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CHAPTER 10 PHARMACY OPERATIONS AND DRUG CONTROL

Section A. Pharmacy Administration.

- 1. <u>Responsibilities</u>.
 - a. <u>Duties of designated person</u>. The person designated in writing as responsible for the pharmacy is accountable to the Chief, Health Services Division, or the executive officer, for properly storing and dispensing drugs, record keeping, and maintaining a pharmacy policy and procedures manual, including HIPAA complaint privacy and security provisions, and ensuring limited access into the pharmacy during and after hours.
 - b. <u>The person in charge of the pharmacy shall acquire, store, compound, and dispense medications according to applicable Federal laws</u> (principally Title 42, United States Code [42 USC] and Title 21, Code of Federal Regulations [21 CFR]) and observe the highest standards of professional practice and established pharmaceutical procedures to ensure the best possible in patient safety and/or patient medication safety practices. The person in charge of the pharmacy shall ensure adequate current pharmacy references, hardbound and/or online access (e.g., Drug Facts and Comparison, a drug interaction reference, a drug identification reference, etc.).
 - c. <u>Request funding</u>. Through medical administration, persons responsible for daily pharmacy operations shall request adequate funding to provide the level of pharmaceutical care required in Section 10.A.2.
 - d. <u>Health Services Division Chiefs</u>. Health Services Division Chiefs shall ensure that all short term, interim, or temporarily assigned pharmacy personnel have successfully completed the Quality Improvement Implementation Guide #41 (Pharmacy Watch Stander Qualification Guide (PWQG)). As well, all regular assigned pharmacy personnel have completed pharmacy technician "C" school training. These minimum standards of qualifications must be documented in the training file of all pharmacy watch standers. The PWQG does not replace the requirement for "C" school trained pharmacy technicians, but will assist clinic personnel in becoming more productive members of the Coast Guard health services team and, in doing so, further enhance the mission of the Coast Guard clinics.
 - e. <u>Pharmacy officer collateral duty oversight shall be provided for all clinics</u> <u>and sickbays that do not have pharmacy officers assigned</u>. A Pharmacy Officer Collateral Duty Program shall be administered by the cognizant Maintenance and Logistic Command (k), who shall:

- (1) Determine cost requirements for the pharmacy officer collateral duty program and submit funding requests to Commandant (CG-112) in the annual operating summary of budget estimates (CG-4144) process.
- (2) Provide direction and funding to pharmacy officers for matters relating to assignments in pharmacy officer collateral duty program.
- (3) Develop work plans specifying units for which the pharmacy officer is responsible.
- (4) Ensure visit schedule will be:
 - (a) The most cost effective.
 - (b) Feasible to maintain responsibilities at the unit where the pharmacy billet is assigned.
 - (c) Coordinated with the unit commanding officer possessing the billet.
- (5) Establish the content and frequency of a reporting system for pharmacy officers on assignment and provide a copy of this report to the unit commanding officer where the billet is assigned.
- (6) Ensure that rating officers of pharmacy officers on assignment in the pharmacy collateral duty program obtain input for completing the USPHS Commissioned Officers' Effectiveness Report from the other units where the pharmacy officer provides oversight.
- (7) Oversees the following responsibilities of collateral duty pharmacy officers who:
 - (a) Report to the Chief, Health Services Division of the unit to which they are assigned.
 - (b) Follow the established chain of command.
 - (c) Serve as a member of the Pharmacy and Therapeutics Committee, and assist those units to which they are assigned with developing and maintaining a drug formulary based on the Department of Defense Basic Core Formulary. This formulary shall be standardized to provide a list of medications stocked in the "therapeutic category" format.
 - (d) Provide direct assistance for all aspects of the Pharmaceutical Prime Vendor Program.

- (e) Assist each unit in eliminating or minimizing the purchase of medication through nonfederal sources by using formulary process and redistributing medication as needed.
- (f) Develop an inventory of limited use pharmaceuticals and/or pharmaceutical supplies for distributing to each unit.
- (g) Serve as the point of contact for redistribution of medication due to expire or are in excessive supply.
- (h) Identify special order medication, label them for each patient and assure that they are not considered formulary items. These should be marked for a specific patient only and removed when the patient no longer requires them.
- (i) Analyze and develop the most cost effective methods for providing non-formulary medication for chronic conditions.
- (j) Provide oversight to the health services technician(s) who normally operate the unit pharmacy and assist in dispensing operation as required.
- (k) Provide and document in-service training to the clinic staff.
- (1) Review all pharmacy operations and policies including controlled substance activities.
- (m) Assist the unit in preparation of the pharmacy, and other areas of the clinic under the responsibility of the pharmacy, for AAAHC and MLC Quality Assurance Surveys.
- (n) Provide current information as obtained from the DoD Shelf Life Extension Program (SLEP) and Medical Material Quality Control (MMQC) messages. Pharmacy personnel can refer to the website for subscribing information at: http://www.usamma.army.mil/apps/nala_qaweb/nala_index.cfm.
- (o) Submit a report of the content and frequency established by MLC

2. <u>Prescribers</u>.

- a. <u>Authorized prescribers include</u>:
 - (1) Medical officers and dental officers as defined in this Manual's Sections 1.B.1. and 1.B.4.
 - (2) Civilian medical and dental providers employed by the Coast Guard.

- (3) HSs may prescribe drugs listed in the <u>Standardized Health Services</u> <u>Technician Drug Formulary, COMDTINST 6570.1 (series)</u>. While performing isolated duty at LORAN stations or underway, HSs may prescribe additional drugs listed in <u>Health Services Allowance List</u> <u>Afloat, COMDTINST 6700.6 (series)</u>. HSs in these situations shall seek medical advice from their assigned Designated Medical Officer Advisor (DMOA).
- (4) Civilian physicians, dentists, and allied health care providers (nurse practitioners, physician assistants, optometrists, etc.) as authorized by State law in their licensing jurisdiction to write prescriptions in practicing their profession.
- (5) Uniformed service medical and dental officers/providers, other than Coast Guard, authorized by their service to write prescriptions in practicing their profession
- b. Prescriptions by uniformed service or civilian medical and dental officers/providers, other than Coast Guard, shall be honored whenever possible and only at Coast Guard clinics where a registered pharmacist or pharmacy officer is physically present. For example, Department of Defense prescription policies (TRICARE) shall be observed to the fullest extent possible within the scope of the primary care nature of Coast Guard Health Care facilities and based on the DoD Basic Core Formulary. Prescriptions by these providers shall be written on the prescription forms authorized by their service. Prescriptions written by outside providers (providers not billeted or assigned to the clinic) will only be honored at Coast Guard facilities with a Registered Pharmacist physically present at the clinic. If a registered pharmacist is not available, new outside prescriptions will not be filled. Pharmacy personnel working in the pharmacy for that day shall inform the patient that a pharmacist is not available for the day and may give the patient the opportunity to decide to return, if a pharmacist is expected within a reasonable time frame, or seek pharmacy services at another location. This policy was implemented in 2002 in order to meet the reasonable standard of care existing in the civilian and other federal sectors. AUTOPENED (electronically signed) outside prescriptions will not be honored at Coast Guard pharmacies.
- c. <u>Prescriptions for eligible beneficiaries from licensed uniformed, civilian or</u> <u>outside physicians, dentists, or podiatrists shall be honored for products on</u> <u>the clinic's formulary provided a pharmacist is available</u>. This is to be based on Department of Defense Basic Core Formulary (BCF) guidelines and the prescribing habits of the providers assigned to that clinic, and only if a registered pharmacist or pharmacy officer is physically present. For those Coast Guard clinics with a pharmacy officer permanently assigned,

the BCF contains the minimum drugs that each pharmacy must have on its formulary and provide to all eligible beneficiaries.

- (1) For those Coast Guard clinics with a pharmacy officer permanently assigned, the BCF contains the minimum drugs that each pharmacy must have on its formulary and provide to all eligible beneficiaries.
- (2) For those Coast Guard clinics without a pharmacy officer permanently assigned, there are no requirements to stock the entire contents of the BCF. Military practitioners or contract providers shall not countersign civilian/outside prescriptions nor shall civilian/outside prescriptions be rewritten during cursory outpatient visits with the intent of authorizing the prescription for dispensing at the facility.
- (3) In the case of multiple strength BCF drugs, all strengths need not be stocked but all prescriptions for that agent will be filled, regardless of strength.
- (4) If additional funding is required for specific, high cost drugs, it shall be requested via the AFC-57 budget process via the cognizant MLC (k).
- (5) For Coast Guard patients referred out of the clinic for specialty care: Patients shall be advised by the referring provider/clinic to have prescriptions, written by the consulting provider, filled at the Military Treatment Facility (MTF) pharmacy where seen, or at a Tricare Retail Network Pharmacy if seen by a civilian consulting provider. This is especially the case if the consulting provider advises the patient to immediately start the medication. Patients shall return to the Coast Guard referring provider with the consultation brief. Likewise, if starting the medication is not of an urgent nature and to maintain continuity of patient care, patients shall return to the Coast Guard referring provider with the consultation brief, recommended treatment plan, and prescriptions to be filled at the clinic pharmacy upon review by the Coast Guard provider.
- d. <u>Authorized prescribers shall not prescribe controlled medications for</u> <u>themselves and/or their family members</u>. If such medication is required and no other prescriber is assigned to the facility, the commanding officer, or executive officer, shall review, approve, and countersign each controlled prescription before it is filled by pharmacy personnel.
- 3. Prescriptions.
 - a. <u>Prescriptions written by Coast Guard providers</u>. Prescriptions written by Coast Guard providers shall be filled at the facility where written. In cases of emergencies where it is advisable for a patient to start a prescription

immediately and it is not available at the pharmacy, prescriptions may be written on form DD-1289 so that the patient may have the prescription filled outside of the clinic. Prescriptions written by health services technicians shall be filled only at the facility where written. Coast Guard clinics may agree among themselves to honor another Coast Guard clinic's physician assistants' or nurse practitioners' prescriptions if stock shortages so necessitate. Other Coast Guard facilities may honor Coast Guard physician assistants' and nurse practitioners' refills (for other than controlled substances) if the patient presents his or her health care record containing the original entry.

- b. <u>Telephoned and verbal prescriptions</u>. At the pharmacy officer's discretion, telephoned and verbal prescriptions may be accepted only in emergencies. The prescriber must write and sign the prescription as soon afterwards as possible. Coast Guard clinics without a pharmacy officer shall not accept faxed or telephone prescriptions. In clinics where there is a pharmacy officer, faxed prescriptions shall not be routinely accepted. The pharmacy officer may authorize faxed prescriptions on a case-by- case basis in the best interest of the patient's care. FAXED PRESCRIPTIONS FOR CONTROLLED/NARCOTICS WILL NOT BE ACCEPTED.
- c. <u>Transferring prescriptions</u>. Prescriptions may be transferred at the discretion of the pharmacist. The transferring of prescriptions shall only be conducted between licensed pharmacists. If a licensed pharmacist is not available, patients shall be requested to obtain a new prescription. ONLY a one time transfer of the same prescription number is authorized. Multiple transfers of the same prescription number are not authorized.
- d. <u>Health Services Technicians shall not contact civilian/outside prescribers to</u> <u>resolve prescription problems</u> but return the problem prescription to the patient and explain why he or she cannot dispense it. The HS may provide the names of suggested available products to the patient.
- e. <u>Prescriptions shall be personalized</u>. If more than one member of a family is prescribed the same drug, a separate prescription blank must be used for each member
- f. <u>Items prescribed must treat conditions within the normal scope of</u> professional practice and the ethics of the prescriber.
- g. <u>Prescriptions for medications to treat cosmetic conditions (baldness,</u> <u>wrinkles, etc.) and for weight loss will not be honored nor shall medications</u> <u>for these conditions be stocked at Coast Guard facilities</u>.
- h. Do not fill prescriptions for animals other than those the Government owns.

- i. <u>Physician assistant</u>. If a physician assistant has clinical privileges at a local DoD facility, he or she may use its prescription form to write prescriptions to be filled at that facility, provided the form contains the statement "To be filled only at [insert designated DoD facility]."
- j. <u>Responsibility of prescribing facility</u>. The prescriber's facility has the responsibility to procure and dispense all medications its staff members (including in-house contract prescribers) prescribe. In the rare event a patient must carry a prescription elsewhere for dispensing, the prescriber shall write the facility's name in addition to the other required information on the form (i.e., facility address/phone number, provider's or clinic's DEA number, date of prescription).
- Providers are tasked with the cost effective use of medications. The DoD k. Basic Core Formulary (BCF) serves as the basis of all Coast Guard clinics' formulary. Pharmaceuticals considered as high dollar and/or for specific patients shall be considered Special Order Medications. A Special Order Medication is defined as: a medication for a specific patient for which the provider has completed a Special Order Medication Request form submitted to the pharmacy and reviewed during the next convening clinic Pharmacy and Therapeutics Committee meeting; a medication chosen due to a patient's treatment failure to a BCF drug in the same therapeutic category as the special order medication; and/or, a medication not therapeutically available from the BCF and clearly indicated as a medical necessity for a specific patient. In the rare event a patient must carry a prescription elsewhere for dispensing, the prescriber shall include the facility's name, facility's address/phone number, provider's or clinic's DEA number, and date of prescription on the prescription blank along with all other pertinent information in order for the patient to have the prescription filled outside of the clinic.
- 4. <u>Prescribing in the Medical Record</u>.
 - a. <u>At the present, all CG pharmacies are migrating to CHCS/PGUI and POE as per Chapter 14 of this Manual</u>. That is the preferred method of prescribing for CG providers. However, until this process is fully implemented, an acceptable alternative remains prescribing using the Medical Record. At all clinics and sickbays, prescribe medications on an SF-600 in the medical record, or when appropriate, SF-558, Emergency Care and Treatment. The medical record thus becomes a more comprehensive repository for all patient health information and also ensures the pharmacy staff has access to the necessary clinical information (age, weight, allergies, lab values, vital signs, etc.) to provide complete pharmaceutical care. In clinics that maintain dental records separately, the dental staff may use prescription forms or write prescriptions on a SF-603A.
 - b. <u>Procedures</u>.

- Document (S.O.A.P. format) the patient visit on an SF-600 or SF-558 in the chart. Under the "Plan" section, list the drug name, strength, directions, quantity, and refills. Prescriptions shall be legibly written. Abbreviated names of medications should be avoided to prevent medication errors and enhance patient safety.
- (2) In the "Plan" section, state a disposition to assist pharmacy staff in coordinating quantities of all chronic medications until the next appointment. Complete the entry with the authorized prescriber's signature (examples: RTC PRN; F/U appt. 10 days; RTC 3 months).
- (3) The terms chronic and maintenance medications are synonymous. A maintenance medication is defined as any medication used to treat a chronic condition. The term "maintenance" implies that a prescriber and patient have gone through a dosage titration process and have determined that the patient should be "maintained" on an effective dose of a medication that is well tolerated. Ultimately, the individuals in a position to make such a determination are the patient and the prescriber. The standard quantity issued for chronic conditions is a 90day supply. If it is necessary to deviate from this amount, prescribe quantities in 30-day increments (30, 60, 90, etc.) if possible. If pharmacy staff, in consultation with the prescriber, deems it advantageous to the patient due to travel, deployment, operational commitments, packaging, etc., they may dispense larger quantities (up to 180 days). Active Duty members deploying OCONUS for greater than 180 days will be advised and instructed on the Tricare Mail Order Program (TMOP).
- (4) For in-house prescriptions and prior to dispensing, in the event of a medication error, incomplete entry, or question/concern regarding a medication, pharmacy staff shall contact/notify the prescriber for further guidance. Upon confirmation/clarification from the prescriber, completely draw a single horizontal line through errors or changes and conspicuously write "Error" next to the item. The person changing the entry shall initial the change or error. If the provider requires further review before making a change, return incorrect or incomplete entries to the prescriber for revision/review.
- (5) Pharmacy staff shall write the prescription number or put the multi-part strip label on the SF-600 and initial to identify the person who prepared the prescription.
- (6) Pharmacy staff shall write the manufacturer's name, lot number, and expiration date to the right of the drug prescription (not required with CHCS). Sickbays not on CHCS also shall maintain a drug dispensing log containing prescription number, patient's name, patient's SSN, drug

name, drug manufacturer, and lot number. Retain this log for record purposes for 3 years.

- (7) For refills, pharmacy staff shall note the date, pharmacy identity and "Rx Refill" on the SF-600, followed by medication name, quantity, original prescription date, manufacturer's name, lot number, expiration date, and remaining refills. If processing through CHCS, the only required information is the pharmacy identity, current date and medication name. The pharmacy staff member charting the refill shall initial the entry. The use of personal stamps to further identify pharmacy personnel is encouraged. Any other services (counseling, vital signs, etc.) provided to the patient shall also be noted in the medical record.
- (8) In addition to the SF-600 or SF-558 entry, written prescriptions are required for all controlled substances or cases where a prescription must be taken to another pharmacy.
- (9) All prescriptions generated from sources outside the clinic shall be filled or refilled using CHCS or the procedures specified in this Chapter and maintained on file in the pharmacy. The pharmacy need not maintain a health care record if the patient receives only basic pharmaceutical care from the facility. Offer such patients the HIPAA MHS Notice of Privacy Practices.
- 5. Signatures.

No prescription or order shall be filled unless it bears the signature of an individual authorized to write prescriptions. All prescriptions shall include the stamped name, rank, and professional discipline (MD, DDS, HS2, etc.) of the prescriber. Prescriptions for controlled substances shall also provide the social security number or DEA number of the prescriber. Pharmacy personnel shall maintain signature examples for in-house and contract prescribers. Professional judgment shall be used to verify authenticity of prescriptions from other sources.

- 6. Dispensing.
 - a. The pharmacy shall serve as the source of supply from which clinics or satellite activities normally obtain required pharmaceuticals and related supplies. In addition, the pharmacy dispenses required, authorized preparations directly to patients.
 - b. <u>Except for OTC program items, the pharmacy shall dispense all stocked</u> <u>items only on receiving a properly written, verified prescription</u>. If pharmacy staff receive an illegible prescription or question its authenticity, dosage, compatibility, or directions to the patient, staff shall obtain clarification from the prescriber before dispensing the medication(s).

- c. <u>Clinics shall have a system (computerized, written, etc.) in place to ensure</u> they can obtain prescriptions in case of a product recall.
- d. <u>Clinics shall submit all pertinent patient adverse reactions or product quality problems on the FDA MEDWATCH system on FDA Form 3500</u>. Obtain MEDWATCH forms and information from the FDA at 1-800-FDA-1088 or at <u>www.fda.gov</u>. VAERS (Vaccine Adverse Event Reporting System) forms can also be obtained at the same website. When it becomes necessary to complete a VAERS form, clinics are responsible to submit, via fax, a completed copy to Commandant (CG-1121) at (202) 267-4685, ATTN: Epidemiologist and to respective MLC (k).
- e. <u>When dispensing medication, the dispenser shall identify the patient and</u> <u>ensure his or her eligibility</u>.
- f. <u>Medication Error</u>. In the event of a MEDICATION ERROR (i.e. an error discovered after a prescription has been dispensed to the patient), a Medication Error Report including pertinent information relevant to the error (name of discoverer, date of discovery and a brief statement describing error) shall be completed. A copy of the report shall be submitted for review during the next convening clinic Quality Assurance Focus Group meeting.
- g. <u>Use child-resistant containers to dispense all prescription legend</u> <u>medications except nitroglycerin, which is dispensed in the original</u> <u>container</u>. The practitioner or patient may specifically request a conventional closure. A practitioner must so indicate on the prescription order. If the patient requests such a closure, enter a statement so saying on the back of the prescription and have the patient sign it. When refilling prescriptions, the pharmacy must ensure the safety closure still functions and the label is legible before dispensing in the original container.
- h. <u>Prescriptions (except for controlled substances-see 10-B-4.c.) may be</u> <u>refilled when authorized by the prescriber</u>. The maximum quantity shall be a year's supply of medication. No prescription shall be refilled after more than one year from the date it was written. PRESCRIPTIONS SHALL NOT BE REFILLED FROM THE LABEL ON THE CONTAINER ONLY.
- i. <u>Coast Guard clinics are encouraged to establish non-prescription medication</u> programs under the following guidelines:
 - (1) Commanding Officer of Coast Guard units assigned with health care personnel may elect to operate a nonprescription drug program. Units not staffed with an HS may operate a nonprescription medication program with oversight provided by a Coast Guard pharmacist or supporting Independent Duty HS. Units electing to offer a

nonprescription drug program shall request authorization through their respective MLC, and verify that they will operate within the guideline.

- (2) All Coast Guard health care facilities shall make condoms available to beneficiaries even if they elect not to offer a nonprescription drug program. Condoms shall be made available to beneficiaries under 18 years of age unless specifically forbidden by law.
- (3) Items available shall be limited to those specifically identified (authorized) in the Nonprescription Medication Program (see Enclosure 1). Units may elect not to offer every product from this list but shall not add unauthorized products.
- (4) A beneficiary family shall be limited to a maximum of two items per week from the program. Occasionally, it may be necessary to extend this limit due to family size. Pharmacy and Therapeutics Committees (if available) and collateral duty pharmacy officers shall provide guidance and monitor any such extensions.
- (5) Items shall only be available during normal operating hours of the pharmacy or sick bay.
- (6) Pharmacy or sick bay personnel shall monitor the program for perceived overuse. Individuals suspected of this shall be referred to a medical officer and may have their access to this privilege denied.
- (7) All products must be dispensed in the Manufacturer's FDA approved packages with required instructions and warnings. Other locally packaged items are not authorized. Local Pharmacy and Therapeutics Committees may develop supplemental information on sheets to provide additional dosage or drug information to the patient.
- (8) Nonprescription drug program items shall not be dispensed to pregnant patients or non active duty beneficiaries under 18 years of age. Local flight surgeons, via the Pharmacy and Therapeutics Committee, shall determine which products may be acquired and which products are restricted to personnel on flight status.
- (9) Facilities offering this service shall keep monthly statistics as to the quantity of items dispensed. This figure shall be separated from regular pharmacy workload statistics and not be counted as a prescription number, but will be added to monthly pharmacy statistics report as requested by the clinic's administrator. Once collected, request forms may be shredded and disposed. Only those items which have been dispensed by a written prescription shall be counted in the facility prescription number totals.

- (10) Beneficiaries are responsible for providing an authorized picture identification card to verify their eligibility (e.g., military identification card).
- (11) To receive a nonprescription item, patients must sign a log or complete a request form which certifies the following:
 - (a) "I do not wish to see a physician or other health care provider for advice before receiving these medications. I understand that the medication is for minor illness or conditions and that if symptoms worsen or persist longer than 48 hours, the person for whom this medication is intended should be seen by a health care provider.
 - (b) "I am not pregnant or under 18 years of age (unless active duty). If on flight status, I understand that I am only authorized to receive over-the-counter items approved by the flight surgeon.
 - (c) The person for whom this medication is intended does not have high blood pressure/cardiac problems, diabetes, thyroid problems, is not taking blood thinners, or is not pregnant.
- (12) Individuals suspected of returning for medication for a non-resolving problem shall be referred to a medical officer for evaluation.
- (13) The log sheet or request form shall also contain the date, patient's name, and the name and quantity of the item(s) received
- (14) Beneficiaries requesting medical advice that, in the opinion of the pharmacy or sick bay personnel, is beyond their expertise shall be referred to the medical officer.
- (15) Funding for independent duty HS assigned units (vessel, groups, etc.) deciding to offer this service shall be from their supporting pharmacy AFC-57 account.
- (16) Enclosure one (1) provides a sample form for the Non Prescription Medication Program with a current list of authorized items.
- j. When the pharmacy is closed, a medical or dental officer, or a person so authorized, shall dispense medication only from a locked cabinet or locker containing pre-packaged or limited supplies of after-hours medications. The after hours locker shall be maintained in a secured location outside of the pharmacy and shall contain limited pharmaceuticals required to treat acute medical conditions to stabilize the patient until he/she can return during normal clinic hours. This procedure shall prevent the need for access into the pharmacy after hours. These drugs are dispensed under the same procedures required when the pharmacy is open, including appropriate

labeling and complete entry in the health record. Prescriptions from civilian or outside providers shall not be filled after hours. Patients presenting with the above will be advised they can return during normal pharmacy hours or shall be referred to another pharmacy source including a Military Treatment Facility or Tricare Retail Network Pharmacy.

- k. Bulk items for use in the clinic may be issued on authorized prescription forms or locally approved requisition forms.
- A sign shall be posted outside of the pharmacy in a highly visible location stating "Please inform our pharmacy staff if you are breast feeding or may be pregnant." Clinic pharmacies shall maintain a written drug information system (USP, CHCS, HIPAA etc.) to provide information to patients when appropriate. Post the MHS Notice of Privacy Practices in an accessible location.
- m. Pharmacies shall adhere to applicable state laws governing generic dispensing of civilian prescriptions. Civilian prescribers may provide the facility with a written statement giving "blanket approval" to dispense generics for their prescriptions.
- n. Drug samples are not authorized at CG facilities.
- o. For guidance on pharmaceutical gifts, the CG Ethics Program can be found in <u>Standards of Ethical Conduct, COMDTINST M5370.8 (series)</u> specifically 2.C
- 7. Labeling.
 - a. <u>A label will be prepared for each prescription dispensed to individuals and</u> <u>will be securely affixed to the container prior to dispensing</u>. The label or appropriate auxiliary labeling will show as a minimum:
 - (2) Facility identity, including the pharmacy address and telephone number.
 - (3) Consecutive identifying number.
 - (4) Prescribers name.
 - (5) Definite, concise directions to the patient.
 - (6) Drug name and strength, unless prescriber directs otherwise.
 - (7) Amount dispensed.
 - (8) Patient's first and last name.

- (9) Initials of person typing the prescription label.
- (10) The legend "KEEP OUT OF THE REACH OF CHILDREN" on all prescription labels.
- (11) Date prescription filled.
- (12) Indication of refills.
- (13) Expiration date (for liquid antibiotics).
- (14) The legend "CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED" (for controlled substances only).
- (15) Necessary supplemental or auxiliary labels.
- b. <u>Directions on labels</u>. If prescription contents are for external use only or require further preparation(s) for use (shaking, dilution, temperature adjustment, or other manipulation or process) include the appropriate directions on the label or affix an additional label to the container. If liquid preparations for external use are poisonous, affix a "poison" label to the container. If medicines prescribed for internal use are poisonous, use sound judgment whether to label them "poison" based on the finished preparation's potency in each case.
- c. <u>Generic names</u>. Medicinal preparations compounded or packaged in the pharmacy for subsequent issue will be identified and labeled with the full generic name, except that trade or brand names may be used provided trade or brand name product actually is in the container. The manufacturer's name, lot number, and expiration date, if any, will be shown on the label.
- d. Drug issued to clinics for subsequent reissue to outpatients shall be adequately labeled in the pharmacy.
- e. <u>All multiple dose injectable vials shall be dated upon opening</u>. Expiration will be thirty days unless the product information from the manufacturer indicates a shorter or longer expiration date is authorized.
- 8. Drug Stock.
 - a. <u>Source of medications</u>. The Defense Supply Center, Philadelphia (DSCP) is the primary source of medications for either the "Depot" system or prime vendor contracts. Other Federal sources (Perry Point IHS Depot, Federal Supply Schedules, MLC-negotiated purchase agreements, etc.) may be used when, due to price or service advantages, it is determined to be the most cost-effective procurement method to meet the needs of the unit. Drug

procurement from retail sources shall be done only when absolutely required for urgent patient needs and when other, less costly, sources cannot meet this need.

- b. <u>Approval of medication</u>. Only those items that have been licensed and approved by the Food and Drug Administration (with the exception of vitamins with an established RDA) are authorized for use in Coast Guard health care facilities. Coast Guard health care facilities shall not purchase or dispense "herbal supplements" or "dietary supplements". Active duty members may neither possess nor purchase, via any venue, herbal supplements, dietary products, or alternative health care substances banned by the FDA for sale or use in the United States. Patients should inform their healthcare providers if taking any type of herbal supplements to avoid potential drug interactions. Aviators and flight crew members shall follow guidance provided in the Aviation Manual, Chapter 12, Section B.3.h. Commands can contact the Collateral Duty Pharmacy Officer or MLC Pharmacy Officer for further guidance.
- c. <u>In storage, separate external use medications from internal use medications</u> <u>and ophthalmic and otic preparations</u>. Caustic acids such as glacial acetic, sulfuric, nitric, concentrated hydrochloric, or oxalic acid shall not be issued to clinics, but shall be stored in separate lockers, clearly marked as to contents. Methyl alcohol shall not be stored, used, or dispensed by the pharmacy.
- d. <u>Store flammable drugs according to accepted fire safety regulations</u>. Additional information regarding hazardous materials can be found at: <u>http://www.uscg.mil/ccs/cit/cim/directives/CI/CI_6260_21B.pdf</u>.
- e. <u>Doors</u>. Solid core doors with one-inch (minimum), throw key-operated, dead-bolt locks shall be used for all pharmacy and medical supply areas and shall be secured at the end of the day. On Dutch doors, both sections shall have this type lock. Pharmacy doors shall have a second keylock or cipher lock to remain secured at all times.
- f. <u>Remove from stock drugs under testing in the FDA/DoD Shelf Life</u> <u>Extension Program; label them with the project number until results are</u> <u>received</u>. While pending, use these items only in emergencies to offset medical allowance list requirements. Upon return of results, items should be destroyed or marked with FDA approved labels with new expiration dates and returned to stock. Oral contraceptives, ophthalmics, otics, and inhaler medications should not be extended.
- g. <u>The pharmacy shall maintain, in the pertinent clinic areas, an adequate</u> <u>supply of emergency medications (or kits), poison antidotes, and the</u> <u>National Poison Control Center telephone number (1-800-222-1222)</u>. Containers for these items shall be closed with break-away seals to prevent

the unreported removal of items. The outside of the container shall post an inventory list with their expiration dates.

- h. <u>Credit return program</u>. Clinics shall establish a credit return program through a pharmaceutical returns vendor that accepts expired pharmaceuticals and disposes of them in accordance with federal law. The company should coordinate and issue refunds from the respective manufacturers of the returned products directly to the clinic's prime vendor who will issue it as available credit for the specific clinic. Expired medications not accepted by the returned goods vendor shall be disposed of as biohazard waste. DSCP currently has an established contract with Guaranteed Returns. Although it is currently not mandatory to use <u>Guaranteed Returns as the vendor, the company must abide by the contract</u> requirements as established by DSCP. If clinics choose not to use Guaranteed Returns, they must follow standard contract solicitation governed by law.
- 9. Pharmacy and Therapeutics Committee.
 - a. <u>This is a mandatory advisory committee in all Coast Guard health service</u> <u>treatment facilities having assigned medical officers and shall meet</u> <u>quarterly (at least four times a year)</u>. The committee is composed of, but not limited to, the following: at least one physician, one dentist, the pharmacist (when available), and a representative from medical administration. The chairman shall be the senior medical officer (if more than one medical officer is on the committee). When a pharmacist is assigned, he or she is the secretary of this committee. In facilities where a pharmacist is not permanently assigned, the pharmacy technician shall serve as the secretary.
 - b. <u>The committee is an advisory group on all matters relating to the acquisition</u> <u>and use of medications</u>. Its recommendations are subject to the approval of the Chief, Health Services Division. The basic responsibilities of this committee are to:
 - Use the Department of Defense Basic Core Formulary (DoD BCF) as guidance to develop and maintain a clinic drug formulary as specified in 10-A-2.c., review newly requested items, and delete unnecessary items.
 - (2) Maintain a unit formulary ensuring items authorized for health service technicians (based on the authorized Coast Guard Standardized Health Services Technician Formulary) are properly notated.
 - (3) Ensure the unit formulary does not include items based primarily on civilian prescriber demand.
 - (4) Prevent unnecessary therapeutic duplications of formulary products.

- (5) Conduct an ongoing review of all non-formulary items the pharmacy procures and dispenses. To accomplish this, the clinic and/or P&T committee reviews:
 - (d) A list of all clinic formulary items not currently in the DoD BCF.
 - (e) A list of all special order items (Special Order Medication Request forms) and the patients for whom procured.
- (6) Conduct an ongoing drug usage evaluation (DUE) program for selected medications.
- (7) Monitor the facility's controlled drug prescribing and usage.
- (8) Review pharmacy policies and procedures as necessary.
- (9) Monitor the quality and accuracy of prescriptions and patient information the pharmacy provides and enacts any quality assurance measures it deems necessary (double checks, etc.).
- (10) Reviews any adverse reaction or product quality reports (VAERS or MEDWATCH).
- (11) Monitors compliance with HIPAA privacy and security mandates.
- c. <u>Minutes shall be prepared for each meeting and approved by the Chief,</u> <u>Health Service Division</u>. A copy shall be forwarded electronically to cognizant MLC (k).
- d. <u>Quality Improvement Implementation Guide (QIIG) #5, Pharmacy and</u> <u>Therapeutics Committee, provides additional guidelines</u>.

USCG (may insert name of clinic or location here) CLINIC NON-PRESCRIPTION MEDICATION PROGRAM Limited to TWO (2) Items Per Family Per Week

This program is for military beneficiaries only. MILITARY ID CARD IS REQUIRED. Please read and sign the following statement:

I do not wish to see a physician or other health care provider for advice before receiving these medications. I understand that these medications are for minor illnesses or conditions and that if symptoms worsen or persist longer than 48 hours, the person for whom this medication is intended should be seen by a health care provider.

I am not under 18 years old (unless active duty). If on flight status, I understand that I am only authorized to receive non-prescription items approved by the flight surgeon.

The person for whom this medication is intended does not have high blood pressure, cardiac problems, diabetes, thyroid problems, is not taking blood thinners, or is not pregnant.

Signature:	
Printed name:	
Date:	

NOTE: Items listed are not guaranteed to always be available.

- Acetaminophen 325mg tabs, 50 count Cetylpyridinium Anesthetic Lozenge, 9 Acetaminophen 81 mg chewable tabs, 30 count Liquid Antacid, 150ml Acetaminophen 160mg/5ml liquid, 120ml Loperamide caplets, 12 count Acetaminophen 0.8mg/0.8ml drops Antichap Lipstick Ibuprofen 200mg tabs, 24 count Bacitracin Ointment, 30gm _____ ____ Analgesic Balm, 30gm Ibuprofen 100mg/5ml, solution Pseudoephedrine 30mg tabs, 24 count Saline Nasal Spray, 45ml Pseudoephedrine 30mg/5ml, 120ml Clotrimazole Topical cream, 30gm Triprolidine/Pseudoephedrine tabs, 24 count Brompheniramine/Pseudoephedring solution, 120ml Tolnaftate powder, 45gm Guaifenesin 100mg/Dextromethorphan 5mg, 120ml Calamine Lotion,
- Diphenhydramine 25mg capsules, 24 count
- Diphenhydramine liquid, 120ml
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- Hydrocortisone 1% topical cream, 30gm
- Male Condoms
- Female Condoms

PHARMACY OPERATION AND DRUG CONTROL

Section B. Controlled Substances.

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CHAPTER 10 PHARMACY OPERATION AND DRUG CONTROL

Section B Controlled Substances.

- 1. General.
 - a. <u>Controlled substances, as used here, are defined as</u>:
 - Drugs or chemicals in DEA Schedules I-V: (for example, the manufacturers label for Acetaminophen with Codeine #3(30 mg.) carries the DEA symbol for Schedule III (C-III) and will be treated as a Schedule III by Coast Guard units.). NOTE: The use of Schedule I, II, III, IV, and V is synonymous to CI, CII, CIII, CIV, and CV, respectively.
 - (2) Precious metals.
 - (3) Ethyl alcohol (excluding denatured).
 - (4) Other drugs or materials the local commanding officer or Pharmacy and Therapeutics Committee determine to have significant abuse potential.
 - b. <u>Coast Guard authorized uses for controlled substances are one of the</u> <u>following</u>:
 - (1) Medicinal purposes.
 - (2) Retention as evidence in legal or disciplinary actions.
 - (3) Other uses CG Regulations specifically authorize.
 - c. <u>Controlled substances not authorized are</u>:
 - (1) Amphetamines for fatigue management or performance enhancement (go-pills).
 - (2) Controlled substances for weight loss.
 - d. <u>Quantity Definitions</u>. Due to the potential for abuse and associated audits required, and the DoD Pharmaceutical Prime Vendor ordering advantage, Coast Guard units should strive to maintain minimal quantities of controlled substances based solely on the prescribing habits of its providers.
- 2. Custody and Controlled Substance Audits.
 - a. Controlled Substance Custodian (CSC).

- (1) Pharmacy officers, when assigned, shall be appointed in writing as the CSC by the commanding officer.
- (2) In the absence of a pharmacy officer, COs shall designate the clinic administrator as CSC.
- (3) Medical and dental officers may not serve as alternate CSC's to avoid possible conflict of interest.
- (4) Temporarily assigned personnel shall not serve as CSCs or alternates.
- (5) Under Coast Guard Regulations, <u>COMDTINST M5000.3 (series)</u>, Chapter 6-2-3-A.(6), the Executive Officer is directly responsible for medical matters if a medical officer is not assigned. For sickbays, the CO shall designate a commissioned officer as the CSC.
- (6) An audit of all controlled substances is required when the CSC is changed. The results of this inventory shall be filed in the command's permanent file and in the Health Services Log. All keys should be transferred and/or combination locks changed at the time of this inventory.
- b. <u>Unit Controlled Substance Audits</u>.
 - (1) Controlled Substance Audit Boards (CSAB). Each unit procuring, storing, or dispensing controlled substances shall have a CSAB.
 - (a) Membership: The CSAB shall consist of two or more disinterested members, E-6 or above, designated in writing by the Commanding Officer. CSAB letters of designation will remain in effect until the members are relieved in writing or detached from the command. In no case may the controlled substance custodian be a member of the CSAB. A DISINTERESTED MEMBER is defined as one not assigned or directly involved in daily clinic operations.
 - (b) The CSAB shall conduct monthly audits of controlled substances at clinics (quarterly at ashore or afloat sickbays) and submit its report to the commanding officer within 5 working days after its audit. Commands shall maintain these reports for three years after which they may be destroyed.
 - (c) Monthly, CSABs shall audit all working and bulk stock of C-II through C-V controlled substances, precious metals, ethyl alcohol, and drugs or other items locally designated as controlled substances due to abuse potential and report all quantities on CG-5353, Monthly Report for Narcotics and Other Controlled Drugs.

- (d) During monthly audits, CSABs shall inspect controlled substances for expiration, deterioration, and inadequate or improper labeling. Expired products or those with other discrepancies shall be removed for disposal.
- (e) The CSAB shall count required controlled substances; review a representative random sample of prescriptions, receipts, and issue documents; and report the results on Monthly Report for Narcotics and Other Controlled Drugs, CG-5353. For sealed containers, a bottle count is sufficient; for open containers an exact count is required. For open liquid containers, an estimate other than an exact volume measurement is adequate. CSABs may use tamper-proof seals on open containers to avoid future counting of partial quantities.
- (f) CSAB members shall be advised that the Coast Guard health care program is committed to the privacy of patient health information. Federal laws (the Privacy Act and the Health Insurance Portability and Accountability Act [HIPAA]) govern uses and disclosures of medical information.
- (g) During the CSAB process, respect patient privacy: do not access information you do not need for CSAB tasks; do not discuss patient information with anyone outside the CSAB. HIPAA is Federal law, and violations may mean civil penalties up to \$50,000 and/or criminal penalties. It is to be reminded that these laws also govern how ones information is protected while even a patient in any CG/DoD health care facility.
- (2) DEA Biennial Inventories. To comply with DEA requirements, all controlled substances shall be inventoried by the custodian during May of even-numbered years. This copy of the CG-5353 shall be maintained on file locally and labeled "FOR DEA BIENNIAL INVENTORY" at the top of the form.
- 3. Drug Enforcement Administration (DEA) Registration. DEA registration is required for those CG clinics with Prime Vender Ordering capability. Purchase of controlled substances from commercial sources is prohibited unless approved and procured by pharmacy officers. Sickbays shall not register with the DEA unless in-house physician services are provided. The unit's Drug Enforcement Agency Registration Form (DEA-244A) shall be signed by the Commanding Officer. By direction signature is not authorized. Forward the signed form to cognizant MLC (k) for signature as approver for fee exempt. The MLC (k) shall forward the form (DEA-244A) to the DEA and provide a photostatic copy to the originating unit. The DEA will issue the registration to the unit. In the case of DEA renewals, (CLINIC RENEWALS

ONLY [NOT INDIVIDUAL PROVIDERS]), this can be accomplished manually or electronically.

- a. For manual renewal of DEA-224A: ensure all boxes in Block 1 are marked; check Block 2 ONLY if DEA 222 order forms are required; item (A) in Block 3 is Not Applicable, but [NO} box for items (B) through (E) shall be marked; leave Block 4 blank; use Block 5 only if current address requires correction or has missing information; Block 6 is Not Applicable; Block 7 is to be completed by MLC(k); Block 8 shall be signed by the unit's Commanding Officer; and, the form shall be forwarded to cognizant MLC(k), via Registered Mail, for review and completion of Block 7.
- b. For electronic renewal of DEA-224A do not complete and send the entire BLANK renewal application to cognizant MLC (k), ATTN: Pharmacy Officer, via Registered Mail who will complete the form electronically. For questions regarding renewal of clinic DEA certificates, contact cognizant MLC Pharmacy Officers for further guidance.
- 4. <u>Reporting Theft or Loss</u>.

Theft or loss of controlled substance is defined as any discrepancy for which all accountability process has been exhausted with negative results. NOTE: Overage or underage of a newly opened bottle of controlled substance does not constitute theft or loss but shall be notated in the Perpetual Inventory as manufacturer's bottling overage or underage. Immediately, upon discovery of theft of loss, notify cognizant MLC (k).

- a. If discovered during the course of a monthly CSAB, a designated command member shall contact the cognizant MLC (k), discuss the circumstances of the discrepancy, and request guidance for further action. MLC will advise the command in writing or by E-mail of the guidance provided. Should MLC determine an investigation is warranted, the command shall appoint one or more members of the command to investigate the discrepancy. The command shall not appoint CSAB members or interested members to investigate an incident they have reported.
- b. If discovered other than during the course of a monthly CSAB, the CSC, via the clinic's proper chain of command, shall notify cognizant MLC (k) and request guidance for further action. Guidelines as indicated in 4. a. above may be followed, if warranted.
 - (1) Review and send to the pertinent MLC (k) the findings of the investigation.
 - (2) The pertinent MLC (k) shall determine if the theft or loss warrants further action or DEA notification, via DEA form 106. A copy of all DEA 106 reports submitted to DEA shall be sent to Commandant (CG-112).

- 5. Procuring, Storing, Transferring, and Disposing of Controlled Substances.
 - a. <u>Procurement</u>.
 - Clinics shall procure controlled substances from the DSCP prime vendor source. Coast Guard vessels shall obtain authorized controlled substances through their collateral duty pharmacy officer.
 - (2) Schedule I controlled substances and alcoholic beverages are prohibited and shall not be procured or stocked in Coast Guard health care facilities.
 - (3) Upon receipt, controlled substances shall immediately be placed in the custody of the designated custodian. The invoice shall be checked against the requisition to verify receipt of all quantities listed on the invoice. The custodian shall acknowledge receipt by signing the invoice. Controlled substance procurement documents shall be maintained in the pharmacy for three years.
 - b. Storage.
 - Controlled substances shall be stored in an all-purpose Class V safe. Chapter 11 of the <u>Coast Guard Physical Security and Force Protection</u> <u>Manual, COMDTINST M5330.1 (series)</u>, offers in depth guidance regarding storage of Controlled Substances.
 - (2) In the case of CANA (Diazepam 10mg Auto Injectors), required quantities are often too bulky to feasibly store in Class V safes. Therefore, storage in a secured locked cabinet in a controlled access area is authorized. For field deployments, CANA may be stored in a secured portable container under the control and custody of the unit Commanding Officer or the Designated Controlled Substance Custodian and, if possible, in a controlled access area. CANA should be stored between 59-86 degrees Fahrenheit. If this temperature cannot be controlled, a log must be maintained indicating storage temperature and conditions. Disposition of CANA shall be documented on the Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, NAVMED 6710/5, from time of receipt to issuance to the primary user. For field deployments, an issue log signed by the recipient is an acceptable form of documentation. Transfer of CANA between units shall be documented via DD-1149. Units are required to include CANA in its Controlled Substance Audits.
 - (3) Afloat units may use existing "built in" containers to store controlled substances.
 - c. <u>Transfer</u>.

- Controlled substances may be transferred between CG and other government facilities using the Requisition and Invoice/Shipping Document (DD-1149). When completed, the document shall include:
 - (a) Names of issuing and receiving facility or unit.
 - (b) Name, strength, and quantity of each drug.
 - (c) Date.
 - (d) Signatures of the issuing and receiving custodians.
- (2) Both units shall adjust inventories as required and file copies of the DD-1149 for three years.
- (3) When the transaction cannot be done in person, it shall be done by registered mail or other mechanism where tracking capability is available. The Registered Mail Return Receipt (PS Form 3806), or tracking document, shall be maintained by the issuing unit until a signed copy of the DD-1149 is returned.
- (4) A copy of the DD-1149 shall be sent to the pharmacy officer with collateral duty responsibility for the facility.
- d. Disposal.
 - Expired, contaminated, excessive, or inadequately labeled controlled substances shall be destroyed by the audit board in accordance with 10.A.8. CSAB reports shall include the drug name, quantity, reason for destruction, and mechanism of destruction. These shall be maintained on file for three years.
 - (2) Controlled substances identified for destruction must be disposed of in accordance with state law. The DEA may also be used to dispose of controlled substances. Contact your pharmacy officer for information on this procedure.
- 6. Prescribing Practices.
 - a. <u>Authorized (Active Duty) prescribers (see 10-A-2.a). are exempt from</u> registration under provision of 21 CFR 1301.25. The officer's social security number may be used in lieu of a DEA registration number. The exemption does not apply when the officer prescribes controlled substances outside of his or her official duties. In that case, the prescriber is required to register with the DEA, at his or her own expense, and comply with applicable state and federal laws.
 - b. <u>Signatures</u>.

- (1) All prescriptions for controlled substances shall be signed by a medical or dental officer. If none is assigned, the prescription shall be signed by the senior health services department representative and countersigned by the executive officer.
- (2) All schedule II controlled substance prescriptions by physician assistants or nurse practitioners shall be countersigned quarterly by their supervising medical officer.
- (3) All controlled substance quantities used in the preparation of other products (compounding, etc.) shall be accounted for on a prescription form and signed by the pharmacy officer or custodian.
- (4) The back of all controlled substance prescriptions shall include the wording "RECEIVED BY:" followed by the patient's signature, address, the date dispensed, and quantity received by the patient. It is recommended the patient observes the amount dispensed during the course of the second (dual integrity) count or at time of dispensing, if time permits.
- c. Quantities and Refills.
 - (1) Controlled substances shall be prescribed in minimal quantities consistent with proper treatment of the patient's condition. Outside prescriptions for controlled substances may only be honored at facilities where a Pharmacy Officer is available and at the discretion of the Pharmacy Officer.
 - (2) Out-of-state controlled substance prescriptions may be dispensed if, in the professional judgment of the pharmacy officer, the prescription appears legitimate. These prescriptions should invoke special scrutiny by the pharmacist
 - (3) Schedule II prescriptions shall not be accepted more than seven days after the date the prescription was written. For Schedule III through V, 30 days shall be the limit.
 - (4) Schedule II prescriptions shall be limited to a maximum of 30 day quantity and shall not be refilled. The only exception shall be medication for Attention Deficit Disorder (ADD) where quantities may be dispensed in up to a 90 day supply with no refills.
 - (5) Schedule III, IV, and V prescriptions shall be limited to 30-day quantities with up to five refills only as authorized by the prescriber. The only exception shall be for chronic seizure medications, which may be dispensed in up to 90-day quantities with one refill (six months' total supply). Outside prescriptions for these medications

shall only be honored for these quantities, at the discretion of the pharmacist. Patients shall be informed of this quantity/refill limit and be offered the opportunity to have the prescriptions filled elsewhere.

- d. Filing Prescriptions.
 - (1) Controlled substance prescriptions shall be serially numbered and maintained in two files:
 - (2) File #1: All C-II, precious metals, and alcohol prescriptions.
 - (3) File #2: All C-III, C-IV, and C-V prescriptions.
 - (4) All prescriptions shall be maintained on file for three years after which they may be destroyed by shredding.
 - (5) All controlled prescriptions shall be posted on NAVMED 6710/5 at the time of each transaction. If time permits, it is recommended to conduct a physical count of the opened bottle in which the prescription was dispensed to verify the remaining balance. The prescription shall then be diagonally lined across and initialed by the pharmacy staff member completing the transaction. A red inked stamp bearing a notation indicating the prescription has been "dispensed and posted" and initialed by the pharmacy staff completing the transaction may be used to meet this criteria.
 - (6) All CII prescriptions shall have a red-ink stamped "N" on the face of the prescription prior to filing. All CIII through CV prescriptions shall have a red-ink stamped "C" on the face of the prescription prior to filing.

PHARMACY OPERATION AND DRUG CONTROL

Section C. Forms and Records.

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CHAPTER 10 PHARMACY OPERATION ANF DRUG CONTROL

Section C. Forms and Records.

1. <u>General</u>.

Records shall be maintained for certain procedures conducted within all Coast Guard Clinics. Among mandatory requirements for record keeping are the prescribing of drugs, handling of controlled substances, and quality control procedures. Standardized forms are available for all procedures except quality control.

- 2. Prescription Forms.
 - a. <u>Clinic providers shall write prescriptions on the DoD prescription form (DD</u> <u>1289) when chart prescribing is not available</u>.
 - b. <u>All prescriptions shall be filed in one of three files:</u>
 - (1) All non-controlled drug prescriptions;
 - (2) Schedule II prescriptions; and
 - (3) Schedule III, IV, and V prescriptions.
 - c. <u>Prescriptions in black or blue ink, indelible pencil, or typewritten must</u> show the information:
 - (1) Patient's full name.
 - (2) Date the prescription was written.
 - (3) Full generic name (or trade name with substitution instructions), dosage form desired, and dosage size or strength written in the metric system. The quantity dispensed shall be clearly specified numerically ("one bottle" or "one package" are not acceptable). When writing for controlled prescriptions, the numeric quantity shall also be written out and in parentheses next to the numeric amount (e.g. Disp. 12 (twelve) tablets). Standard pharmacy abbreviations may be used in writing dispensing and dosage instructions but not in specifying the drug to be dispensed.
 - (4) Complete, explicit directions to the patient are required. Eexpressions such as "take as directed," "label," etc. are not adequate directions and not allowed.
 - (5) Prescriber's legible, legal signature (initials not permitted) with stamped name and professional discipline (MD, DO, DMD, DDS, PA, HS2, etc.).
 - (6) All additional requirements when prescribing controlled substances:
 - (a) Patients complete address.
 - (b) Prescriber's SSN or DEA number.

- (c) ©NOTE: Alterations on prescriptions for CII controlled substances are prohibited.
- d. <u>Multiple prescription forms, such as NAVMED 6710/6 or 6710/10, which</u> are intended for use when prescribing a number of non-controlled drugs for <u>one patient, are authorized</u>.
- e. <u>Maintain all prescriptions on file, including all "prescription logs" related to</u> <u>chart prescribing, for three (3) years, after which they may be destroyed by</u> <u>shredding.</u>
- f. <u>The pharmacy shall have ready access to the patient's medical information</u> <u>including provider's current patient visit entry, patient's current</u> <u>medications, age, allergies, weight, etc., when preparing and dispensing</u> <u>prescriptions</u>.
- 3. <u>Quality Control Forms</u>.

Quality control is important for proper conformity and safety of drug products to be dispensed. The two main areas that benefit from quality control are compounding and prepackaging. A locally prepared form shall be used which will provide clearly definable material sources (manufacturer's name, lot numbers, and expiration dates), procedures used, intermediary and final checks by supervisory personnel, and sample labeling.

- 4. <u>Controlled Drug Forms</u>.
 - a. <u>NAVMED 6710/4-24-Hour Narcotic and Controlled Drug Inventory</u>. This record shall be maintained at Coast Guard facilities providing inpatient care.
 - (1) The NAVMED 6710/4 shall be signed by the senior health services technician on each watch after the drugs have been checked prior to relief. The drugs shall be checked concurrently by the HS reporting for duty as well as by the HS being relieved. Any discrepancies noted shall be reported immediately. The record is used for two (2) weeks, with a one (1) week period on each side. The night HS shall initiate the record.
 - (2) The serial numbers of new NAVMED 6710/1's received from the pharmacy during each watch shall be entered. The serial numbers of completed NAVMED 6710/1's returned to the pharmacy shall be entered and the pharmacist or authorized representative shall acknowledge receipt by initialing in the appropriate column.
 - (3) At the time specified in local instructions, the senior health services technician shall audit the clinic controlled substances supplies. After the audit, the senior health services technician shall date and sign the NAVMED 6710/4.
 - b. <u>NAVMED 6710/1—Narcotic and Controlled Drug Account Record.</u>
 - (1) Upon receipt of a properly completed prescription requisition, a separate Narcotic and Controlled Drug Account Record (NAVMED

6710/1) shall be prepared by the pharmacy for each Schedule II through Schedule V drug, and any other drug which, in the opinion of the commanding officer, requires control procedures.

- (2) All NAVMED 6710/1's shall be kept in a controlled drug book.
- (3) All entries shall be made in blue or black ink. Errors shall be corrected by drawing a single line through the erroneous entry and having the person making the correction sign the entry. The correct entry shall be recorded on the following line, if necessary.
- (4) If a new issue is received before the old issue is completely expended, the new NAVMED 6710/1 shall be inserted in back of the current record. The serial number of the new NAVMED 6710/1 shall be entered on the NAVMED 6710/4.
- (5) The heading for each NAVMED 6710/1 shall be completed at the time of issue. The body shall be used for recording expenditures and balances only.
- (6) Each time a drug is used, complete information shall be recorded: date, time, patient, prescriber's name, dispenser, amount used, and balance remaining on hand (NAVMED 6710/1).
 - (a) Record all amounts in Arabic numerals. Where the unit of measure is a milliliter (ml) and the amount used is less than one ml, it shall be recorded as a decimal (e.g., 0.5 ml) rather than a fraction.
 - (b) When a fraction of the amount is expended to the patient, it shall be placed in parentheses before the amount recorded in the expended column; [e.g., an entry of (0.0005)1 on the morphine sulfate 16 mg/ml record indicates that one-half ml was expended and that 0.008 gm was administered].
 - (c) If a single dose of a controlled substance is accidentally damaged or contaminated during preparation for administration or the patient refuses after preparation, the dose shall be destroyed and a brief statement of the circumstances shall be entered on the NAVMED 6710/1. Such statements shall be signed and witnessed by a second health care provider.
 - (d) ©If multiple doses of a controlled substance are damaged, another senior HS shall record the disposition of the drug, including date, amount of drug, brief statement of disposition, and new balance. Both the senior and witnessing HS shall sign the NAVMED 6710/1.
 - (e) Deteriorated drugs shall be returned to the pharmacy for disposal.
 - (f) The completed NAVMED 6710/1, along with the counter-type dispenser, shall be returned to the pharmacy.

- (g) Monthly, the pharmacy shall report all NAVMED 6710/1s still outstanding 30 days from date of issue. The report shall be verified and returned to the pharmacy for reconciliation. Discrepancies shall be reported to the commanding officer via the Controlled Substances Audit Board Inventory Report.
- c. Narcotic and Controlled Drug Book.
 - (1) Each activity drawing controlled substances from the pharmacy shall maintain a loose leaf notebook containing NAVMED 6710/4—24-Hour Narcotics and Controlled Drug Inventory in the first section and individual NAVMED 6710/1—Narcotic and Controlled Account Records in the latter sections.
 - (2) The senior HS shall remove all filled NAVMED 6710/4's over three(3) months old from the Narcotic and Controlled Drug Book and return them to the pharmacy.
- d. <u>NAVMED 6710/5—Perpetual Inventory of Narcotics, Alcohol, and</u> <u>Controlled Drugs</u>. Separate NAVMED 6710/5 forms are not required for each controlled substance (C-II through C-V) when electronic records or documentation are available via the Composite Health Care System (CHCS) or equivalent software programs. The requirement for hard copy monthly substance audit board report (CG-5353) is still required, however the CHCS software prepares and automates controlled substance inventory reports which are acceptable and can be used as an equivalent to the CG-5353. If software is not consistently available, prepare a separate NAVMED 6710/5 for each controlled substance (C-II through C-V). All boxes and columns below are self-explanatory except as noted:
 - (1) Drug Name. Enter generic or proprietary drug name as appropriate, e.g., "Codeine Sulfate.
 - (2) Strength. Express as gm, mg, etc.
 - (3) Unit. Enter dosage form as appropriate.
 - (4) Prescription or Requisition Number. Enter appropriate prescription or requisition (voucher) number. For issues returned to the pharmacy, enter the source.
 - (5) Recipient. Enter "pharmacy" for receipts. Enter clinic or patient name, <u>as appropriate, for expenditures.</u>
 - (6) NAVMED 6710/1 Returned. The date the NAVMED 6710/1 is returned to the pharmacy shall be entered on the appropriate line bearing the same serial number or prescription number.
- 5. Forms Availability.
 - a. <u>Forms CG-5353, DD-1289, NAVMED 6710/1, NAVMED 6710/4,</u> <u>NAVMED 6710/5, and NAVMED 6710/6 are available from the Coast</u> <u>Guard Supply Center</u>.

- b. <u>Obtain DEA forms from the nearest DEA office</u>. Consult with a pharmacy officer for more information.
- c. Prescription blanks DD1289 can be found at the following web site. http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm.

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PHARMACY OPERATION AND DRUG CONTROL

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CHAPTER 10 PHARMACY OPERATION ANF DRUG CONTROL

Section D. Drug Dispensing Without a Medical Officer.

1. <u>General</u>.

Health Services Technicians (HSs) dispensing prescriptions without a medical officer's direct supervision, (e.g., at independent duty shore stations or vessels), shall be conducted in accordance with provisions of this manual and the Health Services Allowance List. These services shall be provided for **active duty personnel only**. HSs in these situations are encouraged to seek consultation with their assigned collateral duty pharmacy officer when necessary.

2. Child-Resistant Containers.

Prepackaged OTC products should be issued in their original container. For vessels, limited quantities of prescription drugs may be issued in labeled plastic zip-lock bags while underway with proper labeling including name of patient, name of medication, exact instructions, precautions, and warnings regarding the medication, date dispensed, and initials of dispenser. These bags must be inserted in a child resistant container with proper labeling if they are removed from the vessel.

- 3. Controlled Substances.
 - a. <u>All drugs shall be dispensed under the supervision of a health services technician at activities where there are no officers of the health services department.</u>
 - b. <u>An officer, designated by the commanding officer, shall keep in a separate locked</u> <u>compartment, all bulk un-issued controlled substances, alcohol, or items otherwise</u> <u>controlled</u>. The designated officer shall always maintain positive control of the keys or combination. The executive officer, or other designated officer, shall arrange for the care and safe custody of all keys and require strict compliance with instructions concerning the receipt, custody, and issue of controlled substances and alcohol as contained in the law, Coast Guard Regulations, and this manual.
 - c. <u>Custodians or their designated assistants shall retain the keys or combination to the</u> <u>working stock storage area while on duty</u>. When relieved, they shall deliver the keys to their relief or to a responsible person designated by local instructions. A copy of the combination of a safe, if used, shall be sealed in an envelope and deposited with the commanding officer.
 - d. <u>Commanding officers may authorize temporary deviations from the controls</u> established in this Chapter due to operational and/or emergency situations.
- 4. Formulary.

Health Services Technicians on independent duty shall maintain drug formularies consisting of:

a. Standardized Health Services Drug Formulary items.

- b. <u>Health Services Allowance List requirements</u>.
- c. <u>Chronic medications prescribed by a physician for active duty members currently</u> <u>assigned to the duty station</u>.
- d. <u>Other drugs the HS has been authorized to stock for their active duty members for a local contract prescriber working at the facility</u>. A list of these items shall be forwarded to the collateral duty pharmacist for review. The review will ensure compliance of the DoD Basic Core Formulary and Uniform Formulary rules.
- <u>Non-prescription Medication Programs</u>.
 Sickbays are encouraged to operate nonprescription medication programs as described in paragraph 10-A-6.h. in this manual. HSs shall contact their collateral duty pharmacists for guidance and additional support.