmacy point of service (retail, mail order program, or MTF). The date of transfer and the phrase, "Transferred to (name of pharmacy receiving the transfer)" will be recorded in the activity log comment field of the electronic prescription record when discontinuing the prescription to void remaining refills. Schedule III to V prescription may

only be transferred one time. When a prescription originally filled at retail pharmacy is transferred to an MTF (taking into account the type of medication), the MTF will make a notification in the electronic record such as: "Transferred from (name, contact telephone number of retail pharmacy, and name of pharmacist) with date of transfer." Date of prescription entry must be the date of original prescription.

(26) Prior to releasing patient sensitive information to someone other than the patient or the patient's authorized representative, all requests must be approved through the command legal office or appropriate authority. A police officer, agent of the Naval Criminal Investigative Service, agent of the CO, or any agent of higher authority may remove an original prescription from the pharmacy's files for the purpose of an investigation. Whenever this occurs, a photocopy of the original prescription and a receipt from the agent or police officer must be kept in the pharmacy's files.

(27) If a multiple prescription (civilian) is presented for filling and the pharmacy does not stock all the medications ordered, the pharmacy will make a copy of the prescription for the pharmacy's files. Pharmacy staff will indicate "filled at (name of MTF)" on the original prescription, draw a line through the prescriptions filled, and return to the patient. The annotation should also include the MTF's telephone number. The pharmacist or senior technician dispensing the prescription will sign the copy. For controlled substances, see article 21-27(2)(e).

(28) Non-FDA approved products such as nutraceuticals, homeopathic, and therapeutic dietary supplements are not a TRICARE-covered benefit. These agents are not subject to FDA regulation regarding good manufacturing processes which presents legal risks to the MTF. If one of these agents is required, it is subject to formulary review by the P&T Committee and approval by the MTF CO and requires a valid prescription.

(29) Refills for non-controlled maintenance medications may be processed when 75 percent or more of the prior prescription has been used. Refills or renewals for controlled substances may be processed when 85 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). Only a pharmacist can authorize early refills and renewals for controlled substances, after 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.

(30) Prescriptions for formulary medications, written by non-physician prescribers who are duly privileged at one MTF, may be filled or refilled at other MTFs at the discretion of the CO.

(31) Prescriptions for formulary and approved non-formulary medications written by MTF prescribers must be dispensed from that facility unless the beneficiary chooses another option.

(32) All new and refill prescriptions will include FDA-mandated "side effects" statement. The statement may be displayed using one of the following methods:

(a) Sticker attached to the package, vial, or container of the drug product.

(b) Preprinted pharmacy prescription vial cap.

(c) Separate sheet of paper.

(d) In the patient education monograph.

(e) By distribution of the appropriate FDA-approved Medication Guide that contains the side effect statement.

(33) All new prescriptions will include a printed patient education monograph from enterprise data entry system (e.g., CHCS, GENESIS). All new and refill prescriptions will include any required FDA-approved medication guide. Patient counseling of prescription medication by pharmacy personnel must be delivered to appropriately to address barriers to learning which may include but not limited to cultural and religious beliefs, emotional barriers, and physical or cognitive limitation.

(34) The MTF CO and P&T Committee must review the alignment of the MTF formulary to the mission of the MTF, DoD P&T guidance, and the needs of population the MTF serves. The MTF CO must consider the enterprise impact of formulary decisions. Cost-effective formulary management does not include selective deletion of medications commonly prescribed by MTF providers, but that are required for optimal patient care.

(35) When the enterprise data entry system (e.g., CHCS, GENESIS) is down, prescriptions written by civilian and MTF providers may be filled only for urgent medications (antibiotics, pain medications, etc.) unless an adequate downtime system is available that offers complete patient medication profile information and prospective drug utilization review and allergy screening. Labeling will include elements specified by article 21-5(7). All pharmacy services may be ceased at the direction of the MTF CO until system is operational at the recommendation of the pharmacist as deemed necessary to support safe and effective patient care.

(36) Pharmacy personnel will not process (edit, print, fill, or check) prescriptions for controlled substances or locally-designated Drugs with a High Potential for Diversion (as defined in article 21-20) for themselves or their family members. At sites where the lack of other pharmacy personnel requires a pharmacy staff member to process his or her own prescription, the prescription will be reviewed by a licensed independent practitioner, a physician assistant, or a remote site via Telepharmacy prior to dispensing.

(37) Dispensing of medication used solely for its anorexic activity is authorized and must follow guidance provided in CFR §199.4 DoD-2017-HA-RIN 0720. Interim Final Rule and applicable clinical criteria established by the DoD P&T Committee.

21-6 Inpatient Dispensing (Regulatory)

(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 the pharmacist interpreting the provider's orders and monitoring inpatient medication needs.

(2) The preparation of sterile products (chemotherapeutics, syringes, intravenous piggy backs, large and small volume intravenous admixtures, and irrigations) is an important part of the drug delivery system and current United States Postal Service (USPS) regulations must be observed. Centralizing all sterile compounding within the pharmacy department is recommended where resources permit. The pharmacy department head will provide guidance and approve procedures for preparing and labeling parenterals, whenever these functions are not performed under direct pharmacy supervision.

(3) All medication orders must be reconciled when a patient transfers (ward transfer, ward to surgery, etc.) to a different level of care. National Patient Safety Goals and medication reconciliation pro-cedures must be followed.

(4) The pharmacy is responsible for labeling medications. All medications issued in bulk containers to ward and clinics, not dispensed in the original container, must be labeled by the pharmacy with the date of issue, generic and/or trade name, strength, quantity, beyond use date, name of the manufacturer, and lot number or appropriate code to identify the drugs. A repackaging beyond use date will comply with current USPS requirements not to exceed 1 year or the actual manufacturer's expiration date whichever is less, will be added to drugs distributed in other than the original manufacturer package. To minimize contamination, waste, and floor stocks, the use of unit-dose drugs available in commercial packages is recommended for fixed MTFs. This permits drug identification up to the actual time of administration.

(5) Inpatient self-administered and discharge medications should be labeled as outpatient prescriptions following article 21-5(7). The MTF must assess that self-administrated medications are accurately administered and documented on the medical administration record and safely stored to prevent the access by unauthorized individuals.

(6) All medications brought into the hospital by patients will be given to a member of the patient's family to return to the patient's home for safekeeping. If the patient does not have an escort, nursing personnel must collect the medication. 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). The medication must be documented as reviewed by a pharmacist or provider prior to being authorized for use. Medications collected in this manner will not be retained by the patient, except in reference to self-administration per article 21-6(5).

(7) When the provider authorizes a medication for bedside use, they must be reviewed by a pharmacist and documented in the medication administration section of the electronic health record prior to being authorized for patient bedside use. When medications are stored at the patient's bedside, they must be:

(a) Accurately administered.

(b) Documented in the medical administration record.

(c) Safely stored to prevent unauthorized access.

(d) Labels for PRN medications must include frequency and indication for use.

21-7 Drug Stock (Regulatory)

(1) Personnel filling and dispensing medications must understand their roles and responsibilities.

(2) The Prime Vendor System must be used for pharmaceutical purchasing. Exceptions may be made for small purchases of products unavailable from the Prime Vendor.

(3) The Fleet and Marine forces should use their Prime Vendor and reverse distributer to obtain and return medications.

(4) Pharmaceutical inventory will be managed to ensure the stock levels of pharmaceuticals on-hand are not excessive (in general, not to exceed 30-day supply), based on historic utilization patterns, potential urgency of medication use, administrative costs, in addition to considering the limits of the supply system.

(a) Annually, at a minimum, MTFs will establish drug inventory par or stock levels that reflect the level of care, prescription workload, and mission.

(b) MTFs must conduct an annual inventory of all drugs stocked in the pharmacy however, should resource constraints be an impediment, MTFs may choose to perform a monthly sampling and/or a risk based approach until a perpetual inventory system is implemented. Risk-based approach focuses on identifying drugs with high cost, high volume, or high abuse potential.

(c) Pharmacies will segregate duties for ordering, receiving, and inventorying medications to the maximum practicable extent.

(5) Only medications which have been licensed and approved by FDA for sale in the United States, are authorized for use in CONUS MTFs. In rare circumstances to prevent adverse patient outcome, the CO may authorize the purchase of a non-FDA approved medication, via the P&T Committee.

(6) The use of investigational drugs is included in SECNAVINST 3900.39 series. Executive Order 13139 and 10 USC §1107 prohibit use of non-FDA approved drugs on Service members, whether CONUS or OCONUS, unless the member signs a consent form, or the President waives the requirement for member consent. Additional information can be found at: http://www.med.navy.mil/bumed/humanresearch/resource/Pages/RegulatoryGuidance.aspx/.

(7) Each MTF will have a written policy regarding borrowing drugs from another MTF or civilian facility, (an emergency or temporary out-of-stock situation, requirement for a non-formulary item). Policies and procedures will include names and telephone numbers of emergency suppliers, (community pharmacies, hospitals), and methods of reimbursement to the loaner (replacing the same type item at a later date, or with similar items based upon wholesale value).

(8) Investigational drugs must be stored and processed through the pharmacy following SECNAV-INST 3900.39 series.

(9) Cytotoxic drugs will be controlled, prepared, administered, and disposed of following BUMED-INST 6570.3 series.

(10) Caustic substances such as sulfuric, nitric, concentrated hydrochloric, trichloroacetic acid, or oxalic acid, and concentrated potassium hydroxide must be submitted and approved by the P&T Committee prior to being issued to ward and clinics. They must be stored in separate lockers and contents must be clearly marked.

(11) Flammable drugs must be stored following accepted fire safety regulations.

(12) Each MTF must have written procedures for drugs recalled by the FDA. These procedures must be implemented readily and the results documented. Such procedures must include obtaining recall notifications from United States Army Medical Material Agency (USAMMA), FDA, or manufacturer, and documentation of responses to such notifications through the use of the inventory ordering and management system (such as DMLSS) to the maximum extent practicable. The recall procedures will require the inspection of all MTF areas and quarantine of products recalled. Drug recalls affecting outpatients will apply only if directed by the recall notice or the FDA. Information pertaining to drug manufacturer, lot number, and expiration date is not required if there is a drug recall procedure that can be readily implemented.

(13) Facilities will minimize the potential for the dispensing of expired drugs through effective inventory management (see article 21-7(4)), identification of expired drugs, prompt removal of expired drugs, and tracking of expired drugs.

(a) When only a month and year of expiration are provided for a drug, the drug may be used until the last day of that month.

(b) Pharmaceutical inventory will be inspected at least monthly.

(c) During the monthly inspections, pharmaceutical items that will expire within 30 days will be removed from inventory, isolated, and securely stored in an area away from in-date pharmaceuticals. Outpatient medications normally dispensed in 90-day supply or greater should be removed from stock if expiration is within 90 days. To the maximum extent possible, expired medications should be inventoried when removed during the monthly inspections.

(d) The storage area and container for expired pharmaceuticals will be clearly marked to prevent accidental dispensing.

(e) Prior to transfer of drugs to a contracted reverse distributor, an inventory of all returned pharmaceuticals must be validated with the contractor. The inventory must be conducted simultaneously with both an MTF representative and the contractor, before the shipment leaves the facility. If the contractor cannot conduct a simultaneous inventory with MTF personnel prior to a shipment leaving the MTF, the MTF must ensure that an MTF-prepared inventory listing accompanies the shipment and is maintained on file to compare to the contractor's records. MTF staff must ensure the returned pharmaceuticals meet the reverse distribution contract requirements. Management of the returned pharmaceuticals (via reverse distribution process) will be conducted per applicable Federal, State, and local regulations; and DoD and Navy policies.

1. Credits will be monitored to ensure utilization within 120 days after posting at the Prime Vendor or end of fiscal year, whichever is closer. Otherwise, unused credits are sent to the U.S. Department of the Treasury.

2. BUMED MTFs and activities must not receive nor deposit any checks received directly from pharmaceutical manufacturers as part of the reverse distribution (credit returns) program. Pharmaceutical manufacturer checks for returned goods credit delivered directly to pharmacy department will be routed to the respective reverse distributor contractor for processing following the standard operating procedure posted on the DLA Troop Support Defense Supply Center Philadelphia (DSCP) Web site at: https://www.medical.dla.mil/Portal/PrimeVendor/PvPharm/ReverseDistribution.aspx.

3. MTFs must utilize inventory management ordering system (such as DMLSS) to manage credit memos and order pharmaceuticals from the Prime Vendor credit account.

(14) Monthly checks will be made by the pharmacy of all ward and clinics where medications are dispensed, administered, or stored, to verify that at the minimum:

(a) Drugs for external use and disinfectants have been stored separately from internal and injectable medications.

(b) Drugs are not overstocked.

(c) Drugs are stored following current established standards.

(d) Once discovered, outdated or unusable drugs should be segregated and returned to the pharmacy immediately.

(e) There is an adequate and proper supply of P&T Committee-approved emergency drugs.

(f) All drugs in the area are properly labeled.

(15) Multiple dose vials (MDV) containing parenteral medications may be reused if the following procedures are followed to eliminate the risk of infection:

(a) Strict aseptic technique is used.

(b) The parenteral product is prepared in a functionally separate area that is clean and uncluttered to avoid contamination of medications.

(c) Date any opened vial with a beyond use date (BUD). The MDV is not taken into immediate patient treatment areas. The Centers for Disease Control and Prevention defines immediate patient treatment areas as patient rooms or bays and operating rooms. An MDV taken into immediate patient treatment area must be treated as single-dose and discarded after use unless utilized by a single patient for the life of the medication.

(d) Date any opened or entered (such as needle punctured) MDV with an expiration date or BUD, store, and discard following manufacturer's stability data. The BUD is not to exceed 28 days.

(16) Some vaccines may be used, even after initial entry, until the original manufacturer's expiration date. Patient specific compounded allergen extracts compounded by the U.S. Army Centralized Allergen

Extracts Laboratory may be used, even after initial entry, until the product's expiration date. The Military Vaccine Program at: www.vaccines.mil and the American Academy of Allergy, Asthma and Immunology (AAAAI) at: www.aaaai.org standards will be followed for vaccine and allergen dating.

(17) Single Dose Vials used in the preparation of medications external to pharmacy.

(a) Opened or needle punctured single dose injectable containers must be used within 1 hour and any remaining contents discarded. Expiration date and time for single dose containers must be marked upon opening or puncture or immediately discarded.

(b) Medications packaged as single-dose or single-use must not be used for more than one patient. This includes ampules, bags, and bottles of intravenous solutions.

(18) Unless readily retrievable via pharmacy automation system, a log or electronic record of all medications placed in storage counting cells (such as baker cells, drug-o-matic) will be maintained to include initials of the pharmacist or senior technician checking the filled cell, manufacturer, lot number, and expiration date.

Note: There are no articles 21-8 through 21-19.

Section II
CONTROLLED SUBSTANCES

21-20 General (Regulatory)

(1) Controlled substances, as used herein, are drug schedules in the Controlled Substance Act of 1970 (Public Law 91-513).

(2) There are five schedules designated by section 202 of the Federal Act:

(a) *Schedule I*. Drugs with no acceptable medical use and a very high abuse potential.

(b) *Schedule II*. Drugs having an acceptable medical use and a very high abuse potential.

(c) *Schedules III, IV, and V*. Drugs having an acceptable medical use which are considered to have lessening degrees of abuse potential.

Note: Products may migrate between schedules and new products may be added.

(3) Local commands may designate certain drugs as having abuse potential and requiring security measures similar to those for controlled substances. The CO should establish special security and accounting procedures for these command-sensitive items designated as Drugs with a High Potential for Diversion.

(4) Alcoholic beverages must not be stocked or dispensed from Navy MTFs.

21-21 Accountability (Regulatory)

(1) Schedule I and II controlled substances require vault or safe storage and inventory by the Controlled Substance Inventory Board (per article 21-24). Working stock may be kept in a locked area within the pharmacy. At the CO's or OIC's discretion, a copy of the safe combination must be stored in a sealed envelope deposited with the CO, OIC, or representative. The combination must be changed every 6 months, upon change in custodian, or any suspected compromise of the combination. Command must limit the number of personnel who can access the bulk stock vault to the minimum necessary and a vault access list must be maintained.

(2) Schedule III, IV, and V controlled substances require locked cabinet security for storage of bulk drugs. The appointed pharmacy custodian must take an initial inventory of all controlled substances on hand. After the initial inventory is taken, the pharmacy custodian must take a new inventory of all stocks of controlled substances at least every 2 years. The biennial inventory may be taken on any date which is within 2 years of the previous biennial inventory date. If needed, the pharmacy custodian may take a quarterly audit, or more frequently, of high abuse potential Schedule III, IV, and V controlled medications. See article 21-7(4) for inventory management control and stock level requirements.

21-22 Prescribing (Regulatory)

(1) All prescribers authorized in section I of this chapter must prescribe controlled substances either by electronic-order-entry; DD Form 1289, Prescription Form; or coded facsimile, if appropriate.

(2) All eligible, credentialed healthcare providers must obtain a DEA number in addition to the National Provider Identifier number. MTF prescribers, when prescribing drugs in an official capacity within the scope of the Controlled Substances Act, are qualified for fee-exempt DEA registration. Other practitioners' identifiers may not be substituted for the DEA number. The Controlled Substances Act requires each prescription to have the name of the prescriber stamped, typed, or hand printed on it, as well as the signature of the prescriber. Practitioners using prescriber-order-entry electronic pharmacy systems are exempt from the signature requirement of the Controlled Substances Act when the prescription is filled at the MTF. This exemption does not apply when the prescriber provides professional treatment outside official duties, per policy memo "DEA Numbers for DoD Providers" of 7 April 2000. Written prescriptions filled by the mail order program or retail pharmacies must contain the provider's DEA number.

(3) An officer or civilian employed by the Navy, who has been designated by the command to purchase or procure from commercial sources controlled substances or preparations for official use, must be so designated on the command's registration filed with the Registration Branch, DEA, Department of Justice. Only individuals so designated may sign the paper or electronic order form for Schedule II substances. Government registration is for 3 years, but individuals designated may be changed as necessary by letter to the DEA, signed by the CO or OIC.

(4) Ordering, receipt, custody, and issuance must follow Navy audit and chain of custody business practices to include segregation of duties to the maximum practicable extent.

(5) Authority for pharmacists, physician assistants, and nurse practitioners to prescribe Schedule II through V controlled substances may be granted by the CO or OIC, if within their scope of practice and designated in their privileging documents.

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

(7) 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.

(8) When electronic medical records are not utilized, all controlled substances prescribed will be noted in the member's health or dental record at the time prescribed.

21-23 Custody (Regulatory)

(1) Custodial responsibility for controlled substances and those drugs designated as locally-controlled drugs by the CO or OIC, must be vested in a commissioned pharmacy officer, a civilian pharmacist, or a commissioned officer who is appointed in writing. At remote branch clinics that do not have a commissioned officer or a civilian pharmacist, the CO or OIC must designate, in writing, a senior or supervisory member of the branch clinic as the custodian.

21-24 Security (Regulatory)

(1) Controlled substances listed in Schedules II, III, IV, and V must be stored in a securely locked, substantially constructed cabinet. However, MTFs may disperse a minimal working stock of Schedules III through V based on the stock level criteria in article 21-7(4) throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances. COs and OICs may direct stricter storage requirements based on risk of diversion at a specific facility.

(2) Controlled substances classified as Schedule I through V medication require special handling and accounting to provide adequate protection against drug abuse, carelessness, theft, and misappropriation. MTFs may develop and regularly review a list of Drugs with High Potential for Diversion that include controlled substances Schedules II through V and other legend or OTC drugs that represent a risk for drug diversion. Mitigating diversion of controlled substances and Drugs with a High Potential for Diversion should be accomplished using the following guidelines:

(a) The use of functional, strategically placed security cameras in areas where Drugs with a High Potential for Diversion are stored, distributed, and administered may act as a useful deterrent and investigative tool to mitigate drug diversion.

(b) MTFs should develop methods to audit and monitor all controlled substances and Drugs with a High Potential for Diversion from receipt into inventory until dispensed to outpatients or administered to inpatients.

1. Auditing and Monitoring

a. The Drugs with a High Potential for Diversion list should be reviewed annually for additions and deletions based on MTF monitoring techniques and external factors such as newly identified illegitimate uses for drugs.

b. MTFs should establish percent thresholds for Drugs with a High Potential for Diversion that are not controlled substances Schedule IIs, along with a process to track Drugs with a High Potential for Diversion inventory from receipt to dispensing or administration to the patient. The percent threshold is defined as percent of inventory unaccounted for when comparing the difference between the amount ordered and amount dispensed for a particular Drugs with a High Potential for Diversion. Percent thresholds should be as low as possible, but taking into consideration the volumes dispensed, available MTF resources, and patient safety and efficiency. Exceeding the percent threshold for Drugs with a High Potential for Diversions established by the MTF should trigger further investigation and documentation causes. MTFs should utilize the enterprise data entry system to monitor and track Drugs with a High Potential for Diversion.

c. MTFs should develop procedures and reports to audit and monitor Drugs with a High Potential for Diversions from receipt into inventory until dispensed to outpatients or administered to inpatients.

d. All pharmacies with an enterprise data entry system and a controlled substance vault should be required to use the electronic inventory provided in the vault functions of the enterprise data entry system.

e. All pharmacies, without an enterprise data entry system, will keep a perpetual inventory on all controlled substances Schedule II through V.

f. The use of functional, strategically placed security cameras in areas where controlled substances and Drugs with a High Potential for Diversions are stored, distributed, and administrated may act as a useful deterrent and investigative tool to mitigate drug diversion.

g. For pharmacies that use NAVMED 6710/5 Perpetual Inventory of Narcotics, Alcohol and Controlled Drugs, each entry on the inventory record should be verified against the invoice and co-initialed by an authorized person.

2. The Controlled Prescription Menu is a paperless controlled prescription tracking system in CHCS. It may be used in conjunction with the breakout locker or automated dispensing cabinet and provides a perpetual inventory of controlled medications within CHCS. Tracking of controlled medications from the vault to the patient using the NAVMED 6710/5 is not necessary. After each controlled prescription transaction is completed in CHCS, the inventory is decremented automatically and reflects the new quantity. Reports can be generated to track the medication from the automated dispensing cabinet or breakout locker to the patient. For sites with GENESIS installed, the controlled medications' perpetual inventory capability is available to track medication.

a. The controlled substance custodian must account for all quantities of Schedule I and II controlled substances received and expended through a physical inventory. The frequency of the custodian's inventory accounting should be guided by the transaction frequency, but must occur at least weekly. The bulk stock of Schedule I through V substances must be secured using a double-lock system. Steps must be taken to restrict access to controlled substances. Keys and combinations must be safeguarded appropriately.

b. Ward emergency kits and automated pharmacy breakouts are authorized providing the practice is approved by the CO or OIC of the facility, and the following procedures are in place:

1. Controlled substances (of all schedules) at the ward or in the automated dispensing cabinet must be obtained from the main pharmacy per the requirements of article 21-28.

2. Access to each emergency kit or automated dispensing cabinet must be restricted. The type and quantity of controlled substances placed in the emergency kit must be limited to the mission of the facility and approved by the CO through the P&T Committee.

3. The main pharmacy, which supplied the controlled substances for the emergency kit or automated dispensing cabinet, must maintain complete and accurate records and inventories of the substances placed in the kit per article 21-28.

4. IDCs may remove controlled substances from the kit or automated dispensing cabinet in emergent/urgent situations or in special circumstances as approved by the pharmacy department head, only when under direct supervision of a privileged provider who is authorized to prescribe controlled substances, and must conduct the appropriate documentation of the controlled substance transaction.

c. Quarterly (or more frequently, depending on the activity), an inventory of Schedules I and II controlled substances, and those drugs designated by local command must be made by the Controlled Substance Inventory Board as described in BUMEDINST 6710.70 series.

21-25 Reporting Theft or Loss (Regulatory)

(1) Notify the nearest DEA regional office upon the discovery of theft or significant loss of any controlled substance determined by higher authority following DEA regulations. The head of the pharmacy department, in conjunction with the senior member of the Controlled Substance Inventory Board or other appropriate higher authority, will determine if a significant loss occurred. Report a theft or significant loss immediately, using Report of Theft of Controlled Substances, DEA Form 106, available online at: https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp. Prepare an original and four copies. Send the original and one copy to the nearest DEA regional office, one copy to BUMED Pharmacy Consultant, one copy to the MTF region pharmacy representative, and one copy to the nearest field representative of the Naval Criminal Investigative Service. The consignee must submit a sworn statement of facts with the DEA Form 106, if the controlled substances are stolen or lost in transit.

(2) Report any unresolved Schedule II inventory discrepancies to the senior member of the Controlled Substance Inventory Board or appropriate higher authority.

21-26 Deterioration (Regulatory)

(1) Return of expired Schedule II through 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. 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 contractor must be inventoried for destruction. The appointed custodian must request authorization from the CO or OIC via chain of command to destroy non-returnable controlled products and recommend a method of destruction (such as incineration). If destruction is indicated and approved by the CO or OIC, destruction must be accomplished in the presence of a member of the Controlled Substance Inventory Board. A certification must include the complete nomenclature and quantity of the substances to be destroyed, together with the method to be used to accomplish destruction. After the certification is completed, approved by the CO or OIC, and signed by the members witnessing destruction, the certification must be retained in the files as authority for drop-ping the items from the appropriate record. DEA notification is not necessary.

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

(3) The MTF must not accept returns of medications that have been dispensed to the ultimate user (the patient) unless the pharmacy uses a DEA-compliant collection program or mail back program.

21-27 Dispensing by Pharmacy (Regulatory)

(1) The pharmacy must serve as the source from which ward/clinics and other departments of a facility obtain controlled substances for use in connection with the treatment of patients. Authorized outpatient prescriptions for controlled substances must be filled by the pharmacy.

(2) Controlled substances must be dispensed to outpatients on receipt of a prescription completed following article 21-22 with the following additional requirements:

Exception: Schedules II through V controlled substances when prescribed via prescriber-order-entry electronic pharmacy system.

(a) Prescriptions for controlled substances must be written in ink, typewritten, or entered through prescriber-order-entry electronic pharmacy system. Duplicate, carbon copy, photographic reproduction, preprinted, or rubber-stamped orders are not valid prescriptions for controlled substances. For all Schedule II-V prescriptions, the prescriber's signature must be handwritten or comply with DEA electronic prescribing requirements.

(b) Must contain the complete address of the person for whom the prescription is written and may be supplied by patient or agent at time of dispensing.

(c) The legible signature and identifying information of the provider authorized to prescribe per article 21-5. In addition, the name of the prescriber must be stamped, typed, or hand printed on the written prescription or verifiable through additional means.

(d) Erasures or interlineations on prescriptions for controlled substances are prohibited, unless initialed by the prescriber. This does not preclude pharmacy personnel from annotating, after contacting the prescriber that a therapeutic substitution is necessary due to the unavailability of the product prescribed.

(e) 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.

(3) Controlled substance prescriptions will be reviewed for authenticity before dispensing the prescription.

(4) If a sufficient supply of a Schedule II controlled substance is unavailable to fill a prescription, a partial quantity may be dispensed if requested by the patient. In cases where the prescription cannot be completely filled, the remaining portions must be filled not later than 30 days after the date on which the prescription is written. If the remaining balance cannot be filled after 30 days, the provider will be notified, and a new prescription will be required for the balance. The quantity dispensed must be noted on the front of the prescription, or by appropriate means for provider-order-entry prescriptions.

(5) Prescriptions for Schedule II controlled substances must be dated, have the quantity dispensed annotated, and numbered on the prescription at the time of filling. The prescription must also include the date, address, and signature of the recipient of the drug item.

(6) Time and quantity limitations for filling and refilling controlled substance prescriptions

(a) *Schedule II Medications.* A prescription for a controlled substance classified as a Schedule II medication must be filled within 60 days of the date originally written or "do not fill before date" as written by a provider. Schedule II medications are normally limited to a reasonable quantity of medication as defined by MTF policy, usually not to exceed a 30-day supply. Up to a 100-day supply of stimulant medications is authorized. Up to a 90-day supply of pain medications for oncology patients only is authorized. Schedule II prescriptions must not be refilled. Deploying members may receive the deployment supply of Schedule II medications, following guidance of the area of responsibility (AOR).

(b) *Schedule III, IV, and V Medications.* A prescription for a Schedule III, IV, or V medication must be filled within 6 months of the date originally written. These prescriptions may be refilled, if authorized by the prescriber, up to five times within a 6-month period from the date originally written. Schedule III-V medications are normally limited to a reasonable quantity of medication as defined by MTF policy, not to exceed a 100-day supply. Deploying members may receive the deployment supply of Schedule III-V medications, following guidance of the AOR.

(7) A separate prescription file must be maintained for prescription records of Schedule II controlled substances.

(8) Prescription records of controlled substances listed in Schedules III, IV, and V must be maintained separately from all other records of the pharmacy.

(9) Schedule II controlled substances issued to ward/clinics and branch medical clinics must be accompanied by required forms as outlined in section III of this chapter, unless electronically controlled via an automated dispensing cabinet or if a BUMED-approved electronic form is used.

(10) Controlled substances must be dispensed with labels affixed following section I of this chapter. Controlled substances dispensed to ward/clinics must identify the medication schedule number on the pharmacy label or manufacturer's label. For outpatient prescriptions, a label with a clear, concise warning that 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.

(11) NAVMED 6710/1 Narcotic and Controlled Drug Account Record will be used to account for all controlled substances used in the compounding of pharmaceutical preparations. Such orders must be authenticated and signed by the pharmacists in charge of compounding and filed in the appropriate prescription file. The product must be assigned a local prescription, batch, and lot number. The scheduled product must be posted to the pharmacy stock record, unless it is an extemporaneous compound dispensed for a specific single patient prescription, or a product containing alcohol where the only controlled substance in the product is alcohol.

21-28 Control by Nursing Care Units and Clinics (Regulatory)

(1) To provide effective and adequate custody and audit trail accountability for controlled substance distribution and protection, the following controls must be enforced:

(a) A registered nurse, medical, or dental officer will be charged with custodial responsibility for controlled substances following this article and other directives that may be issued.

(b) The custodian of these substances must not permit any such substances to be placed in the possession of other personnel in quantities greater than the amount required for immediate consumption by the patients.

(c) The custodian must maintain a locked container, cabinet, or compartment of an approved nature to keep such substances. Medication storage and preparation areas must be locked unless personnel working in the area have a continuous, unobstructed view of the area. Keys to the containers, unless not required (such as automated dispensing cabinets), must remain in the custody of the individual responsible and transferred only to another authorized individual per nursing policy.

(d) Nursing/clinic supervisors are responsible for and must ensure that a weekly inventory is conducted by nursing staff for controlled medications stored in nursing care area.

(2) Each ward/clinic or other activity drawing controlled substances from the pharmacy must maintain a folder or binder containing the NAVMED 6710/4 Narcotic and Controlled Drug Inventory-24 Hour and the NAVMED 6710/1 or similar automated forms following article 21-42. Those facilities using an automated dispensing cabinet for inventory control are exempted from maintaining the written forms, provided policies and procedures are in place covering security, discrepancy resolution, and down-time procedures. Such a system must provide accurate documentation of the audit trail, including all information that would otherwise be documented on the written form described in section III of this chapter.

(3) Controlled substances may be ordered from the pharmacy on a form approved by the command, and must be signed by an authorized official following article 21-4(1) or by the ward/clinic charge nurse. The supply of controlled substances to ward and clinics may also be by automatic replacement of dispensed stock at a set level by the pharmacy without a signed form.

(4) Pharmacy personnel may deliver controlled substances from the pharmacy to various ward/ clinics. If time does not permit, controlled substances ordered for ward/clinics must be picked up by personnel with custodial responsibility following article 21-28(1). Personnel accepting controlled substances delivery from pharmacy cannot be the same individual who submitted the request of the said substances. For branch clinic pharmacies, refer to article 21-29.

(5) Upon receipt of these substances from the pharmacy, the nurse in charge, medical officer, or dental officer must check the amount of drug and compare serial numbers on the NAVMED 6710/1 and the order form or prescription. This step may be waived in an MTF with a pharmacy controlled automatic replenishment system.

(6) The NAVMED 6710/1 and the reverse side of the DD Form 1289 or other order form, must be signed and dated in the appropriate space (see article 21-42 for information).

(7) If a discrepancy exists and cannot be resolved, a report must be made immediately through the nursing supervisor to the director of nursing services or respective head of service (medical officer custodian). Unresolved discrepancies must also be reported to the head of the pharmacy department and the senior member of the Controlled Substance Inventory Board.

(8) Controlled substances must not be stocked in emergency crash carts.

(9) Controlled substances dispensed using an automated dispensing cabinet should only allow access to one medication at a time, not multiple different medications, and require a blind count by the user.

21-29 Control by Branches to Pharmacy Service (Regulatory)

(1) For branch clinic pharmacies not able to order controlled substances directly from a Prime Vendor, controlled substances must be requested and delivered to pharmacy branches by the main pharmacy in the same manner as hospital ward/clinics are supplied. The branch pharmacy must send a prescription or authorized ordering form, signed by responsible pharmacy personnel for bulk quantities, to the main pharmacy. Per section III of this chapter, a NAVMED 6710/1 must accompany issue of Schedule II controlled substances. The command is responsible for delivery methods. All receipts must be signed for by a commissioned officer, pharmacist, or a pharmacy staff member appointed by the CO who is separate from the person requesting the controlled substance(s).

(2) Controlled Substance Inventory Board inventories of Schedule II controlled substances at branch pharmacies must be performed at least quarterly. Such inventories must be called by the senior member of the Controlled Substance Inventory Board and the results included in the MTF Controlled Substance Inventory Board report, with copies to the branch clinic OIC, senior medical officer, or representative, as applicable, and the parent MTF pharmacy department. At those branch clinics with insufficient staff to form a Controlled Substance Inventory Board, following article 21-24(2), personnel from the parent command may be used to comprise the Controlled Substance Inventory Board.

Note: There are no articles 21-30 through 21-39.

THIS PAGE INTENTIONALLY LEFT BLANK

Section III
FORMS, RECORDS, AND REPORTS

21-40 General (Regulatory)

(1) Records must be maintained describing certain procedures conducted within all Navy medical and dental facilities. Among mandatory requirements for record keeping are the prescribing of drugs, handling of controlled substances, quality control procedures, and investigational drug handling. Standardized forms are available for prescribing of drugs and handling of controlled substances.

(2) Requirements for record keeping may be accomplished by using pharmacy automated data systems capable of producing readily retrievable reports.

21-41 Prescription Forms (Regulatory)

(1) When electronic provider-order-entry is not available, use DD Form 1289, except as provided in article 21-50(11) for all single prescriptions. More than one non-controlled medication may be written on a DD Form 1289 or NAVMED 6710/6. All controlled or investigational drugs must be written on an individual DD Form 1289.

(2) Prescription blanks provided by or preprinted by a commercial company (such as drug manufacturer or distributor) must not be used in an MTF. A rubber stamp may be used on DD Form 1289 for commonly prescribed items, except controlled substances, providing the rubber stamp has been reviewed and approved by the pharmacy department head and MTF P&T Committee. Any preprinted prescription blank or medication order form will be reviewed and approved by the pharmacy department head and MTF P&T Committee prior to use in the MTF. Article 21-27(2)(a) applies.

21-42 Controlled Substance Forms (Regulatory)

(1) *NAVMED 6710/4*

(a) All NAVMED 6710/4 forms must be kept in a controlled substance book. See article 21-42(3).

(b) The oncoming shift custodian must sign the NAVMED 6710/4. This is only done after completing the end of shift inventory of all controlled drugs and prior to being relieved. When the ward/clinic uses an automated dispensing cabinet for controlled substances, no NAVMED 6710/1 or NAVMED 6710/4 are issued to ward/clinics, and no requirement exists for the traditional end of shift counts of controlled substances. The automatic systems must be capable of tracking and recording each controlled substance medication transaction. In this circumstance, nursing supervisors are required to access a dispensing discrepancy report through the dispensing unit at least daily. If it is determined that no transactional discrepancies are found, all controlled substance medication counts are assumed correct by the ward/clinic, unless otherwise notified by the pharmacy. The nurse reporting for duty and the nurse being relieved must check the drugs concurrently. Report any discrepancies immediately to the nursing supervisor and the MTF pharmacy department head for resolution or appropriate action.

(c) The nurse custodian is responsible for the addition of all serial numbers of new NAVMED 6710/1 on the NAVMED 6710/4. The serial number of completed NAVMED 6710/1 forms returned to the pharmacy must be entered in the appropriate column, and the pharmacist or authorized representative must sign to acknowledge receipt.

(d) At least weekly, the ward/clinic supervisor must audit the ward/clinic controlled substances supplies. After the audit, the nursing supervisor must date and sign the NAVMED 6710/4.

(e) Automated dispensing cabinets must be inventoried by the ward/clinic weekly to ensure controlled and Drugs with a High Potential for Diversion are accurately accounted for.

(2) *NAVMED 6710/1*

(a) Upon receipt of a properly completed prescription or order form from the ward or clinic, the pharmacy must prepare a separate NAVMED 6710/1 or similar automated form for each Schedule II-V controlled substance and any command controlled drug.

(b) If used, all NAVMED 6710/1 forms must be filed in a controlled substance book. See article 21-42(3).

(c) All entries must be made in indelible ink. Errors must be corrected by drawing a single line through the erroneous entry and legibly initialing it. The correct entry must be recorded on the following line, if necessary.

(d) If a new issue is received before the old issue is completely expended, the new NAVMED 6710/1 must be inserted in back of the current record. The serial number of the new NAVMED 6710/1 must be entered on the NAVMED 6710/4.

(e) The heading for each NAVMED 6710/1 must be completed at the time of issue. The body of the form must be used for recording expenditures and balances only.

(f) Each time a drug is expended, complete information must be recorded: date, time, patient, doctor's name, by whom given, amount expended, and the balance on hand (NAVMED 6710/1). See article 21-42(l)(b).

1. All amounts must be recorded in Arabic numerals. Where the unit of measure is a milliliter (ml) and the amount used is less than one ml, record as a decimal (such as 0.5 ml).

2. When the unit expended to the patient is a fractional dose, the unit administered must be placed in parentheses before the number of units in the expended column, such as an entry of "(35) 1" for a Meperidine 50 milligrams (mg) tubex indicates that one tubex of Meperidine 50 mg was expended and 35 mg was administered or "(35) 2" for Meperidine 25 mg tubex indicates that two tubexes of Meperidine 25 mg expended, only 35 mg was administered. The remaining unused portion of a whole dosage unit, if wasted, must be recorded as destroyed on the NAVMED 6710/1, including the date, amount, new balance, and signed by the authorized individual involved and a second authorized person. See article 21-42(l)(b).

3. If a single dose of a controlled substance is accidentally damaged or contaminated during preparation for administration, or is refused by the patient after preparation, the dose must be destroyed. A brief statement of the circumstances must be entered on the NAVMED 6710/1 or entered into the automated dispensing cabinet database by the authorized individual involved. Circumstances outlined above and in article 21-42(2)(c) must be signed on the NAVMED 6710/1 by the authorized individual involved and a second authorized person.

4. If multiple doses of a controlled substance are damaged or contaminated, the supervisor must record the disposition of the drug, including the date, amount of drug, brief statement of disposition, and new balance. The supervisor, the witnessing nurse, physician or dentist, and the authorized individual involved must sign the NAVMED 6710/1.

5. Deteriorated drugs must be returned to the pharmacy by ward/clinics. Drugs must be disposed of following article 21-26.

(g) The completed NAVMED 6710/1 must be returned to the pharmacy. The pharmacy officer or authorized representative must enter on the NAVMED 6710/5 the date the form was returned to the pharmacy. This information must be entered on the appropriate line bearing the same serial number (prescription number) as the NAVMED 6710/1.

(h) Monthly, the pharmacy must report to the Director of the Nursing Service or appropriate department head, all NAVMED 6710/1 forms 30 days overdue from date of issue. The report must be verified and returned to the pharmacy for reconciliation. Report discrepancies to the CO via report of the Controlled Substance Inventory Board.

(i) A locally prepared form or form generated by the pharmacy's automated data system may be substituted for NAVMED 6710/1, providing the form, at a minimum, bears the same data fields.

(3) Controlled Substance Book (for facilities not using automated dispensing cabinets)

(a) Each ward/clinic or other activity drawing controlled substances from the pharmacy (bulk stock) must maintain a binder containing the NAVMED 6710/4, in the first section, and the individual NAVMED 6710/1, Narcotic and Controlled Account Records in the latter sections.

(b) The nursing supervisor must remove all completed NAVMED 6710/4 forms over 3 months old from the Narcotic and Controlled Drug Book, and transfer the completed NAVMED 6710/4 forms to the pharmacy for storage for a minimum of 2 years.

(4) *NAVMED 6710/5*

(a) A separate NAVMED 6710/5 must be prepared for each Schedule II controlled substance. All boxes and columns except as noted below are self-explanatory:

1. Name of Drug. Enter generic name of drug or proprietary name as appropriate (Codeine Sulfate).

2. Strength (expressed as gram (gm) or mg).

3. Unit. Enter tablet or ampule, as appropriate; for liquids or powders enter “ml” or “gm.”

4. Prescription or Requisition Number. Enter appropriate prescription number requisition (voucher) number. For issues returned to the pharmacy, enter the source.

5. Recipient. Enter “pharmacy” for receipts. Enter ward/clinic number or name of patient, as appropriate, for expenditures.

6. NAVMED 6710/1 Returned. Enter the date the NAVMED 6710/l is returned to the pharmacy on the appropriate line bearing the same serial number or prescription number.

(b) On request of the Controlled Substance Inventory Board, the pharmacy department head, or authorized assistant, must total the quantity-received column and the quantity-expended column for inspection by the board.

(c) Upon completion of inspection, one board member must initial the receipts and expenditures columns or document on NAVMED 6710/1 that inventory was accurate.

(d) The foregoing procedures may be modified to record the information and maintain surveillance using computers.

21-43 Quality Control Forms (Regulatory)

(1) A compounding/Pre-pack Log will be used to provide clearly definable material sources (manufacturers’ names, lot number, and expiration dates), procedures used, intermediary and final checks by supervisory personnel, and sample labeling for all compounded and repackaged pharmaceuticals.

21-44 Availability of Forms (Regulatory)

(1) NAVMED 6710/1 Narcotic and Controlled Drug Account Record; NAVMED 6710/4 Narcotic and Controlled Drug Inventory-24 Hour; NAVMED 6710/5 Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs; and NAVMED 6710/6 Poly Prescription, S/N 0105-LF-206-7130 are available for order from the Naval Forms Online Web site at: https://navalforms.documentservices.dla.mil/web/public/home.

(2) The DD Form 1289 DoD Prescription, S/N 0102-LF-012-6201 is available at: http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm.

(3) DEA Form 106 Report of Theft of Controlled Substances may be obtained from: www.deadiversion.usdoj.gov/21cfr_reports/theft/.

21-45 Disposition of Records (Regulatory)

(1) All prescriptions may be destroyed after 2 years and are no longer needed for reference. All Schedule II through V controlled substance prescriptions and non-invoice accounting records (NAVMED 6710 forms) will be maintained and readily retrievable for at least 2 years. Invoice records must be stored according to SECNAV Manual 5210.1 section III 4-19.

Note: There are no articles 21-46 through 21-49.

THIS PAGE INTENTIONALLY LEFT BLANK

Section IV
DRUG DISPENSING WITHOUT A PHARMACIST

21-50 Physician Assistants, Nurse Providers, and Hospital Corps Personnel on Independent Duty (Regulatory)

(1) Physician assistants, nurse practitioners, and IDC may be assigned to medical duties on small vessels, shore stations, Fleet Marine Force, and mobile field units to which a medical officer is not attached. They perform all duties required of the Medical Department. These duties include Medical Department administration and to the extent for which qualified, the professional duties prescribed for medical officers of ships and stations.

(2) Custodial responsibility for controlled substances must be vested in a commissioned officer.

(3) Members of the Medical Department of the Navy must not take nor receive into custody, on board ship or in any Navy or Marine Corps establishment, any controlled substances except as authorized:

(a) For medicinal purposes.

(b) For retention as evidence in disciplinary actions.

(c) By Navy Regulations.

(4) Working stocks of controlled substances may be issued from the main pharmacy from time to time for dispensing purposes to the individual in charge of this pharmacy. This individual must be required to keep an accurate record of receipts and expenditures and to keep these substances under lock when not in use. Except as provided above, a custodial officer must not permit any of these substances to be placed in the possession of any person in quantities other than that required for immediate consumption by patients, or for use in emergency, such as combat. All drugs must be dispensed under the supervision of Medical Department representatives at activities where there are no officers of the Medical Department.

(5) Officers of the Medical Department are authorized to issue controlled substances, for medicinal purposes only, to COs of ships and to pilots of aircraft to which no Medical Corps officer is attached.

(6) An officer of the Medical Department, or if no such officer is available an officer designated by the CO, must keep all controlled substances in a separate locked compartment. The Controlled Substance Inventory Board must conduct an inventory quarterly or more frequently per article 21-29. A report will be made to the CO. Personnel of the Medical Department must assure all such substances under their charge are properly labeled.

(7) The executive officer, or other designated officer, must arrange for the care and safe custody of all keys, and require strict compliance with instructions concerning the receipt, custody, and issue of controlled substances contained in the law, U.S. Navy Regulations, and this manual. The keys must always be in the custody of an officer.

(8) Custodians, or their designated assistants, must retain the keys to the place of storage while on duty. When relieved, they must deliver the keys to their relief, or to a responsible person designated by local instructions. A copy of the combination of a safe, if used, must be sealed in an envelope and deposited with the CO or an officer designated by the CO.

(9) The senior Medical Department representative must take charge of the medical storeroom and maintain custody of the key. However, the medical officer, if one is assigned, or such other officer or petty officer designated by the CO, must be responsible for the security of the contents of the medical stores kept therein. Controlled substances must be kept in separate lockers and the keys to these lockers must always be in the custody of an officer.

(10) Directives issued by fleet force, type commander, CO, or other appropriate authority, may authorize the following deviations from the controls established in this chapter:

(a) Physician assistants, nurse practitioners, or the IDC at an activity not having a medical officer may be authorized to deviate from the control procedures established by this chapter, but not the intent regarding receipt, custody, and issuance of controlled substances. This deviation in no way relieves a command of the responsibility for controlled material.

(b) Physician assistants, nurse practitioners, or IDC may prescribe and administer only those controlled substances listed in the activity's AMAL. Authority to make revision or augmentation of controlled substances in AMALs will be obtained in writing from the type commander. A DD Form 1289 must be prepared and filed following this chapter.

(11) Physician assistants, nurse practitioners, or hospital corpsmen on independent duty are not required to use the DD Form 1289 for prescribing drugs given directly to the patient, other than controlled drugs, unless directed by the CO or higher authority. This does not relieve personnel on independent duty from complying with article 21-5(7).

21-51 Operational or Emergency Situations (Regulatory)

(1) If operational commitments call for deviation from the established controls of this chapter, special instructions must be issued by appropriate authority relative to the receipt, custody, and issuance of controlled substances, hazardous materials and other medications as needed.

Section V
REFERENCES AND ACRONYMS

21-52 References

BUMEDINST 6010.13 series, Quality Assurance Program
Available at: http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx

BUMEDINST 6010.17 series, Naval Medical Staff Bylaws
Available at: http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx

BUMEDINST 6570.3 series, Safe Handling and Disposal of Occupationally Hazardous Drugs and Environmentally Hazardous Drugs *(Personnel that need access to this instruction must submit a request to: usn.ncr.bumedfchva.mbx.bumed-directives@mail.mil)*

OPNAVINST 6400.1 series, Training, Certification, Supervision Program, and Employment of Independent Duty Hospital Corpsmen
Available at: https://doni.documentservices.dla.mil/secnav.aspx

SECNAVINST 3900.39 series, Human Research Protection Program
Available at: https://doni.documentservices.dla.mil/secnav.aspx

SECNAV Manual 5210.1 section III, page III-4-19
Available at: https://doni.documentservices.dla.mil/secnavmanuals.aspx

Executive Order 13139
Available at: https://www.gpo.gov/fdsys/pkg/FR-1999-10-05/pdf/99-26078.pdf

Controlled Substance Act of 1970 (Public Law 91-513)
Available at: https://www.drugs.com/csa-schedule.html

10 USC §1107
Available at: http://uscode.house.gov/search/criteria.shtml

THIS PAGE INTENTIONALLY LEFT BLANK

21-53 Acronyms

AAAAI	American Academy of Allergy, Asthma and Immunology
ACPE	Accreditation Council for Pharmacy Education
AD	Active Duty
AMAL	Authorized Medical Allowance List
AOR	Area of Responsibility
BCF	Basic Core Formulary
BSC	Biological Safety Cabinet
BSO	Budge Submitting Office
BUD	Beyond Use Date
BUMED	Bureau of Medicine and Surgery
CHCS	Composite Health Care System
CO	Commanding Officer
CONUS	Inside of the continental United States
DEERS	Defense Enrollment Eligibility Reporting System
DEA	Drug Enforcement Administration
DOD	Department of Defense
DMLSS	Defense Medical Logistics Standard Support
DSCP	Defense Supply Center Philadelphia
FDA	U.S. Food and Drug Administration
GM	Gram
HEPA	High-Efficiency Particulate Air
ID	Identification
IDC	Independent Duty Corpsman
MDV	Multiple Dose Vials
MG	Milligram
ML	Milliliter
MTF	Medical Treatment Facility
NEC	Navy Enlisted Classification
OCONUS	Outside of the Continental United States
OIC	Officer in Charge
OTC	Over-the-Counter
P&T	Pharmacy and Therapeutics
PRN	Pro Re Nata (as needed)
USAMMA	United States Army Medical Material Agency

THIS PAGE INTENTIONALLY LEFT BLANK