

Change 133
Manual of the Medical Department
U.S. Navy
NAVMED P-117

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To: Holders of the Manual of the Medical Department

1. This Change Completely revises Chapter 21, Pharmacy Operation and Drug Control. MANMED Chapter 21 is guidance for pharmacy operations. A pharmacist's clinical judgment and a patient's immediate needs should always be considered when deciding to deviate from written guidance, recognizing that in no case shall Federal law be violated.

2. Action

- a. Remove Chapter 21 and replace with new Chapter 21.
- b. Record this Change 133 in the Record of Page Changes.

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Chapter 21

Pharmacy Operation and Drug Control



Chapter 21

CONTENTS



Sections	Page
Section I. Pharmacy Administration	21-3
Section II. Controlled Substances	21-19
Section III. Forms, Records, and Reports	21-29
Section IV. Drug Dispensing without a Pharmacist	21-33

Section I

PHARMACY ADMINISTRATION

Article		Page
21-1	Facilities (Regulatory)	21-3
21-2	Personnel (Regulatory)	21-3
21-3	Responsibilities (Regulatory)	21-4
21-4	Prescribers (Regulatory)	21-7
21-5	Outpatient Prescriptions (Regulatory)	21-8
21-6	Inpatient Dispensing (Regulatory)	21-14
21-7	Drug Stock (Regulatory)	21-15

21-1

Facilities (Regulatory)

(1) Naval medical treatment facilities (MTFs) 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 are graduates of accredited (by the Accreditation Council for Pharmacy Education (ACPE)) pharmacy colleges or have a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate and are actively licensed in one of the 50 United States, the District of Columbia, or Puerto Rico. A licensed pharmacist will provide professional oversight of pharmacy services at all fixed MTFs (Budget Submitting Office (BSO-18) facilities) in the United States and overseas where a pharmacy is operated.

(2) The number of pharmacists and technicians assigned to a facility is determined by the Bureau of Medicine and Surgery (BUMED) Pharmacy Staffing Standard.

(3) At fixed MTFs where a pharmacist is not available, pharmacies may be operated:

(a) By military-trained pharmacy technicians operating under the Department of Defense (DoD)/The Joint Commission (TJC) protocol (reference Interim Protocol dated 2006).

(b) Using a telepharmacist option (e.g., a licensed pharmacist at a central pharmacy site checks prescriptions prior to dispensing to the patient at a remote telepharmacy site through the use of video conferencing technology. This technology shall be able to support two-way communication between the pharmacist and the patient).

(c) By the use of remote pharmacists to support inpatient pharmacy operations to ensure adherence to TJC medical management standards of prospectively checking medication orders. MTFs will ensure that inpatient pharmacy policies and procedures provide for maximum patient safety when 24/7 pharmacist coverage is not available due to staffing shortfalls.

21-3

Responsibilities (Regulatory)

(1) The commanding officer (CO) is responsible for the operation of the pharmacy. The pharmacy shall be operated per Federal and State law, service regulations, and accepted standards of practice, such as those defined by TJC 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 HM-8482 pharmacy technician will be assigned supervisory responsibilities. The CO and/or officer in charge (OIC) responsible for a BSO-18 MTF, without an active duty pharmacist assigned (e.g., branch clinic),

shall ensure that pharmacy operations are revised through site visits and inspections. For non-BSO-18 activities without a pharmacist, the CO may assign responsibility to an enlisted pharmacy technician (NEC 8482), under the supervision of a physician or nurse practitioner.

(2) The CO shall:

(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, Drug Diversion Guidance.

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

1. Providing drug information and policy assistance to authorized individuals in the proper writing of prescriptions. In particular, advise 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, and 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. Providing inspections, at least monthly, of all areas where pharmaceuticals are dispensed, administered, or stored. The inspections should include, but not necessarily be limited to: adequate labeling, appropriate storage conditions, stock level, evaluation of condition and potency based on expiration dates and check markings of storage areas for expired drugs.

3. Maintaining current drug information resources, and routinely disseminating drug information to medical provider staff and patients.

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

5. Maintaining and publicizing, either electronic or hard copy, an MTF formulary for use in the facility and by its patients and external customers (e.g., civilian network providers, other local MTFs, etc.). MTFs shall have the DoD basic core formulary 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. Providing proper and separate storage, safeguarding, labeling, and dispensing of investigational drugs.

b. Maintaining investigational drug files.

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

d. Maintaining 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: Operating a pharmacy sterile products program to include the preparation and delivery of pharmaceutical sterile products in compliance with the United States Pharmacopeia (USP) standards.

Maintaining laminar flow hood, biological safety cabinet (BSC) quality control requirements which shall 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. Centralizing all sterile compounding procedures within the pharmacy department or its satellites.

8. Providing, for the safety and economy, a 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 system is in place.

d. A patient medication profile is concurrently maintained by the pharmacy for each patient.

e. Minimize the use of floor stock medications.

9. Ensuring 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 shall 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 shall ensure all appropriate data is retained for on-line data entry as soon as possible when the computer system is available.

10. Ensuring prescriptions are filled only for eligible beneficiaries. Use TRICARE Eligibility Web site at: <http://www.tricare.mil/mybenefit/> - select overview tab, then select eligibility.

11. Assuring, 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. Assuring 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 medical needs. This may include, but not be limited to:

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

b. Obtaining access to deployable forces current medication information.

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

13. Ensuring security measures are adequate to prevent unauthorized entry into the pharmacy. Such measures will include, but 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. Use of surveillance cameras and alarm protection to the maximum practical extent is encouraged. Maintain records of pharmacy door lock and alarm code changes and their frequency.

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

15. Ensuring written cautionary information is provided with prescription medications dispensed to patients, as required by law (e.g., hormone products). Drug information to include appropriate cautions on medication usage, possible side effects,

and potentially hazardous interactions with foods, should be available or provided to patients for all medications dispensed. Patient counseling along with medication labels, cautionary labels, and written pharmaceutical manufacturer guidelines shall be provided to the patient to the maximum extent possible following Federal Law and applicable professional guidelines.

16. Generally, if a specific pharmaceutical is not on a government contract, the MTF shall 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 Orange Book.

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 shall 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, purchasing of non-contracted items are allowed.

18. MTFs shall utilize an inventory management ordering system (e.g., Defense Medical Logistics Standard Support (DMLSS)) to manage their credit memos and order pharmaceuticals from their Prime Vendor credit account.

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

(a) Each parent MTF, with an organic pharmacy department, shall 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. The Committee will be composed of an interdisciplinary team with representatives from the medical, nursing, risk management, and pharmacy communities. Others disciplines (e.g., administrative and logistics communities) may be appointed as needed. The local P&T Committee shall 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 shall maximize its use of the Basic Core Formulary (BCF) and Extended Core Formulary (ECF) DoD P&T Committee decisions to avoid duplication of efforts.

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

4. Reviews all reported medication and misadventures (e.g., adverse drug reactions, adverse drug events) and medication errors including evaluation of all errors and trend analyses with risk management. A near-miss is defined as an event or situation that could have resulted in harm to a patient, if it had reached the patient..

5. Recommends policies to ensure the safe use of drugs in the facility, including the initial and annual review of pharmaceuticals approved for floor stock including items stored in automated dispensing cabinets.

6. Oversees drug usage evaluations and reviews.

7. Approves and reviews annually all pre-printed paper and electronic forms that include medications prior to their use in the MTF.

8. Complies with all National Patient Safety Goals (NPSG), TJC medication management standards, and other guidelines as directed by BUMED.

9. Recommends policies, to provide reason-able access to the facility by manufacturer representatives, to govern their conduct and activities while at the MTF.

10. Participates in risk management and quality improvement activities related to medication use.

11. Recommends policies and procedures for evaluation and acquisition of non-formulary medications in compliance with DoD Uniform Formulary decisions. (See article 21-5(10)).

12. Reviews and approves formularies for providers with limited prescribing privilege (e.g., Independent Duty Hospital Corpsmen (IDCs) and if applicable, nurse practitioners, physician assistants, and other mid-level practitioners.).

21-4

Prescribers
(Regulatory)

(1) Prescriptions from MTF and DoD authorized providers for formulary drugs will be honored. Authorized prescribers may include: Medical and Dental Corps officers, optometrists, physician assistants, pharmacists, physical therapists, podiatrists, nurse practitioners (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 Independent Duty Hospital Corpsmen (IDC) personnel authorized in Section IV of this chapter, and others authorized in writing by the CO (or delegated representative) to prescribe in their official capacities and defined by the MTF Professional Affairs office.

(2) Prescriptions written by civilian practitioners, other than those employed by the DoD, may be filled for authorized beneficiaries, providing the prescribed item is on the MTF formulary and a pharmacist verifies the prescription per current regulations.

(3) Pharmacies will fill all valid non-controlled prescriptions that are presented, regardless of the geographic location of the beneficiary or prescriber, providing the medication is on the MTF formulary, and the prescription conforms to applicable laws and regulations. Valid prescriptions will be filled following quantity restrictions and refill limitations.

(4) Medical Department personnel shall 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. 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) In MTFs located in a State where generic product selection by the pharmacist is not authorized, (or if the prescription is from another State where the authorization for product selection is unclear), the generic equivalent will not be substituted for a brand name drug on a civilian prescription, without prior approval of the prescriber. (TRICARE policy on generic medications is available at: <http://www.tricare.mil/mybenefit/home/Prescriptions/Medications/GenericMedications?>)

(b) 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. Dispensing host-nation provider prescription memorandum, April 10, 2007, provides guidance. Inside of the continental United States (CONUS), MTFs may only accept civilian prescriptions from CONUS providers.

(c) Civilian practitioner prescription service may not be withdrawn or curtailed without consent of BUMED via your respective Regional Command.

(5) IDCs shall 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 (e.g., controlled substances) shall be plainly stated. A copy of the letter shall be retained in the IDC Certification and Training Record with a copy provided to the pharmacy. OPNAVINST 6400.1 series provides guidance for training, certifying, and supervising IDCs.

(6) Prescriptions from civilian optometrists, nurse practitioners, physician's assistants, pharmacists, or other non-physician health care providers authorized to prescribe by State law and not under the employ of the Navy will be dispensed following the law of the governing State where the MTF resides.

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 only be used during periods of electronic-order entry system downtime. See special provisions for IDC personnel in article 21-50(1). 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 item. Prescriptions are acceptable when written by authorized prescribers on prescription forms authorized by other services and forms conforming to the State pharmacy laws from civilian practitioners. 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 written in ink, indelible pencil, typewritten, or a printed form generated from a computerized program and shall show the following:

(a) Patient's full name.

(b) Date prescription was written.

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

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

(e) Clear directions use for the patient.

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

(g) Valid legible signature of the prescriber.

Electronic signatures are accepted only for non-controlled substances if authorized by pharmacy law in the State where the prescriber is located. Consult local State Board of Pharmacy for clarification at: <http://www.nabp.net/ftpfiles/NABP01/ROSTER.pdf>.

- (h) Refill authorization (as applicable).
 - (i) Additional requirements for controlled substances are found in article 21-27.
 - (j) When prescriber-order-entry electronic pharmacy systems are used, the electronic signature is acceptable for all prescriptions, non-controlled substances, and for controlled substances in Schedules II through V. However, if a patient chooses to have a prescription filled in a community pharmacy or through the TRICARE Mail Order Program (e.g., TMOP), the physician is required to write a traditional prescription and sign it as required by 21 CFR 1306.05(a). Prescriptions for Drug Enforcement Administration (DEA) scheduled medications filled outside the MTF must also have the practitioner's government sponsored DEA number on the prescription.
 - (k) Other requirements per Federal law.
- (3) Outpatient prescription containers must be labeled properly and include:
- (a) The MTF dispensing the prescription, including the pharmacy telephone number.
 - (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).

- (i) Number of refills remaining.
- (j) Beyond-use date, if applicable.
- (k) Proper auxiliary or cautionary labels as indicated.
- (l) Other requirements per Federal law.

(4) Telephone or oral prescriptions will not be accepted, except in an emergency or under extraordinary situations, directly from an authorized prescriber. Telephone and oral prescriptions shall be immediately reduced to writing and read back to the provider for verification. 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. 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 shall comply with the requirements in article 21-5(2).

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

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

(7) MTFs will not routinely dispense prescriptions by mail. A TRICARE and Department of Veteran's Affairs (in certain areas only) mail order benefit (e.g., TMOP/consolidated mail out pharmacy (CMOP)) 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, 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. Mailing of prescriptions will follow the United States Postal Service Domestic Mail Manual.

(8) 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 medication and non-Food and Drug Administration (FDA) approved products are not covered under the TRICARE benefit.

(9) MTF pharmacies shall 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: http://www.pec.ha.osd.mil/MTF/UF_Info.htm, otherwise an alternative medication should be prescribed. This does not preclude the patient from choosing to have the prescription filled elsewhere. Under the Uniform Formulary guidance, certain medications require the completion of either a Medical Necessity form and/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).

(10) Prescriptions will be honored when written by military medical facility 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. Prescriptions from non-referral MTFs and civilian providers for non-formulary drugs need not be honored. See paragraph 1b under "General Policies" in the TRICARE Pharmacy Policy Guidance (ASD(HA) Policy Memo 95-011 of 26 Jul 1995) available at: <http://www.tricare.mil/policy/fy95/pharmpol.html>.

(11) Prescription medications for oral use by outpatients 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 shall be authorized by a notation in CHCS for the individual prescriptions or in the pharmacy comment section following the Poison Prevention Packaging Act of 1970 (as amended in 2008) available at: <http://www.cpsc.gov/businfo/pppa.pdf>. If CHCS is not available, then these

prescriptions shall be authorized by the patient's signature and such documentation shall remain on file within the MTF.

(12) 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 health care services.

(13) Acceptance of pharmaceutical samples from sales representatives for dispensing to patients is prohibited. Should a practitioner desire to evaluate a pharmaceutical, the practitioner's department head will request a review by the P&T Committee. If approved by the P&T Committee:

(a) Parameters will be established to allow evaluation.

(b) The product will be purchased via established procedures.

(c) After a reasonable evaluation period, the P&T Committee must determine if the product warrants formulary status.

(14) 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.

(15) A system designed to protect patient privacy and assure accurate identification of outpatients at the time they receive prescribed medications shall be established. Identification shall involve the use of two identifiers, the patient's name on the DoD military identification (ID) card and birth date or Social Security Number. 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 (e.g., authorization letter and front and back photocopy of patient's ID) for the release of medical information and prescriptions. Expired IDs will be confiscated via local MTF policy.

Eligibility can be confirmed temporarily by a Defense Enrollment Eligibility Reporting System (DEERS) check in the CHCS and a copy of the expired ID can be provided as a reference to obtain a new ID. Children under age 10 can generally use a parent's or guardian's ID card, but they shall be registered in DEERS. At age 10, the sponsor shall obtain an ID card for the child. DEERS ID Card Policies are available at: <http://www.tricare.mil/mybenefit/> - select Overview; select Eligibility; then select ID Cards (on the left side bar).

(16) The parent MTF CO may authorize a limited number of over-the-counter (OTC) drugs to be dispensed from the pharmacy in conjunction with a health care screener. Under no circumstances will a patient be authorized to select their own medications. A non-physician health care screener, identified by the MTF shall assess a patient's symptoms then either enters a prescription into CHCS for recommended OTC drugs, selects the appropriate item(s) on the approved list, and sends it with the patient to the pharmacy, or refers the patient for more definitive care. Guidelines for an OTC health care 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 shall 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 shall be dispensed in the manufacturer's original container.

(d) OTCs dispensed in these programs shall be recorded into the patient's pharmacy profile.

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

(f) The following items shall be included on the locally developed pharmacy dispensing form:

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1. Title - OTC medication request.
 2. Sponsor's name.
 3. Sponsor's social security number.
 4. Recipient's name.
 5. Duty or home telephone number.
 6. Date.
 7. List OTC items approved by the P&T Committee.
 8. Signature of health care screener.
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(17) MTFs shall have written procedures for obtaining drugs when the pharmacy is closed and pharmacy personnel are unavailable as defined by current Joint Commission standards.

(18) Report and record all medication errors, including near-misses, via command's error reporting mechanism, and BUMED guidance.

(19) 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 prescription is not for a controlled substance drug listed in DEA Schedules II through V. An exception: Controlled substance medications used for seizure control may be provided in a quantity not to exceed a 72-hour supply (e.g., Clonazepam and Phenobarbital).

(b) Documentation in the CHCS prescription comment field will include that the fill was provided on a one-time basis.

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

(a) **Schedule II medications.** A prescription for a controlled substance classified as a DEA Schedule II shall be filled within 30 days of the date originally written. Based on the clinical judgement of the pharmacist, exceptions for controlled substances can be made beyond the 30-day timeframe if allowable within the limits of State or Federal Law. Note: State law or command policy may be more restrictive. Schedule II medications are normally

limited to a reasonable quantity of medication as defined by MTF policy, usually not exceeding a 30-day supply. Up to a 100-day supply of stimulant medications is also authorized. Exceptions to the 30-day limit can be made based on medical necessity based on MTF policy within the limits of State and Federal regulation. Schedule II prescriptions shall not be refilled. Deploying members may receive up to a 90-day supply of Schedule II medications.

(b) *Schedule III, IV, and V medications.* A prescription for a controlled substance classified in DEA Schedule III, IV, or V shall 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 II-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 up to a 180-day supply of Schedule III-V medications.

(c) *Non-controlled medications.* A prescription for a non-controlled medication shall 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. Active duty beneficiary prescriptions may be dispensed larger quantities to meet readiness requirements. Since there are many reasons the prescriber may want to limit drug supplies to certain patients, MTF policies shall retain enough flexibility for the provider to limit the quantity of medication dispensed to an individual patient.

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

(d) Non-controlled prescriptions marked with PRN refills may be refilled up to 1 year from the date originally written.

(e) If an MTF is located in a State with a law that provides a more restrictive time limit, the State law will be followed when filling or refilling a prescription written by a civilian practitioner not employed by the DoD.

(21) The Prescribers Medication Dispensing Program (PMDP) is usually associated with military sick calls or specialized outpatient clinics (e.g., the dispensing of prenatal vitamins in obstetrics clinics and operated under the supervision of the prescriber or designee. Unless included in the PMDP or the OTC health care screener program, article 21-5(16), outpatient medications will be dispensed only on receipt of a prescription. With the exception of controlled substances, medications may be dispensed directly to the patient by an approved prescriber or designee after appropriate medical evaluation and appropriate medical record entries providing that:

(a) A specific protocol is used, which includes a method to monitor the distribution of the medications and a mechanism to certify and monitor the dispensing activities of the approved prescriber designee. For example, a log can be used that includes the date, patient's name, and sponsor's Social Security Number with patient identifying prefix, medication and strength, prescriber, any patient drug allergies, and name of the dispenser.

(b) The list of medications used in the PMDP has been reviewed by the P&T Committee or other appropriate medical staff committee and approved by the CO.

(c) All drug products are provided by the pharmacy and properly labeled.

(d) If required, the patient's name, prescriber, and date shall be affixed to the label when the product is dispensed.

(e) The prescriber-dispenser is responsible for implementing quality control measures to ensure the safe dispensing of all drugs in the PMDP. These measures must include, but are not limited to:

1. An annual review and revision of the protocol for dispensing the medications, that includes the list of medications.

2. Written criteria-based quality improvement reviews to ensure personnel dispensing medications from the PMDP comply with the protocol.

3. Appropriate designed medication use evaluations to ensure proper use of the medications.

4. Necessary security measures are followed to prevent unauthorized dispensing of drug products from the PMDP.

(f) The effective and efficient operation of the PMDP shall be included in the planned and systematic monitoring and evaluation of the MTF's Quality Improvement Program.

(g) The effective and efficient operation of PMDP shall include a process to document the prescribed medication into the patient's electronic medication profile.

(22) 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.

(23) 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 copy)" will be recorded in the activity log comment field of the electronic prescription record when discontinuing the prescription to void remaining refills. Once a Schedule III to V prescription has been transferred to a civilian pharmacy, the same prescription cannot be accepted for transfer back into the MTF. When a prescription originally filled at a 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 shall be the date of original prescription.

(24) Prior to releasing patient sensitive information, all requests shall 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 shall be kept in the pharmacy's files.

(25) A pharmacy may use a photographic reproduction, carbon copy, or electronically transmitted facsimile of discharge orders as a prescription order for outpatient dispensing when patients are being discharged from the facility, to include prescriptions for Schedules II through V controlled substances. The discharge order shall meet the minimum requirements of article 21-5(2) and be filed following article 21-27(6) and (7).

(26) 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 prescription number and telephone number. The pharmacist or senior technician dispensing the prescription will sign the copy. For controlled substances, see article 21-27(2)(e).

(27) Non-FDA approved products such as nutraceuticals, homeopathic, and therapeutic dietary supplements are not a TRICARE-covered benefit, therefore, not dispensed by the pharmacy department. These agents are not subject to FDA regulation regarding good manufacturing processes which presents legal risks to the MTF. If required, these agents are subject to review by the P&T Committee and approval by the MTF CO. These items are typically provided by departments outside of the pharmacy or brought into the facility by the patient.

(28) Injectable medications to be administered by home health care 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. MTF pharmacists shall ensure patients receiving injectable medications for self-administration have been trained on proper storage, use, and disposal.

(29) Refills for maintenance medications may be requested when 75 percent or more of the prior prescription has been used. A pharmacy officer may authorize an early refill, under special circumstances (e.g., patient on travel out of the area, disasters, or contingency operations).

(30) Prescriptions for formulary medications, written by physician extenders who are duly credentialed 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 shall be dispensed from that facility unless the beneficiary chooses another option.

(32) All new and refill prescriptions will be dispensed to include a printed Patient Education Monograph from CHCS along with any appropriate FDA-approved Medication Guide to distribute the side effect statement as required by the Federal Register 21 CFR Parts 201, 208, and 209 [Docket No. 2003N-0342]. Pharmacies may also in addition to but not in lieu of; distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product or on a preprinted pharmacy prescription vial cap.

(33) The MTF CO and P&T Committee shall 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 shall 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.

(34) When the enterprise data entry system (CHCS) is down, only prescriptions written by civilian and MTF providers for urgent medications (i.e., antibiotics, pain medications) may be filled unless an adequate downtime system is available that offers complete patient medication profile information. Labeling will include elements specified by paragraphs 21-5(2) and 21-5(3). 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.

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 medication dispensing systems, which shall include the pharmacist interpreting the physician's orders and monitoring inpatient medication needs.

(2) The preparation of sterile products, (e.g., chemotherapeutics, large and small volume intravenous admixtures, and irrigations) is an important part of the drug delivery system. Centralizing all sterile compounding within the pharmacy department is recommended where resources permit. COs will ensure USP 795 and 797 are observed. The pharmacy department head is responsible for providing written guidelines and approving procedures for preparing, sterilizing, and labeling parenterals, whenever these functions are not performed under direct pharmacy supervision. (View latest revision to USP 797 Standards at: <http://www.usp.org/pdf/EN/USPNF/PF797.pdf>.)

(3) Monthly checks will be made by the pharmacy of all nursing care units or other areas 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.

(4) Automatic stop orders for drugs dispensed to inpatients are to be determined by the medical staff and the P&T Committee. Recommended drugs to be included in automatic stop order policies are antibiotics, anticoagulants, controlled substances, hypnotics, and sedatives. There shall be a system to notify the practitioner responsible for the patient of the impending expiration of a drug order, so the practitioner may determine whether the drug administration is to be continued or altered.

(5) When a patient transfers to a different level of care, all orders shall be automatically canceled and rewritten (i.e., ward transfers, ward to surgery, etc.). National Patient Safety Goals (NSPG) and medication reconciliation procedures shall be followed.

(6) The pharmacy is responsible for labeling medications. All medications issued in bulk containers to nursing care units or clinics, not dispensed in the original container, shall be labeled by the pharmacy with the date of issue, generic and 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 USP requirements not to exceed 1 year or the actual manufacturers 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.

(7) Drugs issued to clinics for subsequent reissue to patients will be properly labeled with adequate directions for patient use. Information listed in article 21-5(3)(a), (e), (f), (j), and (k) shall be included on the label in the pharmacy or shall be added in the clinic.

(8) Inpatient self-care and discharge medications should be labeled as outpatient prescriptions following article 21-5(3). The MTF shall assess that self-administered medications are safely and accurately administered.

(9) Nursing personnel shall collect all medications brought to the hospital by patients admitted to nursing care units. When possible, these drugs will be given to a member of the patient's family to return to the

patient's home for safekeeping. Medications collected in this manner will not be retained by the patient, unless an order is written by the practitioner responsible for the patient that the patient may use his or her own medication following established MTF policy (e.g., "keep personal medications at bedside," "patient may take own medications"). Those medications not given to a family member shall be reviewed by a pharmacist prior to being authorized for patient bedside use and shall be stored in a lockable storage cabinet at the patient's bedside, or in the pharmacy. All medications will be identified, inventoried, secured, and held until the patient is discharged. The medications may be returned to the patient upon discharge. Any medications remaining 15 days after date of discharge shall be destroyed following locally established destruction procedures.

21-7

Drug Stock (Regulatory)

(1) Personnel filling and dispensing medications shall understand their actions and shall have general knowledge regarding the dosage range and contraindications.

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

(3) 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 shall 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.

(4) Only those items, which have been licensed and approved by FDA for sale in the United States, are authorized for use in CONUS MTFs. (The use of investigational drugs is included in BUMEDINST 6710.69 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.

(5) Each MTF will have a written policy regarding borrowing drugs from another MTF or civilian facility, (e.g., 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, (e.g., community pharmacies, hospitals), and methods of reimbursement to the loaner, (e.g., replacing the same type item at a later date, or with similar items based upon wholesale value).

(6) Investigational drugs shall be stored and processed through the pharmacy following BUMED-INST 6710.69 series.

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

(8) Caustic substances such as glacial acetic, sulfuric, nitric, concentrated hydrochloric, trichloroacetic acid, or oxalic acid, and concentrated potassium hydroxide shall be submitted and approved by the MTF CO prior to being issued to nursing care units, clinics, or outpatients. They shall be stored in separate lockers and contents shall be clearly marked.

(9) Flammable drugs shall be stored following accepted fire safety regulations.

(10) Each MTF shall have written procedures for drugs recalled by the FDA. These procedures shall be implemented readily and the results documented.

Such procedures shall include obtaining recall notifications from United States Army Medical Material Agency (USAMMA) and documentation of responses to such notifications through the use of the inventory ordering and management system (e.g., 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.

(11) Facilities will minimize the potential for the dispensing of expired drugs through effective inventory management (see article 21-7(3)), 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) Pharmaceuticals that will expire first shall be placed in a position to be used first.

(d) 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. Special consideration should be given to medications normally dispensed in 90-day supply or greater. To the maximum extent when possible, expired medications should be inventoried when removed during the monthly inspections.

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

(f) Prior to transfer of drugs to a contracted reverse distributor, an inventory of all returned pharmaceuticals shall be validated with the contractor. The inventory shall 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 shall ensure that an MTF-prepared inventory listing accompanies the shipment and is maintained on file to compare to the contractor's records.

1. Credits will be monitored to ensure utilization within 90 days after posting at the Prime Vendor. (Otherwise, unused credits are sent to the U.S. Treasury.)

2. BUMED MTFs and activities shall 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 Defense Supply Center Philadelphia (DSCP) Web site at: <http://www.dmmonline.dscp.dla.mil/pharm/reversedistribution.asp>.

3. MTFs shall utilize inventory management ordering system (e.g., DMLSS) to manage credit memos and order pharmaceuticals from the Prime Vendor credit account.

(12) Manufacturing and handling of sterile products shall follow current USP 797 recommendations.

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

- (a) Use strict aseptic technique.

(b) Upon reconstitution, date an MDV that requires addition of a diluent, label with a beyond-use date, store, and discard following the manufacturer's stability data, not to exceed the current reference standard as stated in USP 797. For multiple-dose vial vaccines, follow BUMEDINST 6230.15 series and CDC guidance for vaccines as it is specific for each agent (the Centers for Disease Control (CDC) Vaccine Management Book is available at: <http://www.cdc.gov/vaccines/pubs/downloads/bk-vac-mgt.pdf>). If CDC, FDA, or manufacturer's literature does not exist, then follow USP 797.

(c) Date any opened or entered (e.g., needle punctured) MDV, which does not require addition of a diluent and discard according to the current reference standard as stated in USP 797. The beyond-use date for MDVs with an antimicrobial preservative is 28 days, unless otherwise specified by the manufacturer. Opened or needle punctured single dose containers shall be used within 1 hour and any remaining contents discarded. Date and time for single dose must be marked upon opening or puncture.

(d) Discard contaminated vials immediately upon detection.

(e) Include observation of adherence to this article in the monthly inspections required by article 21-3(2)(f)(2).

(14) A log or electronic record of all medications placed in storage counting cells (e.g., 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.

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Section II

CONTROLLED SUBSTANCES

Article		Page
21-20	General (Regulatory)	21-19
21-21	Accountability (Regulatory)	21-20
21-22	Prescribing (Regulatory)	21-20
21-23	Custody (Regulatory)	21-21
21-24	Security (Regulatory)	21-21
21-25	Reporting Theft or Loss (Regulatory)	21-23
21-26	Deterioration (Regulatory)	21-24
21-27	Dispensing by Pharmacy (Regulatory)	21-24
21-28	Control by Nursing Care Units and Clinics (Regulatory)	21-25
21-29	Control by Branches to Pharmacy Service (Regulatory)	21-26

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 will establish special security and accounting procedures for these command-sensitive items designated as “drugs with a high potential for diversion (DHPD).”

(4) Alcoholic beverages shall 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 (CSIB) (per article 21-24). Working stock may be kept in a locked area within the pharmacy. At the CO’s discretion, a copy of the safe combination shall be stored in a sealed envelope deposited with the CO or representative. The combination shall be changed every 6 months or upon change in custodian or any suspected compromise of the combination. Command shall limit the number of personnel who can access the bulk stock vault to the minimum necessary and a vault access list shall be maintained.

(2) Schedule III, IV, and V controlled substances require locked cabinet security for storage of bulk drugs. The appointed pharmacy custodian will conduct a biennial inventory, on or about 1 May of odd numbered years, of all controlled substances following DEA law, and if needed, a quarterly audit, or more frequently, of high abuse potential Schedule III, IV, and V controlled medications. See article 21-7(3) for inventory management control and stock level requirements.

21-22

Prescribing (Regulatory)

(1) All prescribers authorized in section I of this chapter shall prescribe controlled substances either by electronic-order-entry; DD Form 1289, Prescription Form; NAVMED 6710/6, Poly Prescription; or coded facsimile, if appropriate.

(2) Authorized prescribers, when prescribing drugs in an official capacity within the scope of the Controlled Substances Act, are exempt from registration under provision of 21 CFR 1301.25 of the Controlled Substances Act. A prescriber exempted from registration under 21 CFR 1301.25 shall include on all prescriptions the prescriber’s branch of service or agency (e.g., “United States Navy” or “Public Health Service”) and must include the practitioner’s service identification number or Social Security Number as required by 21 CFR 1306.05(h). Other practitioners’ identifiers (National Provider Identifier) may not be substituted for the DEA number. In addition, 21 CFR 1306.05 of the Controlled Substances Act requires each prescription 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 21 CFR 1306.05(a) and 21 CFR 1306.11 when the prescription is filled at the MTF. This exemption does not apply when the prescriber provides professional treatment outside official duties. (The TMA policy on DEA Numbers for DoD providers is available at: <http://www.tricare.mil/policy/ha00pol/000407.htm>. Written prescriptions filled by the mail order program or retail pharmacies must contain the provider’s government sponsored 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, shall be so designated on the command’s registration filed with the Registration Branch, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. Only individuals so designated may sign the official order form for Schedule II substances.

Government registration is for 3 years, but individuals designated may be changed as necessary by letter to DEA, signed by the CO.

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

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

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

(7) Providers shall 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) Prescriptions for controlled substances will be filled only from prescribers in the local area, exception to be made at the discretion of the pharmacy department head or as defined by the MTF CO.

(9) 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.

21-24

***Security
(Regulatory)***

(1) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, MTFs may dispense a minimal working stock containing no more than 4 days of Schedules III through V based on the stock level criteria in article 21-7(3) 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. MTF Commanders should strongly consider closed-caption video technology and controlled access technology to minimize the risk of drug diversion.

(2) Controlled substances classified as DEA Schedule I through V require special handling and accounting to provide adequate protection against drug abuse, carelessness, theft, and misappropriation. Mitigating diversion of controlled substances and Drugs with High Potential for Diversion (DHPD) should be accomplished using the following guidelines:

(a) MTFs should develop and regularly review a list of DHPD that include controlled substances Schedules II through V and other legend or OTC drugs that represent a risk for drug diversion. The use of functional, strategically placed security cameras in areas where DHPDs 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 DHPDs from receipt into inventory until dispensed to outpatients or administered to inpatients. Further, MTFs should establish percent thresholds for DHPDs that are not controlled substances Schedule IIs, along with a process to track DHPD 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

21-23

***Custody
(Regulatory)***

(1) Custodial responsibility for controlled substances and those drugs designated as locally-controlled drugs by the CO, shall be vested in a commissioned pharmacy officer, a civil service 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 shall designate, in writing, a member of the branch clinic as the custodian.

DHPD, 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 DHPDs established by the MTF should trigger further investigation and documentation causes. MTFs should utilize CHCS and other automated methods to monitor and track DHPD.

1. Auditing and Monitoring

a. MTFs must develop a list of DHPDs. The DHPD 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. For monitoring DHPDs that are not classified as a controlled substance Schedule II, Navy MTFs should establish a percent threshold to trigger further investigation. This percentage should be as low as possible, but will vary depending on the volume of DHPDs dispensed and available MTF resources.

c. MTFs should develop procedures and reports to audit and monitor DHPDs from receipt into inventory until dispensed to outpatients or administered to inpatients.

d. All pharmacies with CHCS and a narcotic vault should be required to use the electronic inventory provided in the vault functions of CHCS and required to follow the procedures outlined in the Appendix, for the drugs deemed DHPDs at their site and at the determined interval.

e. All pharmacies, without CHCS, will keep a perpetual inventory on all controlled substances II through V and on all non-controlled drugs deemed DHPDs.

f. The use of functional, strategically placed security cameras in areas where DHPDs are stored, distributed, and administered may act a useful deterrent and investigative tool to mitigate drug diversion.

g. Current and new contract employee pharmacy positions shall include a drug testing provision equal to that required for GS or NSPS employees. This should include personnel in direct contact with narcotic, controlled, and other

DHPDs. Contracted personnel shall read and sign the Notice of Random Drug Testing under the Department of the Navy Drug-Free Workplace Program.

h. A "Transaction Report (specific)" should be run via <PRM-->NRR-->STR>, printed and attached to the invoice after DHPD items are added to the vault inventory in CHCS. The report should be run specific to the supply voucher number (usually the invoice number). A second person should verify the quantities added to the vault comparing this report against the invoice. If all entries are correct, the report is signed and dated by the second person and filed with the invoice, and kept on file for at least 2 years. Either the pharmacy department head or their designee will verify these reports.

i. 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. Automated Dispensing Machine (Pyxis). Allows for dispensing using user ID and password or BioID technology. Reports can be generated in Pyxis to track the medication from the Pyxis to the patient including filler demographics.

3. Controlled Prescription Menu. Is a paperless controlled prescription tracking system in CHCS. It may be used in conjunction with the breakout locker or Pyxis dispenser 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, Perpetual Inventory of Narcotics, Alcohol and Controlled Drugs, is no longer 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 Pyxis dispenser or breakout locker to the patient.

a. The controlled substance custodian shall 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 shall occur at least weekly. The bulk stock of Schedule I through V substances shall be secured using a double-lock

system. Steps shall be taken to restrict access to controlled substances. Keys and combinations shall be safeguarded appropriately.

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

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

- Access to each emergency kit or ADC shall be restricted. The type and quantity of controlled substances placed in the emergency kit shall be limited to the mission of the facility and approved by the CO through the P&T Committee.

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

- Hospital corpsmen may remove controlled substances from the kit or ADC 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 shall conduct the appropriate documentation of the controlled substance transaction.

c. Quarterly (or more frequently, depending on the activity), an unannounced inventory of Schedules I and II controlled substances, and those drugs designated by local command shall be made by the CSIB. The CSIB will have a minimum of three members. The CO may approve exceptions to the minimum requirement. At least one member of the board shall be a commissioned officer. The CO will appoint each member, in writing. Senior enlisted personnel in pay grades E-7 through E-9 and DON civilians in grades GS-7 and above or equivalent NSPS may serve as members at the discretion of the CO. Additional members may be appointed per article 21-29. The senior officer assigned to the board will be designated as the senior member. At least one officer of the board shall be a Medical Corps,

Dental Corps, Medical Service Corps, or Nurse Corps officer, except when not available. No member of the board may be directly responsible for the substances being inventoried. A sample of all prescribed accounting records and prescriptions for the accountable substances for the audit period will be checked for compliance with regulations, particularly as to dating, proper preparation, and required signature. The board shall ensure the records inspected constitute a complete audit trail and reflect transactions that occurred during the accounting period. Pharmacy stock, perpetual inventory records, requisitions, receipts, and issue documentation shall be audited. The identity of any questionable items of inventoried stock shall be ascertained. Nursing records and outpatient clinics that store controlled substances shall be checked to verify proper accounting for all documents and medications. CSIB will also ensure physical security of pharmacy spaces and monitor controlled access. Supply department records shall be reviewed, as required, to verify proper accounting for all documents. For this purpose, the supply department shall provide, directly to the senior member of the board, a copy of all issue documents for Schedules I and II controlled substances.

4. See article 21-45 concerning Controlled Substances Inventory Report. BUMEDINST 6710.70 series provides guidance for CSIBs.

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 following DEA regulations. The head of the pharmacy department, in conjunction with the senior member of the CSIB 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. Prepare an original and

three copies. Send the original and one copy to the nearest DEA regional office, one copy to BUMED Pharmacy Specialty Leader, one copy to the MTF region pharmacy representative, and one copy to the nearest field representative of the Naval Criminal Investigative Service. The consignee shall 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 narcotic inventory discrepancies to the senior member of the CSIB or appropriate higher authority.

21-26

**Deterioration
(Regulatory)**

(1) Return of expired Schedule I 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 (e.g., products that have deteriorated and are not usable, are of questionable purity or potency, or have had their identity compromised) through the contractor shall be inventoried for destruction. The appointed custodian may request authorization to destroy non-returnable controlled products and recommend a method of destruction (e.g., incineration). If destruction is indicated and approved by the CO, destruction shall be accomplished in the presence of a member of the CSIB. A certification shall 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, and signed by the members witnessing destruction, the certification shall be retained in the files as authority for dropping the items from the appropriate record. DEA notification is not necessary.

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

21-27

**Dispensing by
Pharmacy
(Regulatory)**

(1) The pharmacy shall serve as the source from which nursing care units, 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 shall be filled by the pharmacy. Ethyl alcohol may be issued directly to the laboratory providing such stocks are included in the quarterly audit conducted by the CSIB.

(2) Controlled substances shall 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 shall be written in ink, typewritten, or entered through prescriber-order-entry electronic pharmacy system. Duplicate, carbon copy, photographic reproduction, preprinted, rubber-stamped, or addressographed orders are not valid prescriptions for controlled substances, unless authorized by the law of the State in which the MTF resides, and approved by the MTF CO or OIC. In all cases, the prescriber's signature shall be handwritten.

Exception: See article 21-5(25).

(b) Shall 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 shall 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, if such practice is allowable per local State law.

(e) Each controlled substance prescription shall 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 prescriptions will be reviewed for authenticity before dispensing the prescription.

(4) Prescriptions for Schedule II controlled substances shall not be refilled. (See article 21-5(22) for time and refill limits on prescriptions.) 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 within 72 hours, the provider will be notified, and a new prescription will be required for the balance. The quantity dispensed shall be noted on the front of the prescription, or by appropriate means for provider-order-entry prescriptions.

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

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

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

(8) Schedule II controlled substances issued to nursing care units, outpatient clinics, and branch medical clinics shall be accompanied by required forms as outlined in section III of this chapter, unless

electronically controlled via an automated medication dispensing cabinet (AMDC) or a BUMED-approved electronic form is used.

(9) Controlled substances shall be dispensed with labels affixed following Section I of this chapter. 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 shall be affixed to the containers. In addition, controlled substances dispensed to nursing care units and clinics shall identify the DEA schedule on the pharmacy label or manufacturer's label.

(10) NAVMED 6710/1 forms will be used to account for all controlled substances used in the compounding of pharmaceutical preparations. Such orders shall be authenticated and signed by the pharmacists in charge of compounding and filed in the appropriate prescription file. The product shall be assigned a local prescription, batch, and lot number. The scheduled product shall 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 shall 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 shall 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 shall maintain a locked container, cabinet, or compartment of an approved nature to keep such substances. Medication storage and preparation areas shall be locked unless personnel working in the area have a continuous, unobstructed view of the area. Keys, unless not required (e.g., AMDCs), to the containers shall remain in the custody of the individual responsible and transferred only to another authorized professional.

(2) Each nursing care unit, clinic, or other activity drawing controlled substances from the pharmacy shall maintain a loose-leaf notebook containing the NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour and the NAVMED 6710/1, Narcotic and Controlled Drug Account Record or similar automated forms following article 21-42. Those facilities using an AMDC for inventory control are exempted from maintaining the written forms, provided policies and procedures are in place covering security, discrepancy resolution, and downtime procedures. Such a system shall 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 shall be signed by an authorized official following article 21-4(1) or by the nursing care unit charge nurse. The supply of controlled substances to nursing care units 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 nursing care units and MTF clinics. If time does not permit, controlled substances ordered for nursing care units and ambulatory clinics shall 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 shall check the amount of drug and

compare serial numbers on the NAVMED 6710/1, Narcotic and Controlled Drug Account Record 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, Narcotic and Controlled Drug Account Record and the reverse side of the DD Form 1289 or other order form, shall be signed and dated in the appropriate space. (See articles 21-42 and 21-43 for information.)

(7) Regulations governing the automatic stop order for controlled substances are in article 21-6(4).

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

(9) Scheduled controlled substances shall not be stocked in emergency crash carts.

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 shall be requested and delivered to pharmacy branches by the main pharmacy in the same manner as hospital nursing care units and clinics are supplied. The branch pharmacy shall 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, Narcotic and Controlled Drug Account Record, shall accompany issue of Schedule II controlled substances. The command is responsible for delivery methods. All receipts shall 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) Unannounced CSIB inventories of Schedule II controlled substances at branch pharmacies shall be performed at least quarterly. Such inventories shall be called by the senior member of the CSIB board and the results included in the MTF CSIB 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 CSIB, following article 21-24(2), personnel from the parent command may be used to comprise the CSIB.



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

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Section III

FORMS, RECORDS, AND REPORTS

Article		Page
21-40	General (Regulatory)	21-29
21-41	Prescription Forms (Regulatory)	21-29
21-42	Controlled Substances Forms (Regulatory)	21-30
21-43	Quality Control Forms (Regulatory)	21-32
21-44	Availability of Forms (Regulatory)	21-32
21-45	Disposition on Records (Regulatory)	21-32

21-40

General (Regulatory)

(1) Records shall 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 all procedures except quality control.

(2) All 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 articles 21-50(10) and 21-5(2)(i) for all single prescriptions. More than one non-controlled medication may be written on a DD Form 1289. All controlled or investigational drugs shall be written on individual DD Form 1289.

(2) Prescription blanks provided by or preprinted by a commercial company (i.e., drug manufacturer or distributor) shall not be used in an MTF. Rubber stamp or addressograph plate may be used on DD Form 1289 for commonly prescribed items, except

controlled substances, providing the rubber stamp or addressograph plate 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

Substances Forms (Regulatory)

(1) NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour

(a) All NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour forms shall be kept in a controlled substance book. See article 21-42(3).

(b) The oncoming shift custodian shall sign the NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour accountability record. This is only done after completing the end of shift inventory of all controlled drugs and prior to being relieved. When the nursing unit uses an automatic narcotic and controlled substance dispensing unit, no NAVMED 6710/1, Narcotic and Controlled Drug Account Record or NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour sheets are issued to nursing units, and no requirement exists for the traditional end of shift counts of controls and narcotics. The automatic systems shall be capable of tracking and recording each narcotic and controlled 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 narcotic and controlled medication counts are assumed correct by the nursing unit, unless otherwise notified by the pharmacy. The nurse reporting for duty and the nurse being relieved shall 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 6710/1s on the NAVMED 6710/4. The serial number of completed NAVMED 6710/1s returned to the pharmacy shall be entered in the appropriate column, and the pharmacist or authorized representative shall sign to acknowledge receipt.

(d) At least weekly, the nursing unit supervisor shall audit the nursing care unit controlled substances supplies. After the audit, the nursing supervisor shall date and sign the NAVMED 6710/4.

(e) AMDCs shall be inventoried by the pharmacy department weekly to ensure controlled and DHPD are accurately accounted for.

(2) NAVMED 6710/1, Narcotic and Controlled Drug Account Record:

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

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

(c) All entries shall be made in indelible ink. Errors shall be corrected by drawing a single line through the erroneous entry and legibly signing it. The correct entry shall 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 shall be inserted in back of the current record. The serial number of the new NAVMED 6710/1 shall be entered on the NAVMED 6710/4.

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

(f) Each time a drug is expended, complete information shall 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(1)(b).

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

2. When the unit expended to the patient is a fractional dose, the unit administered shall be placed in parentheses before the number of units in the expended column, e.g., an entry of "(35) 1" for a Meperidine 50 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, shall 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(1)(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 shall be destroyed. A brief statement of the circumstances shall be entered on the NAVMED 6710/1 or entered into the automatic narcotic and controlled substance dispensing unit database by the authorized individual involved. Circumstances outlined above and in article 21-42(2)(c) shall 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 shall 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 shall sign the NAVMED 6710/1.

5. Deteriorated drugs shall be returned to the pharmacy by nursing care units and clinics. Drugs shall be disposed of following article 21-26.

(g) The completed NAVMED 6710/1 shall be returned to the pharmacy. The pharmacy officer or authorized representative shall enter on the NAVMED 6710/5 the date the form was returned to

the pharmacy. This information shall be entered on the appropriate line bearing the same serial number (prescription number) as the NAVMED 6710/1.

(h) Monthly, the pharmacy shall report to the Director of the Nursing Service or appropriate department head, all NAVMED 6710/1s outstanding 30 days from date of issue. The report shall be verified and returned to the pharmacy for reconciliation. Report discrepancies to the CO via report of the CSIB.

(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 AMDCs)*

(a) Each nursing care unit, clinic, or other activity drawing controlled substances from the pharmacy (bulk stock) shall maintain a loose-leaf notebook containing the NAVMED 6710/4, Narcotic and Controlled Drug Inventory-24 Hour in the first section, and the individual NAVMED 6710/1, Narcotic and Controlled Account Records in the latter sections. The only exception to this policy is any unit using and storing all controlled medications in an automatic narcotic and controlled medication-dispensing unit.

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

(4) *NAVMED 6710/5, Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs*

(a) A separate NAVMED 6710/5 shall 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, e.g., Codeine Sulfate.

2. *Strength.* Expressed as 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 nursing care unit number, clinic, or name of patient, as appropriate, for expenditures.

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

(b) On request of the senior member of the CSIB, the pharmacy department head, or authorized assistant, shall total the quantity-received column and the quantity-expended column for inspection by the board.

(c) Upon completion of inspection, one board member shall 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) The NAVMED 6570/2, Compounding/Prepack 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) DD Form 1289 (NOV 1971), DoD Prescription, S/N 0102-LF-012-6201 and NAVMED 6710/6 (Rev. 3-1984), Poly Prescription, S/N 0105-LF-206-7130 are available for order from the Naval Forms Online Web site at: <https://navalforms.daps.dla.mil/web/public/home>.

(2) NAVMED 6570/2 (12-2008), Compounding/Prepack Log; NAVMED 6710/1 (Rev. 1-2002), Narcotic and Controlled Drug Account Record; NAVMED 6710/4 (4-72), Narcotic and Controlled Drug Inventory-24 Hour; and NAVMED 6710/5 (4-72), Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs are available on the Navy Medicine Web site at: <http://navymedicine.med.navy.mil/default.cfm?seltab+directives> at the Forms tab.

(3) DEA Form 106, Report of Theft of Controlled Substances may be obtained from the nearest regional drug enforcement office or the Drug Enforcement Administration, 1405 “I” Street, NW, Washington, DC 20537.

21-45 *Disposition of Records*
(Regulatory)

(1) All prescriptions, formularies, and drug lists may be destroyed when 2 years old or superseded and no longer needed for reference. All Schedules II through V controlled substance prescriptions and accounting records will be available for at least 2 years.

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

Section IV

DRUG DISPENSING WITHOUT A PHARMACIST

Article		Page
21-50	Physician Assistants, Nurse Providers, and Hospital Corps Personnel on Independent Duty (Regulatory)	21-33
21-51	Operational or Emergency Situations (Regulatory)	21-34

21-50

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

(1) Physician assistants, nurse practitioners, and hospital corps personnel 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 shall be vested in a commissioned officer.

(3) Members of the Medical Department of the Navy shall 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 shall 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 shall 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, then an officer designated by the CO, shall keep in a separate locked compartment, all controlled substances and substances classified as dangerous or otherwise controlled. The CSIB

shall conduct an inventory quarterly or more frequently per article 21-24. The inventory will be unannounced. A report will be made to the CO. The keys shall always be in the custody of an officer. Personnel of the Medical Department shall assure all such substances under their charge are properly labeled.

(7) The executive officer, or other designated officer, shall 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.

(8) Custodians, or their designated assistants, shall retain the keys to the place of storage while on duty. When relieved, they shall 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, shall be sealed in an envelope and deposited with the CO or an officer designated by the CO.

(9) The senior Medical Department representative shall 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, shall be responsible for the security of the contents of the medical stores kept therein. Controlled substances shall be kept in separate lockers and the keys to these lockers shall 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 senior hospital corps member 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, and other dangerous and controlled drugs. This deviation in no way relieves a command of the responsibility for controlled material.

(b) Physician assistants, nurse practitioners, or senior hospital corps members may prescribe and administer only those controlled substances listed in the activity's authorized medical allowance list (AMAL). Only type commanders, medical officers, or their higher authority may make any revision or augmentation of controlled substances in AMALs of activities without medical or dental officers. A DD Form 1289, DoD Prescription, must be prepared and filed following this chapter. Prescriptions not signed by a medical officer, dental officer, podiatrist, physician assistant, nurse practitioner, or civilian physician employed by the Armed Forces shall be counter signed by the CO or a duly appointed officer representative. See article 21-5.

(11) Physician assistants, nurse practitioners, or hospital corpsmen on independent duty are not required to use the DD Form 1289, DoD Prescription, for prescribing drugs, 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(9).

21-51

Operational or Emergency Situations (Regulatory)

(1) If operational commitments call for deviation from the established controls of this chapter, special instructions shall be issued by appropriate authority relative to the receipt, custody, and issuance of controlled substances, ethyl alcohol, and dangerous and controlled drugs.