Change 121
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.

2. **Action**

   a. Remove Chapter 21 and replace with new Chapter 21.

   b. Record this Change 121 in the Record of Page Changes.

D. C. ARTHUR
Chief, Bureau of
Medicine and Surgery

Chapter 21

Pharmacy Operation and Drug Control

Chapter 21
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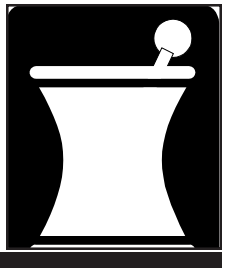
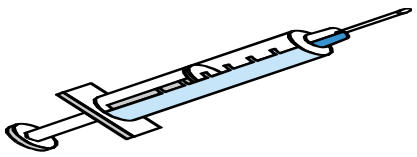


Sections Page

Section I
PHARMACY ADMINISTRATION

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 will determine the type and quantity of pharmacy personnel assigned and the drugs to be stocked.



21-2 *Personnel (Regulatory)*

(1) Pharmacists are graduates of accredited pharmacy colleges and actively registered in one of the 50 United States, the District of Columbia, or Puerto Rico. Using the following guide, at least one pharmacist should be assigned duty at all fixed MTFs in the United States and overseas where a pharmacy is operated. The civilian standard of care requires a pharmacy to operate only under the direct supervision of a licensed pharmacist. The intent of this section is to ensure the Navy emulates the civilian standard. To achieve this goal, prudent use of military, civil service, and contract pharmacists is necessary.

(2) The number of pharmacists and technicians assigned to a facility is determined by the Bureau of Medicine and Surgery (BUMED) Pharmacy Staffing Standard. The standard is based on several workload factors including: number of prescriptions dispensed, population, and scope of services provided. The hours of operation also need to be part of the staffing decision. If the complexity of services provided at the clinic is high, (e.g., family practice or civilian prescriptions, family members or retirees are seen and treated), then the standard of care calls for a pharmacist to supervise the pharmacy operation and review all prescriptions prior to dispensing. The DOD/JCAHO protocol outlines an "equivalency" standard.

(3) At fixed MTFs where the use of a full-time pharmacist would not be justified, pharmacies may be operated:

(a) On a part-time basis by officers who are pharmacists, but who are assigned other primary duties or who cover a number of such facilities.

(b) By a part-time civil service or contract pharmacist.

(c) By dispensing physicians.

(d) By military trained pharmacy technicians at fixed MTFs and any mobile activities dispensing computerized provider-order-entry prescriptions, under the supervisory responsibility of a pharmacy officer or a dispensing physician or dentist specified in writing by the commanding officer (CO).

Note: Care and attention in these situations should be given to article 21-2(2) above.

(4) In general, positions for pharmacists in MTF pharmacies outside the United States will be filled with experienced, commissioned military pharmacists who rotate with pharmacy officers stationed in the United States.

(5) Continuing education opportunities will be made available to all pharmacy staff to update and increase their knowledge of the drugs they dispense.

21-3 *Responsibilities (Regulatory)*

(1) The CO is responsible for the operation of the pharmacy. The CO must exercise careful supervision over all phases of its operations, including employment of recognized professional procedures and establishing policies to ensure conformity with the highest standards of the pharmaceutical profession. The pharmacy must be operated in accordance with Federal Law, service regulations, and accepted standards of practice such as those defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and other professional organizations. Supervision is normally exercised through a commissioned pharmacy officer, who is a graduate of a recognized school or college of pharmacy and actively licensed to practice pharmacy in one of the 50 states, the District of Columbia, or Puerto Rico. When a commissioned officer (pharmacist) is not assigned to an MTF, a civilian pharmacist or a Medical or Dental Corps officer will be assigned supervisory responsibilities. The CO and/or officer in charge (OIC) responsible for a claimancy 18 MTF, without a pharmacist assigned (e.g., branch clinic), shall ensure that pharmacy operations are reviewed by a pharmacist through site visits and inspections. For mobile MTFs without a pharmacist (i.e., non-claimancy 18 activity), the CO may assign responsibility to an enlisted pharmacy technician (NEC 8482), a Medical Corps officer, physician assistant, nurse practitioner, certified nurse midwife, certified nurse anesthetist, privileged nurse provider, or a senior hospital corpsman. A claimancy 18 CO or OIC of an MTF in the immediate area of an operational unit, may assign a pharmacy officer to assist the commander and pharmacy staff of the operational pharmacy in a manner similar to that for a branch clinic, if support is requested by the commander of the operational unit.

(2) The CO must establish policies to ensure rational prescribing, to ensure quantities of drugs prescribed are not excessive, and to ensure drug dispensing is based on a formulary system.

(3) The CO must ensure that the staffing levels and funding are aligned to meet the mission requirements.

(4) The pharmacy department head is responsible for recognizing, identifying, selecting, preparing, safeguarding, evaluating, dispensing, and patient counseling on substances dispensed by and used in preventive or curative medicine at the facility. The pharmacy department head and assistants are required to keep abreast of new developments in the field of pharmacy and serve as pharmaceutical subject matter experts to the MTF personnel they serve. The pharmacy department head is responsible for:

(a) 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.

(b) Assisting and advising personnel of nursing care units and clinics or departments within the MTF whose duties involve stocking pharmaceutical items by conducting inspections at least monthly, or more often if required. Provide inspections of all areas where pharmaceuticals are dispensed, administered, or stored. The inspections should include, but not necessarily be limited to: review of adequacy of identification, sufficiency of storage, safeguards, and evaluation of condition and potency of stocked items based on normal expiration dates, assays, observations or such other criteria as are accepted as good practice by the pharmaceutical profession.

(c) Maintaining current drug information resources, and routinely disseminating drug information to medical and dental staff and patients.

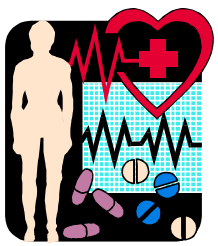
(d) Providing information concerning advances in the field of pharmacy and related matters.

(e) Maintaining and publicizing, either electronic or hard copy, an MTF formulary for use in the facility. MTFs must have the 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.

(f) If the facility conducts research with investigational drugs: Providing proper storage, safeguarding, labeling, and dispensing of investigational drugs. Maintaining investigational drug files. Publishing essential information concerning investigational drugs to personnel who administer such drugs or care for patients receiving such drugs. Maintaining a reference file copy in the pharmacy of the current protocols for all investigational drugs being used in the MTF.

(g) Where required to support inpatient care: Operating a pharmacy sterile products program to include the preparation and delivery of pharmaceutical sterile products. Maintaining laminar flow hood quality control requirements which must include cleaning of the equipment used on each shift, and periodic checks for operational efficiency by a qualified inspector at least twice yearly, or when the hood is moved. Maintaining written records of these actions. Centralizing all sterile compounding procedures within the pharmacy department or its satellites.

(h) Providing, for safety and economy, a unit-dose system or automatic medication dispensing system as the preferred method to distribute pharmaceuticals to hospital patients at fixed MTFs. Though these systems may differ in form depending on specific needs, resources, and characteristics of each MTF, four elements are common to all:



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

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

3. 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.

4. A patient medication profile is concurrently maintained in the pharmacy for each patient. Minimize the use of any floor stock medications.

(i) Ensuring any computer system used in the pharmacy includes adequate safeguards to maintain the confidentiality of patient records. Data on controlled substances must be readily retrievable in printed form from the system. The computer system must have the capability of recording drug allergies and age within the patient's profile.

Note: Auxiliary procedures must be in place to continue pharmacy functions during equipment downtime. Such auxiliary procedures must ensure all appropriate data is retained for on-line data entry as soon as possible when the computer system is available.

(j) Ensuring prescriptions are filled only for eligible beneficiaries.

(k) 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.

(l) 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, an assessment of therapeutic disease state management of shipboard and field personnel; getting access for deployable forces to appropriate and current medication information; and ensuring appropriate types and quantities of medication are available and stored following current standards.

(m) Ensuring security measures are adequate to prevent unauthorized entry into the pharmacy.

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

(o) Ensuring written cautionary information be 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.

(p) 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.

(q) Pharmacies must honor government contracts, if established, when purchasing pharmaceuticals.

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

(a) Each 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, pharmacy, administrative, and logistics communities. Others may be appointed as needed. The local P&T Committee should be aligned with the Department of Defense (DOD) P&T Committee.

(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, diagnostic materials, and protocols of investigational or experimental drugs.

2. Evaluates clinical data on drugs or preparations requested for use in the MTF.

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

4. Reviews all reported adverse drug reactions and medication errors.

5. Recommends policies to ensure the safe use of drugs in the facility.

6. Oversees drug usage evaluations and reviews.

7. Oversees cost management technical business plan.

8. Monitors the use of controlled drugs.

9. Develops a standard list of abbreviations and recommends safety guidelines for use in prescribing medications. Complies with Navy Medicine's "Do Not Use List of Abbreviations" referenced in BUMED letter 6000 Ser M3M22/0001 of 13 Jan 2004 and on the NMO Pharmacy Web site: http://navymedicine.med.navy.mil/ (you must log into this site and create a password, then select "Hosted Sites" tab, scroll down and select Navy Pharmacy - On the left side, under Manager's Corner, select JCAHO, select the file named, JCAHO Patient Safety Goals).

10. Complies with all National Patient Safety Goals (NPSG) and complies with guidelines as directed by BUMED.

11. Recommends policies, to provide reasonable access to the facility by manufacturer's representatives, to govern their conduct and activities while at the MTF.

12. Participates in risk management and quality improvement activities related to the clinical aspects of drug usage in patient care and safety.

13. Recommends policies and procedures for evaluation and acquisition of non-formulary medications.

21-4 Prescribers (Regulatory)

(1) Authorized prescribers may include: Medical and Dental Corps officers, optometrists, physician assistants, pharmacists, podiatrists, nurse practitioners, nurse anesthetists and midwives, or civilian physicians employed by the Navy or the Military Health System. Authorized prescribers also include Navy Independent Duty Hospital Corps (IDC) personnel authorized in Section IV, and others authorized in writing by the CO (or delegated representative) to prescribe in their official capacities.

(2) Prescriptions written by civilian practitioners, other than those employed by the Navy, may be filled for authorized beneficiaries, providing the prescribed item is on the MTF formulary and a pharmacist oversees the process. "Equivalency" standards are outlined in the DOD/JCAHO protocol. These prescriptions may be filled up to the prescribed quantity or within the limitations established by the CO.

(3) Pharmacies will fill all valid non-controlled prescriptions that are presented, regardless of the geographic location of the beneficiary or prescriber as defined in article 21-4(5) and 21-4(6), providing the medication is on the MTF formulary, and the prescription conforms to applicable laws and regulations. Valid prescriptions will be filled in accordance with quantity restrictions and refill limitations.

(4) The act of filling a prescription written by a civilian practitioner does not imply knowledge of, or responsibility for, a patient's medical condition.

(5) Medical Department personnel shall not countersign nor rewrite non-MTF practitioner's prescriptions without an 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.

(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. Inside of the continental United States (CONUS) MTFs may only accept civilian prescriptions from CONUS providers. Prescriptions for controlled substances will be filled only from prescribers in the local area, as defined by the MTF CO.

(c) Civilian practitioner prescription service may not be withdrawn or curtailed without consent of BUMED.

(6) Military, civil service, and contract nurse practitioners, midwives, nurse anesthetists, optometrists, pharmacists, physical therapists, and physician assistants privileged to practice in the MTF are authorized to prescribe medications and durable products consistent with their scope of practice and privileges.

(7) IDCs may write prescriptions when authorized, in writing, by the CO. They must prescribe only those drugs and quantities approved by the CO as recommended by the P&T Committee.

(8) 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, DOD Prescription (DD 1289), or Poly Prescription (NAVMED 6710/6). See special provisions for IDC personnel in article 21-50(1). 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 1289 to write prescriptions for personal use, except for controlled substances. (See article 21-22(5).)

(2) Prescriptions must be written in ink, indelible pencil, or typewritten and must 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) Full name of drug, form of drug, dosage size or strength written in the metric system, and quantity to be dispensed. Prescriptions should be written generically.

(e) Directions for the patient.

(f) Legible signature of the prescriber.

(g) Refill authorization (as applicable).

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

(i) 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 DEA number on the prescription.

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

(a) The MTF dispensing the prescription, including the pharmacy telephone number.

(b) Identifying serial number (prescription number).

(c) Patient's full name.

(d) Date the prescription is originally filled or date refilled.

(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) Typist's initials.

(i) Number of refills remaining.

(j) Expiration date, if applicable.

(k) Proper auxiliary or cautionary labels as indicated.

(4) Telephone or oral prescriptions will not be accepted, except in an emergency or under extraordinary situations, directly from an authorized prescriber. Emergency prescriptions must be reduced to writing within 72 hours. Civilian prescriptions may be faxed to the pharmacy, in accordance with local policy, and State law for the State in which the MTF resides. Orders from providers within the MTF may be faxed, and will be considered as the original order. Prescription information intended for the purpose of filling or refilling a prescription through the establishment of a virtual pharmacy (Internet) may be used if safeguards for patient privacy and provider identification are established. Each transaction must comply with the requirements in article 21-5(2).

(5) Prescriptions should be personalized. If more than one member of a family is prescribed the same medication, a separate prescription blank will be used for each member. Should more than one member of a family be prescribed the same medication on a single prescription blank, each member must be identified on said prescription. In the case of Composite Health Care System (CHCS) provider generated labels, each family member must have their own prescription entered and label generated. The pharmacy may record the identification of the member upon receipt of the prescription, if omitted by the prescriber, to facilitate proper labeling and where available, record the medication in the pharmacy's patient medication profile system.

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

(7) MTFs will not be routinely dispensed prescriptions by mail. A TRICARE mail order benefit (e.g., TMOP) 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. Exceptions, with prior approval by the MTF CO or 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) Each MTF must have written procedures for drugs recalled by the Food and Drug Administration (FDA). These procedures must be implemented readily and the results documented. The recall procedures will require the inspection of all MTF areas and recall of products quarantined. Drug recalls affecting outpatients will apply only if directed by the recall notice or the CO. 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.

(9) All controlled substances prescribed, including those for medical and dental staff members, will be noted in the member's health or dental record at the time prescribed.

(10) Except in extraordinary situations, practitioners may not prescribe controlled substances for patients who are not under their direct care.

(11) At their discretion, MTFs may direct patients with civilian prescriptions to use the TMOP or the Managed Care Support Contractors (MCSC) pharmacies to fill certain special medications not routinely provided by the MTF formulary. However, the MTF pharmacy must fill, or provide the opportunity to have filled, all prescriptions written by its providers. This does not preclude the patient from choosing to have the prescription filled elsewhere. MTFs should fill 100 percent of their enrollees prescriptions.

(12) Prescriptions will be honored when written by a military medical facility acting in a consultant capacity. If the drug is not on the formulary, it will be processed according to the MTF's 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.

(13) 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 must be authorized by a notation in CHCS for the individual prescriptions or in the pharmacy comment section in accordance with the Poison Prevention Packaging Act of 1974. If CHCS is not available, then these prescriptions must be authorized by the patient's signature and such documentation must remain on file within the MTF.

(14) Acceptance of pharmaceutical samples from sales representatives for dispensing to patients is prohibited. Should a practitioner desire to evaluate a pharmaceutical, the pharmacy 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.

(15) 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.

(16) A system designed to protect patient privacy and assure accurate identification of outpatients at the time they receive prescribed medications must be established. 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 for the release of medical information and prescriptions.

(17) Use of over the counter (OTC) self-care medications. The MTF CO or OIC may authorize a limited number of OTC drugs to be dispensed from the pharmacy in conjunction with a self-care program. A self-care program is defined as a program that uses a non-physician health care screener to assess a patient's symptoms. The provider or screener either recommends which OTC drugs to select from a list at the pharmacy, or refers the patient for more definitive care. When authorized by the CO, the P&T Committee will develop a list of OTC items that may be dispensed without a prescription using the following guidelines:

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

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

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

(d) MTFs with an operational, fully capable, automated pharmacy computer system must record the OTC drug, strength, and quantity into the patient profile. MTFs not having a pharmacy computer system do not have to enter OTC items into the patient's medical record, but pharmacies must keep separate records to preclude abuse of the service.

(e) Each OTC item dispensed must be counted as a pharmacy work unit equal to a prescription.

(f) Each OTC encounter must be documented as outlined in the coding instruction.

(g) When pharmacies are closed, OTC items may only be dispensed consistent with policies governing dispensing from treatment centers.

(h) The following items must be included on the locally developed pharmacy dispensing form:

1. Title - OTC medication request.
2. Certification by signing the following statement: "I understand the medication is for use in minor illnesses or conditions and if symptoms worsen or do not improve within 48 hours, the person for whom the medication is intended should be seen by a medical provider."
3. Sponsor's name.
4. Sponsor's social security number.
5. Recipient's name.
6. Duty or home telephone number.
7. Date.
8. Signature of recipient.
9. List OTC items approved by the P&T Committee.
10. Appropriate Privacy Act statement.

(18) MTFs must have written procedures for obtaining drugs when the pharmacy is closed and pharmacy personnel are unavailable.

(19) Report and record dispensing errors involving incorrect medication, strength, dosage, directions, etc.

Note: A form or electronic method similar to Figure 21-1 below is suggested for tabulating and reporting medication misadventures to the P&T Committee and any quality improvement activities deemed appropriate at the command.

Type of Errors:

A - Wrong Medication
B - Wrong Strength
C - Incorrect SIG
D - Wrong Patient
E - Mixed Medications in Vial
F - Omission
G - Wrong Dosage Form or Route
H - Wrong Preparation or Quantity
I - Extra Dose
J - Wrong Dose
K - Wrong Rate
L - Other

Break Down Point in Process:

0 - Wrong Medication Dispensed
1 - Labeling Problem
2 - Physician Order Problem
3 - Communication Problem
4 - Medication Administration Error
5 - Transcribing Error
6 - Charting Error
7 - Verbal Order vs. Written Order
8 - Other

[Figure 21-1]

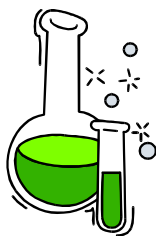
(20) When a pharmacy receives a prescription refill request but no further refills are authorized, and the patient is unable to readily obtain a new prescription, the pharmacist may use professional judgement to dispense a one-time emergency refill. The amount should be of a reasonable amount, up to a 1-month supply, to maintain the patient until the patient can contact the prescriber. 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) The medication is essential to maintain life or continue therapy of a chronic condition.

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

Note: The pharmacy must record on the front of the prescription or on another uniformly maintained, readily retrievable record, such as a computerized patient profile; the date, quantity dispensed, the words "emergency refill" and the dispenser's initials or name.



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

(a) Patient's full name.

(b) Prescribing practitioner's name.

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

(d) Date the prescription was first dispensed.

(e) Date of dispensing for each refill.

(f) Quantity dispensed.

(g) Original prescription serial number.

(h) Number of refills dispensed to date.

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

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

(22) Time limitations for filling and refilling prescriptions:

(a) A prescription for a controlled substance classified as a DEA Schedule II must be filled within 30 days of the date originally written.

Note: State law or command policy may be more restrictive. Schedule II prescriptions must not be refilled.

(b) A prescription for a controlled substance classified in the DEA Schedule III, IV, or V must be filled within 6 months of the date originally written. These prescriptions may be refilled, if authorized by the prescriber, up to five times within a 6-month period from the date originally written.

(c) A prescription for a non-controlled medication must be filled within 1 year of the date originally written. These prescriptions may be refilled, if authorized by the prescriber, up to 12 months from the date originally written.

(d) 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 Navy.

(23) 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 handout program, article 21-5(17), 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 entrees providing that:

(a) Specific protocol is used that 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 must 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 must 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 must include a process to get the prescription documented in CHCS.

(24) All prescriptions, except Schedule II medications, originally written (hard copy or electronic) at one DOD MTF may be filled or refilled at another MTF 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 a single emergency refill, or the transfer of remaining refills, thus voiding any remaining refills at the original MTF. An electronic record will be made of the prescription such as: Transferred to "(name of MTF)" with date of transfer. Schedule II medication prescriptions, originally written electronically at one DOD MTF may be filled and dispensed at another MTF if the pharmacy data processing systems access the same prescription records, and verification is made that the prescription was not dispensed and received by the patient (or his or her representative) at the originating MTF.

(25) When requested by the patient, a pharmacist may transfer a prescription for a Schedule III, IV, or V controlled substance or, any non-controlled prescription, to a community pharmacy for refill purposes. In the absence of a pharmacist, a physician or dentist may complete the transfer. The date of transfer and the phrase, "Transferred to (name of pharmacy receiving the copy)" will be recorded on the face of the original prescription, or the activity log comment field of the electronic prescriptions record when discontinuing prescription to void remaining refills. All remaining refills must be voided.

(26) A police officer, agent of the Naval Criminal Investigative Service, agent of the CO, or any agent of higher authority may remove an original prescription from the pharmacy's files for the purpose of an investigation. Whenever this occurs, a photocopy of the original prescription, and a receipt from the agent or police officer must be kept in the pharmacy's files.

(27) Prescription quantities will be filled as written up to a 90-day supply for maintenance medications at all MTFs. Active duty beneficiary prescriptions may be dispensed in larger quantities to meet readiness requirements. Since there are many reasons the prescriber may want to limit drug supplies to certain patients, MTF policies must retain enough flexibility for the provider to limit the quantity of medication dispensed to an individual patient.

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

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(28) 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 must meet the minimum requirements of article 21-5(2) and be filed following article 21-27(6) and (7).

(29) 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).

(30) Therapeutic dietary supplements are specially manufactured formulas used in many instances as the sole source of nutrition for patients and are considered therapeutic agents subject to review by the P&T Committee and approval by the MTF CO.

(a) Inpatients will be provided therapeutic dietary supplements consistent with appropriate professional care as directed by a physician or dentist. For inpatients, the dietary department, supply department, or appropriate department must store, prepare, and distribute these items. If any medication is added to a dietary product, the pharmacy department will prepare the compound.

(b) Outpatients, under the care of an MTF physician or dentist, will be provided these items only in exceptional cases. The Nutritional Support Committee or P&T Committee and the CO will review the need on an individual basis. For outpatients, these items will be stored and dispensed by the MTF dietary department.

(c) Patients with aminoacidopathies consisting of phenylketonuria, maple syrup urine disease, homocystinuria, histidinemia, and tyrosinemia who are under the care of an MTF provider, will be given special amino acid modified nutrient preparations by the pharmacy or dietary department upon presentation of a valid prescription. The CO will ensure that such individuals are under close medical supervision and are supplied with required dietary supplements. The pharmacy or dietary departments will maintain adequate supplies to avoid disruption of patient care.

(31) 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, contingency operations).

(32) Prescriptions from MTF authorized providers for formulary drugs will be honored.

(33) 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.

(34) Prescriptions written by MTF prescribers shall be dispensed from that facility unless the beneficiary chooses another option.

(35) The MTF CO and P&T Committee shall review the alignment of the MTF formulary to the mission and scope of care of the MTF and the needs of the population the MTF serves. The MTF CO shall consider enterprise impact of formulary decisions. Cost-effective formulary management does not include selective deletion of medications commonly prescribed by MTF providers, but considered by the MTF as too costly to maintain on the MTF formulary. Major changes to the MTF formulary must be coordinated through BUMED.

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 must include the pharmacist interpreting the physicians 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 USC 795 and 797 are observed. The pharmacy department head is responsible for providing written guidelines and approving procedures for preparing, sterlizing, and labeling parenterals whenever these functions are not performed under direct pharmacy supervision.

(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) Outdated or unusable drugs have been identified and their distribution and administration prevented.

(e) There is an adequate and proper supply of medical staff-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. Drugs to be included in automatic stop order policies are antibiotics, anticoagulants, controlled substances, hypnotics, and sedatives. Standing drug orders must be automatically canceled when a patient undergoes surgery. There must 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. NPSG and medication reconcilation procedures must be followed.

(5) The pharmacy is responsible for labeling of medications. All medications issued in bulk containers to nursing care units or clinics not dispensed in the original container, must be labeled by the pharmacy with the date of issue, generic and trade name, strength, quantity, expiration date, name of the manufacturer, and lot number or appropriate code to identify the drugs. A repacking expiration date, not to exceed 1 year or the actual manufacturer's expiration date whichever is less, will be added to drugs distributed in other than the original manufacturer's 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.

(6) Drugs issued to clinics for subsequent reissue to patients will be adequately labeled in the pharmacy. Information listed in article 21-5(3)(a), (e), (f), (j), and (k) must be included on the label in the pharmacy or must be added in the clinic.

(7) Inpatient self-care and discharge medications should be labeled as outpatient prescriptions following article 21-5(3).

(8) Nursing personnel will collect all medications brought to the hospital by patients admitted to nursing care units. Whenever 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, (e.g., "keep personal medications at bedside," or "patient may take own medications"). Those medications not given to a family member will be stored at the nursing unit, in the pharmacy, or at a central location (e.g., valuables vault). 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 may be destroyed following locally established destruction procedures.

21-7 *Drug Stock (Regulatory)*

(1) Personnel handling medications must understand their actions and know the dosage range and contraindications. Pharmacy leaders will ensure necessary continuing education is provided to individuals dispensing medications and counseling patients.

(2) The Prime Vendor System exists to serve the needs of the Medical Department. Generally, Prime Vendor will 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, generally not greater than 7 days.

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

(b) Pharmacies may have situations that require stocking levels that are greater than 7 days, examples include: OCONUS facilities, controlled substances, special pricing, and end of year buys. The pharmacy must be able to justify the costs and benefits of situations that may require greater stocking levels.

(c) Facilities will verify, at least annually, that pharmaceutical stock levels are adequate but not excessive, and are aligned with the MTF mission.

(d) An annual inventory and audit will be conducted on all drugs stocked in the pharmacy. Managers will ensure that inventory management is a Management Control Program (MCP) accessible unit, and that they track their inventory process, beginning with drug purchase and ending with drug distribution.

(e) MCP discrepancies will be noted and an improvement plan written and sent to BUMED.

(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 investigation drugs is included in BUMEDINST 6710.69 series.) Executive Order 13139 and 10 USC 1107 prohibit use of non-FDA approved drugs on servicemembers, 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 the borrowing of drugs from another MTF or civilian facility, (e.g., a 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 must be stored and processed through the pharmacy following BUMEDINST 6710.69 series.

(7) Cytotoxic drugs will be controlled, prepared, administered, and disposed of, following NAVMEDCOMINST 6570.1 series.

(8) Caustic substances, such as glacial acetic, sulfuric, nitric, concentrated hydrochloric, or oxalic acid, and concentrated potassium hydroxide, must not be issued to nursing care units, clinics, or outpatients. These substances must be stored in separate lockers and contents must be clearly marked. Methyl alcohol must not be stored, used, or dispensed by the pharmacy.

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

(10) 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.

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

(f) Prior to transfer of drugs to a Returns Vendor, an inventory of all returned pharmaceuticals shall be prepared and validated against the "returned goods" contractor's inventory before the shipment leaves the facility.

1. Credits and costs associated with pharmaceutical returns services shall be tracked and verified for accuracy and completeness.

2. Returned pharmaceuticals data will be analyzed, at least quarterly, for trends that indicate a need to modify inventory levels or ordering practices.

3. MTFs are strongly encouraged to use the DOD's contracted pharmaceutical returns management program contractor. MTFs not using the DOD's contractor must have valid authorization to procure and pay for services received from another pharmaceutical returns company.

(11) Discard sterile water and normal saline solution used in conjunction with respiratory therapy equipment after initial use.

(12) 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, and discard following the manufacturer's stability data.

(c) Discard any opened MDV, which does not require addition of a diluent, on the expiration date specified by the manufacturer's label.

(d) Discard contaminated vials immediately upon detection.

(e) Do not store MDVs in the MTF refrigerator unless required to do so by the manufacturer.

(f) Include observation of adherence to this article in the monthly inspections required by article 21-3(4)(b).

(13) A log of all medication 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.

21-8 Antidotes and Antidote Lockers (Regulatory)

(1) MTFs having emergency room services are not required to have antidote lockers, but must have all appropriate medications as determined by the P&T Committee.

(2) MTFs without emergency room services should maintain an antidote locker as prescribed by NAVMED P-5095, Drugs, Poison Overdoses, Antidotes, and Emergency First Aid, available at: http:/navymedicine.med.navy.mil/default.cfm?selTab=Directives (select the Publications tab on the left-hand side of the page) or through the Navy Supply System, NSN 0510-LP-096-9000; however it is at the discretion of the MTF CO.

Note: There are no articles 21-9 through 21-19.

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Section II
CONTROLLED SUBSTANCES

21-20 General (Regulatory)

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

(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 require security measures similar to those for controlled substances. The CO will establish special security and accounting procedures for these command-sensitive items designated as "Locally Controlled Substances."

(4) Alcoholic beverages must not be stocked or dispensed from Navy MTFs. Ethyl alcohol will not be dispensed to patients.

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. A copy of the safe combination must be kept in a sealed envelope deposited with the CO or representative.

(2) Schedule III, IV, and V controlled substances require locked cabinet security for storage of bulk drugs. A minimum amount of working stock may be dispersed among other pharmacy stock, provided the pharmacy itself is secure. Otherwise, all stock in this category must be kept in a locked cabinet. The appointed pharmacy custodian will conduct an annual inventory and audit of all Schedule III, IV, and V controlled medications. See article 21-7(3)(d) for inventory management control requirements.

21-22 Prescribing (Regulatory)

(1) All prescribers authorized in Section I must prescribe controlled substances either by electronic-order-entry or on the DD 1289 or by coded facsimile if appropriate. NAVMED 6710/6, the Poly Prescription, may be used to prescribe for a controlled substance only if no other type of drug is prescribed on the poly prescription at the same time.

(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 section 1301.25 of the Act. A prescriber exempted from registration under section 1301.25 must include on all prescriptions the prescriber's branch of service or agency (e.g., "USN" or "Public Health Service") and social security number in lieu of the DEA registration number required on civilian prescriptions. In addition, section 1306.05 of the 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 2l 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.

(3) An officer or civilian employed by the Navy, who has been designated by the command to purchase or procure from commercial sources controlled substances or preparations for official use, must be so designated on the command's registration filed with the Registration Branch, 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 1 year, but individuals designated may be changed as necessary by letter to DEA, signed by the CO.

(4) Ordering, receipt, custudy, and issuance must follow Navy audit and chain of custudy business practices.

(5) Authority for physician assistants 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 person will prescribe or furnish a controlled substance for themselves or members of their immediate family.

(7) Providers will 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.

21-23 Custody (Regulatory)

(1) Stocks of controlled substances and ethyl alcohol carried in the Navy Stock Account and located at wholesale stock points, Navy retail stock points, or mobile logistic support ships are not within the scope of this chapter. Procedures for handling these materials at such activities are published by the Commander, Naval Supply Systems Command (COMNAVSUPSYSCOM). All quantities of controlled substances and ethyl alcohol issued at the patient use level must be managed in accordance with this section and any other current instructions, as applicable.

(2) Custodial responsibility for controlled substances, ethyl alcohol, and dangerous drugs must be vested in a commissioned officer or a civilian pharmacist, who is appointed in writing. At remote branch clinics that do not have a commissioned officer or a civilian pharmacist, the CO must designate, in writing, a member of the branch clinic as the custodian.

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 disperse a working stock of such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances. COs and OICs may direct stricter storage requirements based on risk of diversion at a specific facility.

(2) Controlled substances classified as DEA Schedules I through V require special handling and accounting to provide adequate protection against drug abuse, carelessness, theft, and misappropriation. Accordingly, the following measures, in addition to those prescribed elsewhere in this chapter, must be enforced in all activities except stock points of the medical and dental supply system. The security measures for handling materiel at medical and dental stock points are included in the COMNAVSUPSYSCOM manuals and current directives.

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

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

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

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

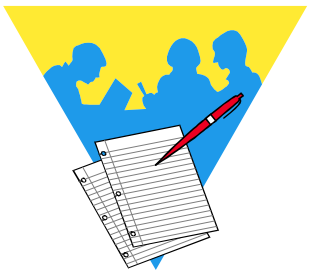
3. The main pharmacy which supplied the controlled substances for the emergency kit or automated dispensing machine must maintain complete and accurate records and inventories of the substances placed in the kit per article 21-28.

4. In emergent/urgent situations, only personnel authorized by a specific provider, privileged to prescribe controlled substances, can remove and administer controlled substances from the kit or automated dispensing machine.

(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 must 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 must be a commissioned officer. The CO

will appoint each member, in writing. Senior enlisted personnel in pay grades E-7 through E-9 and Department of the Navy civilians in grades GS-7 and above 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 must 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 must 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 must be audited. The identity of any questionable items of inventoried stock must be ascertained. Nursing records and outpatient clinics that store controlled substances must be checked to verify proper accounting for all documents and medications. Supply department records must be checked, as required, to verify proper accounting for all documents. For this purpose, the supply department must provide, directly to the senior member of the board, a copy of all issue documents for Schedule I and II controlled substances and ethyl alcohol.

(d) See article 21-46 concerning Controlled Drug Inventory Report. BUMEDINST 6710.70 series provides guidance for Controlled Substances Inventory Boards.



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, and one copy to the nearest field representative of the Naval Criminal Investigative Service. The consignee must submit a sworn statement of facts with the DEA Form 106, if the controlled substances are stolen or lost in transit.

(2) Report any unreconciled narcotic inventory discrepancies to the senior member of the CSIB or appropriate higher authority.

21-26 Deterioration (Regulatory)

(1) The bulk stock custodian will report to the CO Schedule I through V controlled substances, ethyl alcohol, and locally controlled drugs, which have deteriorated and are not usable, are of questionable purity or potency, or have had their identity compromised. The appointed custodian may request authorization to destroy deteriorated products and recommend a method of destruction (e.g., incineration). If destruction is indicated and directed by the CO, destruction must be accomplished in the presence of a member of the CSIB. A certification must include the complete nomenclature and quantity of the substances to be destroyed, together with the method to be used to accomplish destruction. After

certification is completed, approved by the CO, and signed by the members witnessing destruction, the certification must be retained in the files as authority for dropping the items from the appropriate record. DEA notification is not necessary.

(2) Destruction may also be accomplished through a return goods contractor, if the contractor is authorized by the DEA.

21-27 Dispensing by Pharmacy (Regulatory)

(1) The pharmacy must serve as the source from which nursing care units, clinics, and other departments of a facility normally obtain controlled substances for use in connection with the treatment of patients. Authorized outpatient prescriptions for controlled substances must 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 must be dispensed to outpatients on receipt of a prescription completed following article 21-22 with the following additional requirements:

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

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

Exception: See article 21-5(28).

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

(c) The legible signature and social security number of the Medical Department member authorized to prescribe per article 21-4. In addition, the name of the prescriber must be stamped, typed, or hand printed on the prescription.

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

(e) Each controlled substance prescription must be a separate document. Controlled substance prescriptions written on a poly prescription in combination with other prescriptions are not valid, unless specifically allowed by the law of State in which the MTF resides, and approved by the MTF CO and OIC.

(3) Controlled prescriptions will be reviewed for authenticity before dispensing the prescription. The Pharmacist's Manual, published by the U.S. Department of Justice, should be used as a guideline for detecting fraudulent prescriptions. (The Pharmacist's Manual may be obtained from U.S. Department of Justice, Drug Enforcement Administration, Washington, DC 20357-0001.)

(4) Prescriptions for Schedule II controlled substances must 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 such cases, the provider will be notified and a new prescription will be required for the balance. The quantity dispensed must be noted on the front of the prescription or by appropriate means for provider-order-entry prescriptions.

(5) Prescriptions for Schedule II controlled substances must be dated, have the quantity dispensed annotated, numbered, and signed by the dispenser on the front of the prescription, at the time of filling. The reverse side of the prescription must include the

wording "received by" in addition to date, address, telephone number, and signature of the recipient of the drug item.

Exception: None.

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

(7) Prescription records of controlled substances listed in Schedules III, IV, and V must be maintained separately from all other records of the pharmacy. Discharge orders containing a Schedule III through V controlled substance must be filed with the controlled substance prescription records.

(8) Ethyl alcohol, although not included in any schedule of the Controlled Substances Act, must be received, accounted for, and dispensed in the same manner as Schedules III, IV, or V substances. Patient prescriptions for this substance will not be filled. Internal prescriptions for ethyl alcohol for hospital or clinic use must be given a serial file number and must be filed with all other prescriptions of similar schedule.

(9) Schedule II controlled substances issued to nursing care units and branch medical clinics must be accompanied by forms outlined in Section III.

(10) Controlled substances must 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 must be affixed to the containers. In addition, controlled substances dispensed to nursing care units and clinics must identify the DEA schedule on the pharmacy label or manufacturer's label.

(11) Accounting is required for controlled substances used in the manufacture of pharmaceutical preparations. Prescription forms will be used to account for all controlled substances used in the manufacture of pharmaceutical preparations. Such orders will be authenticated and signed by the pharmacists in charge of manufacturing and filed in the appropriate prescription file. The product will be assigned a local prescription, batch, and lot number. The scheduled product will 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.

(12) Controlled substance histories recorded in patient medication profiles for prescriptions that originate from civilian practitioners will be made available to MTF prescribers. Based upon pharmacy automation capability, controlled substances prescribed for patients by civilian practitioners are automatically recorded and maintained in the patient's computer-generated medication profile. Upon request from MTF prescribers, the pharmacy department will provide the requesting practitioner's a copy of the patient's automated medication profile.

(13) A hard copy order and prescription file system is not required when an electronic-order-entry system approved by the DEA is used.

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

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

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

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

(c) The custodian must maintain a locked container, cabinet, or compartment of an approved nature to keep such substances. Medication storage and preparation areas must be locked unless personnel working in the area have a continuous, unobstructed view of the area. Keys to the containers must 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 must maintain a loose-leaf notebook containing the Narcotic and Controlled Drug Inventory-24 Hour (NAVMED 6710/4) and the Narcotic and Controlled Drug Account Record (NAVMED 6710/1) or similar automated forms following article 21-42. Those facilities using an automated medication dispensing system (e.g., Pyxis or SurMed) 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 must provide accurate documentation of the audit trail, including all information that would otherwise be documented on the written form described in Section III.

(3) Controlled substances may be ordered from the pharmacy on any suitable form approved by the command, and may 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 must be picked up by personnel with custodial responsibility following article 21-28(1). For branch clinic pharmacies refer to article 21-29.

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

(6) The NAVMED 6710/1, and the reverse side of the DD 1289 or other order form, must 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 must be made immediately through the nursing supervisor to the director of nursing services or respective head of service (medical officer custodian). Such discrepancies must also be reported to the head of the pharmacy department and the senior member of the CSIB.

(9) Schedules III through V controlled substances, stocked in quantities intended for emergency use only, may be stored within an emergency drug kit or in emergency crash carts. The kits or carts should be equipped with a disposable locking or sealing device, and provide adequate security for such controlled substances. The stock must be maintained, inventoried, and all required record keeping procedures complied with. The medical staff and CO must approve the medications and quantities stocked. See article 21-24(2)(b).

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

(1) For branch clinic pharmacies not able to order controlled substances directly from a Prime Vendor, controlled substances must be requested and delivered to pharmacy branches by the main pharmacy in the same manner as hospital nursing care units and clinics are supplied. The branch pharmacy must send a prescription signed by responsible pharmacy personnel for bulk quantities to the main pharmacy. A NAVMED 6710/1, per Section III of this chapter, must accompany issue of Schedule II controlled substances. The command is responsible for delivery methods. In regions where geographical limitations or quantities of controlled substances used by the branch clinic make the above process impracticable, the branch clinic may order its controlled substances as it does other medical supplies. The same controls necessary for the regional supply office pertain. All receipts must be signed for by a commissioned officer, pharmacist, or a person appointed by the CO.

(2) The unannounced inventory of Schedule II controlled substances at branch pharmacies must be accomplished by an additional member to the CSIB, stationed at the MTF being inventoried but having no custodial responsibilities. Such inventory must be called by the senior member of the board and the

results sent to such member, with copies to the branch clinic OIC, or senior medical officer, or representative, as applicable, and the pharmacy department.

(3) At those branch clinics with insufficient staff to form a CSIB in accordance with article 21-24(2), personnel from the host command may be used to comprise the CSIB.

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

Section III
FORMS, RECORDS, AND REPORTS

21-40 *General (Regulatory)*

(1) Records must be maintained describing certain procedures conducted within all Navy medical and dental facilities. Among mandatory requirements for record keeping are the prescribing of drugs, handling of controlled substances, quality control procedures, and investigational drug handling. Standardized forms are available for 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 1289, except as provided in articles 21-50(10) and 21-5(2)(i) for all single prescriptions.

(2) The Poly Prescription (NAVMED 6710/6) may be used when a number of drugs are prescribed for one patient. If used for controlled or investigational drugs, no other drugs may be written on the prescription. Restrictions outlined in article 21-5(2) apply.

(3) Prescription blanks provided by or preprinted by a commercial company (i.e., drug manufacturer or distributor) will not be used in an MTF. Rubber stamp or addressograph plate may be used on DD 1289 or NAVMED 6710/6 for commonly prescribed

items, except controlled substances, providing the rubber stamp or addressograph plate has been reviewed and approved by the pharmacy department head. Any preprinted prescription blank or medication order form will be revised and approved by the pharmacy department head prior to use in the MTF. Article 21-27(2)(a) applies.

21-42 Controlled Substances Forms (Regulatory)

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

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

(b) The oncoming shift custodian must sign the NAVMED 6710/4, 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 or NAVMED 6710/4 sheets are issued to nursing units, and no requirement exists for the traditional end of shift counts of controls and narcotics. The automatic systems must 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 periodically. 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. Where feasible and practicable, it is strongly recommended the nurse reporting for duty and the nurse being relieved check the drugs concurrently. Report any discrepancies immediately to the nursing supervisor. The record is usable for 2 weeks, 1-week period on each side.

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

(d) Periodically, as determined by local MTF policy, the nursing unit supervisor must audit the nursing care unit controlled substances supplies. After the audit, the nursing supervisor must date and sign the NAVMED 6710/4.

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

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

(b) All NAVMED 6710/1's must be kept in a controlled substance book. See article 21-42(3).

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

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

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

1. All amounts are 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 is 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, must be recorded as destroyed on the NAVMED 6710/1, including the date, amount, new balance and signed by the individual involved and a second cognizant person. See article 21-42(l)(b).

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

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

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

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

(h) Monthly, the pharmacy must report to director of the nursing service or appropriate department head all NAVMED 6710/1's outstanding 30 days from date of issue. The report must be verified and returned to the pharmacy for reconciliation. Report discrepancies to the CO via report of the 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***

(a) Each nursing care unit, clinic, or other activity drawing controlled substances from the pharmacy (bulk stock) must 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 must remove all filled NAVMED 6710/4's over 3 months old from the Narcotic and Controlled Substances Book, and transfer them to the MTF archives for disposition following SECNAVINST 5212.5 series.

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

(a) A separate NAVMED 6710/5 must be prepared for each Schedule II controlled substance and ethyl alcohol. 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 g. 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/l 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, must total the quantity-received column and the quantity-expended column for inspection by the board.

(c) Upon completion of inspection, one board member must initial the receipts and expenditures columns.

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

21-43 Quality Control Forms (Regulatory)

(1) A locally prepared compounding and preparation form 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) Reports generated by electronic data processing systems may be substituted provided items required by this chapter are included in such report.

(2) DD 1289 (Rev. 5-72), S/N 0102-LF-012-6201 is available through normal supply channels.

(3) NAVMED 6710/1 (Rev. 1-2002); NAVMED 6710/4 (Rev. 4-72); NAVMED 6710/5 (Rev. 4-72); and NAVMED 6710/6 (Rev. 3-84) are available on the Web at: http://navymedicine.med.navy.mil/default.cfm?seltab=directives at the Forms tab.

(4) 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 Publications (Regulatory)

(1) NAVMED P-5095, First Aid for Poisoning and Overdoses, is available at: http://navymedicine.med.navy.mil/default.cfm?selTab=Directives (Select Publications Tab).

21-46 Report (Regulatory)

(1) ***Controlled Substances Inventory Report***

(a) The Controlled Substances Inventory Report must be prepared and submitted by the senior member of the CSIB after each inventory. The pharmacy department may assist in the preparation of the report, but the senior member of the CSIB will be responsible for the content and delivery of the report to the CO or his or her designee. This report must list each item in stock, together with its strength and unit of issue. The pharmacy department may assist in the preparation of the report. This report must list each item in stock, together with its strength and unit of issue. The report must show the amount remaining from last report, quantity received, quantity expended, and balance on hand.

(b) The Controlled Drug Inventory Report must be submitted for approval to the CO by the CSIB stating the inventory was conducted per this chapter and existing local instructions. In addition, this report must state the findings (discrepancies) of the board and any recommendations. MTFs must use the Controlled Substance Inventory Audit Criteria and Report forms outlined in BUMEDINST 6710.70 series.

21-47 *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 21-48 or 21-49.

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Section IV
DRUG DISPENSING WITHOUT A PHARMACIST

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

(1) Physician assistants, privileged nurse providers, 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 and ethyl alcohol must be vested in a commissioned officer.

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

(a) For medicinal purposes.

(b) For retention as evidence in disciplinary actions.

(c) By Navy Regulations.

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

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

(6) An officer of the Medical Department, or if no such officer is available, then an officer designated by the CO, must keep in a separate locked compartment, all controlled substances, and substances classified as dangerous, or otherwise controlled. The CSIB

must 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 must always be in the custody of an officer. Personnel of the Medical Department must assure all such substances under their charge are properly labeled.

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

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

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

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

(a) Physician assistants, privileged nurse providers, 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, privileged nurse providers, 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 1289 must be prepared and filed following this chapter. Prescriptions not signed by a medical officer, dental officer, podiatrist, physician assistant, nurse provider, or civilian physician employed by the Armed Forces must be counter signed by the CO or a duly appointed officer representative. See article 21-5.

(11) Physician assistants, nurse providers, or hospital corpsmen on independent duty are not required to use the DOD Prescription (DD 1289) 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.