

**CHAPTER 10**

**PHARMACY OPERATIONS AND DRUG CONTROL**

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**CHAPTER TEN – PHARMACY OPERATIONS AND DRUG CONTROL****A. Pharmacy Administration.****1. Responsibilities.**

- a. Duties of designated person. The person designated in writing as responsible for the pharmacy is accountable to the Senior Health Services Office (SHSO), 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. Responsibility. The person in charge of the pharmacy shall acquire, store, compound, and dispense medications according to applicable Federal laws (principally Title 42, United States Code and Title 21, Code of Federal Regulations 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. This responsibility includes maintaining appropriate inventory and monitoring of expiration dates of all pharmaceuticals. Specific units have been/will be tasked by Commandant (CG-11) to maintain special stocks of pharmaceuticals. Quarterly, all units maintaining pharmaceuticals used for the purpose of anthrax prophylaxis or pandemic influenza prophylaxis are to provide summary data to the HSWL SC Pharmacy Officer to include name(s) of pharmaceutical agent, amount on hand, lot number, and expiration date. The HSWL SC Pharmacy Officer shall maintain this information and provide to Commandant (CG-11) when directed.
- c. Pharmacy references. The person in charge of the pharmacy shall ensure adequate and appropriate current pharmacy references, hardbound and/or online access (e.g., Drug Facts and Comparison, a drug information handbook, a drug interaction reference, a drug identification reference, Sanford Guide to Antimicrobial Therapy, Mosby's Nursing Drug Reference, a pediatric dosage handbook, a drugs during pregnancy and lactation reference, etc.).
- d. Request funding. 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.
- e. Regional Pharmacy Executive Oversight. Regional Pharmacy Executive (RPE) collateral duty oversight shall be provided for all regional practice site locations and sickbays that do not have Pharmacy Officers assigned. The details of the Pharmacy Officer Collateral Duty Program are delineated in QIIG 45, which shall be administered by the HSWL SC, 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 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 CO possessing the billet.
- (5) Supervisors and those regional practice site commands desiring input into the Regional Pharmacy Executive's USPHS Commissioned Officers' Effectiveness Report (COER) are referred to the HSWL Supervisor's Guide for guidance and forms.
- (6) Oversees the following responsibilities of collateral duty Pharmacy Officers who:
  - (a) Report to the SHSO of the unit to which they are assigned.
  - (b) Follow the established chain of command.
  - (c) Serve as the secretary of the Pharmacy and Therapeutics Committee (PTC) for the regional practice.
  - (d) Be responsible for all aspects of the Prime Vendor (PV) Pharmaceutical 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) Provide oversight to the Health Services Technician(s) who normally operate the regional practice site pharmacy and assist in dispensing operation as required.
  - (g) Provide and document in-service training to the regional practice site staff. Provide and document all training provided to Health Service corpsmen (other than "C" school pharmacy trained technicians working with the pharmacist in the pharmacy), including those IDHS corpsmen at regional practice site locations.
  - (h) Review all pharmacy operations and policies including controlled substance activities.
  - (i) Assist the regional practice site in preparation of the pharmacy, and other areas of the practice site under the responsibility of the pharmacy, for AAAHC and HSWL SC Quality Improvement Surveys.

- (j) Update quarterly information on the DoD Shelf Life Extension Program (SLEP), making it available to the CG SLEP Coordinator for submission to the HSWL SC Pharmacy Officer (op-m). For access to the SLEP website, information can be obtained at: [https://slep.dmsbfda.army.mil/portal/page/portal/SLEP\\_PAGE\\_GRP/SLEP\\_HOME](https://slep.dmsbfda.army.mil/portal/page/portal/SLEP_PAGE_GRP/SLEP_HOME). Provide current information as provided in the Medical Material Quality Control (MMQC) messages. Pharmacies will document review of MMQC messages that contain information on medication recall or warnings and the appropriate actions taken as described in the message. Documents shall be retained for period of three years after which they be destroyed. Ensure messages include reviewer's initial, date of review and the action taken.
- (k) Reference QIIG 45, Regional Pharmacy Executive (RPE) Area of Responsibility (AOR) Program, for additional guidance.

## 2. Prescribers.

### a. Authorized prescribers include:

- (1) Medical Officers and Dental Officers as defined in Sections 1.B.1. and 1.B.4. of this Manual.
- (2) Civilian medical and dental providers employed by the CG.
- (3) While performing isolated duty or underway, HSs may prescribe additional drugs listed in Health Services Allowance List Afloat, COMDTINST 6700.6 (series). HSs in these situations shall seek medical direction and 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 within the scope of their professional practice.
- (5) Uniformed service medical and dental officers/providers, other than CG, authorized by their service to write prescriptions within the scope of their professional practice.

- b. Non-clinic issued prescriptions. Prescriptions written by other uniformed services or civilian medical or dental officers/providers for formulary medications shall be honored at CG pharmacy locations where a registered pharmacist is physically present on site. If a registered pharmacist is not available, presented prescriptions will not be filled or dispensed. DoD prescription policies (i.e. TRICARE) shall be observed to the fullest extent possible within the scope of the primary care nature of CG Health Care facilities and based upon the DoD Basic Core Formulary (BCF). Prescriptions that are auto-opened, computer generated or electronically signed will NOT be accepted in CG pharmacy practice site locations. Prescriptions written for medications that are not included on the practice site formulary will be

returned to the patient and the patient will be referred to a nearby Military Treatment Facility (MTF) or to the TRICARE prescription network.

- c. Formulary medications. Prescriptions for eligible beneficiaries from licensed uniformed, civilian or outside physicians, dentists, or podiatrists shall be honored for products on the clinic's formulary provided a registered pharmacist is available on site. Regional practice site formularies are to be based on DoD BCF guidelines and the CG regional practice.
- (1) For those CG 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 CG 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. Pharmacists shall use discretion to determine if the prescribed dose can be filled using the available strengths the pharmacy carries (e.g. hydrochlorothiazide 25 mg can be filled with 50 mg strength with pharmacy instruction on the label to read "take ½ tablet").
  - (4) If additional funding is required for specific, high cost drugs, it shall be requested via the AFC-57 budget process via the HSWL SC.
  - (5) For CG patients referred out of the practice site for specialty care: Patients shall be advised by their referring CG provider that prescriptions written by the consulting provider may be filled at the CG practice site pharmacy location where the consultation was generated IF the medication prescribed is included on the practice site's formulary. Prescription written may, also, be filled at a DoD MTF pharmacy, or through the TRICARE prescription network (retail or mail order). After completion of the patient's consultant appointment, patients shall return to the referring CG provider with the consultation brief, maintaining the continuity of care and assessment of the treatment plan.
- d. Self Prescribing. Authorized prescribers shall not prescribe controlled medications for themselves and/or their family members. If such medication is required and no other authorized prescriber is assigned to the regional practice site or sickbay, the CO, or XO, shall review, approve, and countersign each controlled prescription before it is filled by pharmacy personnel.

3. Prescriptions.
- a. Prescriptions written by CG providers. Prescriptions written by CG 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 a Prescription Form, DD-1289 or other approved prescription blank (s) so that the patient may have the prescription filled through the TRICARE prescription network (retail or mail order). Prescriptions written by Health Services Technicians shall be filled only at the practice site facility where written. CG practice sites may agree amongst themselves to honor another CG regional practice site's provider prescriptions if stock shortages so necessitate. Other CG facilities may honor CG 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. Telephoned and verbal prescriptions. At the Pharmacy Officer's discretion, telephoned and verbal prescriptions may be accepted only in emergencies. CG clinics without a Pharmacy Officer shall not accept telephone prescriptions.
  - c. Facsimile prescriptions. At the Pharmacy Officer's discretion, faxed prescriptions may be accepted. Faxed prescriptions for controlled/narcotics will NOT be accepted. CG regional practice sites without a registered pharmacy officer will not accept faxed prescriptions under any circumstances.
  - d. Transferring prescriptions. 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.
  - e. Contacting providers. Health Services Technicians shall not contact civilian/outside prescribers to resolve prescription problems but shall return the problem prescription back to the patient and explain the reason the prescription cannot be dispensed. The HS may provide a copy of the regional practice's formulary for reference if the reason for the unacceptable prescription is that the medication is not included on the practice site's formulary.
  - f. Prescriptions shall be personalized. If more than one member of a family is prescribed the same drug, a separate prescription shall be generated for each member.
  - g. Scope of practice. Items prescribed must treat conditions within the normal scope of prescriber's professional practice and the ethics of the prescriber.
  - h. Cosmetic conditions. Prescriptions for medications to treat cosmetic conditions (baldness, wrinkles, etc.) or for weight loss will not be honored nor shall these medications be stocked at CG practice site facilities.

- i. Prescriptions for animals. Prescriptions for animals other than Government owned shall not be filled.
  - j. CG Provider. If a CG provider 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]."
  - k. Special order medications. Special order medications will not be ordered at CG regional practice sites for dispensing. Medications dispensed at regional practice sites will be those medications that are included in the CG regional practice site formulary. Patients receiving a prescription for a medication that is not on the practice site formulary will be referred to the TRICARE prescription network.
4. Prescribing in the Medical Record.
- a. Process. The CG method of prescribing for Medical Providers is the Provider Graphic User Interface (PGUI) and Point of Entry (POE) as per Chapter 14 of this Manual. At all regional practice sites and sickbays, patient medications will be ordered by utilizing the Chronological Record of Care, Form SF-600 or when appropriate an Emergency Care and Treatment, Form SF-558. The medical record thus becomes a more comprehensive repository for all patient health information and ensures the pharmacy staff has access to the necessary clinical information (age, weight, allergies, laboratory values, vital signs, etc.). In the case of dental care, Dental Providers shall write prescriptions in the dental record on Dental Record Continuation, Form SF-603A. For controlled prescriptions written by Dental Providers, a single hard copy of the prescription (e.g., Prescription Form, DD-1289) is required as well. For medical providers utilizing PGUI or POE or controlled substances an additional Prescription Form, DD-1289 is not required. However for proper documentation and accountability of the controlled substance, the Pharmacy Staff will generate a duplicate pharmacy label of the ordered controlled substance medication, placing it on a prescription blank. The patient shall sign the back of this "generated prescription" with the appropriate documentation as designated in the Coast Guard Medical Manual, COMDTINST M6000.1 (series), Chapter 10-B.6.b.4.
  - b. Procedures.
    - (1) Documentation shall be subjective, objective, assessment and plan (SOAP) format, notating the patient visit on a Chronological Record of Care, Form SF-600 or Emergency Care and Treatment, Form SF-558 in the chart. Under the "Plan" section, the drug name, strength, directions, quantity, and refills will be listed. Prescriptions shall be legibly written. Abbreviated names of medications and unapproved acronyms shall 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.

- (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 90-day supply. If it is necessary to deviate from this amount, prescribe quantities in 30-day increments (30, 60, 90, etc.) if possible. If pharmacy personnel 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 outside the continental United States (OCONUS) for greater than 180 days will be instructed to use 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. The medication error shall be documented in a Medication Error Report.
- (5) Pharmacy personnel will adhere one-part of the multi-part strip of the prescription label that designates the patient name, drug, and quantity on the PGUI or POE generated Chronological Record of Care, Form SF-600 and all members will initial in ink to signify who prepared the prescription (i.e., the member filling the prescription and the member checking the prescription). For refills, a prescription log or book shall be established and utilized. The pharmacy staff will adhere one-part of the multi-part strip of the prescription label that states the patient name, drug, and quantity in the log or book and all members will initial the label in ink to signify who prepared the prescription (i.e., the member filling the prescription and the member checking 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 utilizing CHCS shall maintain a drug dispensing log, containing prescription number, patient's name, patient's SSN, drug name, drug manufacturer, lot number and the medication's expiration date. This log shall be retained for 3 years.

- (7) In addition to the Chronological Record of Care, Form SF-600, or Emergency Care and Treatment, Form SF-558, entry, written prescriptions are required for all prescriptions (including controlled substances) in the event a prescription must be taken to another MTF pharmacy facility or through the TRICARE prescription network for dispensing. When controlled substance prescriptions are processed in-house, documentation shall be separated, maintained and filed appropriately (i.e., CII file and CIII-V file) by pharmacy staff and retained in the pharmacy.
  - (8) All prescriptions generated from sources other than the regional practice site shall be filled or re-filled using the CHCS system and maintained on file in the pharmacy. For patients utilizing the regional practice site pharmacy services only and not maintaining a health care record at the facility will be offered the HIPAA MHS Notice of Privacy Practices. Pharmacy personnel shall ensure DEERS eligibility with every prescription visit.
  - (9) At regional practice sites where a Pharmacy Officer/Pharmacist is available, the Pharmacy Officer/Pharmacist shall make a significant effort to ensure all prescriptions are double-checked by a pharmacist, prior to dispensing to the patient. At regional practice sites where the Pharmacy Officer/Pharmacist is unavailable, the RPE may allow a "C" school trained pharmacy technician to prepare and dispense prescriptions. Recommendation is made for the "C school trained pharmacy HS technician to be double checked by another "C" school pharmacy trained HS technician, ensuring an extra level of patient safety. At practice sites where neither a pharmacist nor a "C" school pharmacy trained technician is available, corpsmen that have completed the Watchstander qualification (QIIG 41.1) may on a TEMPORARY BASIS, but not more than 6 months, prepare and dispense prescriptions that have been double checked (with appropriate MO document) by the medical provider at the local regional practice site.
5. Signatures. No prescription order shall be filled unless it bears the signature of an individual authorized to write prescriptions. All prescriptions shall include the printed or stamped name, rank, and professional discipline (MD, DDS, HS2, etc.) of the prescriber. Prescriptions for controlled substances shall also provide the NPI 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 that are generated from a source other than an in-house CG provider.
6. Dispensing.
  - a. The pharmacy shall serve as the source of supply from which regional practice sites or satellite activities normally obtain required pharmaceuticals and related supplies. In addition, the pharmacy dispenses medications and preparations as authorized directly to patients.

- b. Prescription verification. Except for approved non-prescription program items, the pharmacy/sickbay will dispense all stocked items only on receiving a properly written, verified prescription or an in-house computer generated prescription. If the pharmacy staff receives an illegible prescription or questions its authenticity, dosage, compatibility or directions to the patient, clarification from the prescriber will be obtained prior to the dispensing the medication(s).
- c. Medication recall. Regional practice sites and sickbays shall have a system (computerized, written, etc.) in place to ensure that prescriptions can be retrieved in the event of a product recall and be able to segregate the recalled product until additional guidance is provided.
- d. Adverse medication reaction reporting. Regional practice sites shall submit patient adverse reactions or product quality problems via the FDA MEDWATCH system on FDA Form 3500, which can be obtained from the FDA at 1-800-FDA-1088 or at the FDA website: [www.fda.gov](http://www.fda.gov). Vaccine Adverse Event Reporting System (VAERS) forms can also be obtained at the same website.
- e. Patient identification. When dispensing medication(s) to patient(s), the dispenser shall identify the patient through a military identification card and ensure DEERS eligibility.
- f. Medication information. Pharmacy personnel shall ensure patients receive a printed copy of the medication's patient education monograph with all new prescriptions that accompanies the CHCS generated prescription label. Additionally, FDA required Medication Guides that are currently not included in the patient education monograph shall be made available to the patient. These can be obtained from the FDA website at <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>.
- g. Medication Error. In the event of a medication error (i.e. an error discovered after a prescription has been dispensed to the patient), a Pharmacy Error Report including pertinent information relevant to the error (name of discoverer, date of discovery, a brief statement describing error, and steps taken to prevent recurrence) shall be completed. A copy of the report shall be submitted for review during the next convening Regional Practice Pharmacy and Therapeutics Committee (PTC) meeting and a copy of the completed PTC meeting minutes will be forwarded for review and inclusion in the minutes of the next convening Regional Practice Quality Improvement Focus Group meeting.
- h. Medication containers. Child-resistant containers shall be used to dispense all prescription legend medications except sublingual nitroglycerin tablets, which are to be dispensed in the original packaging. The prescribing provider or the patient may specifically request a conventional (non-child resistant) closure. When the request is generated by the provider, the prescription order will be indicated accordingly. If the patient requests such a closure, a statement on the backside of the prescription will be notated and the patient will sign and date

the annotation. In the case where a patient is requesting ALL of his/her prescription to be dispensed with a conventional closure, the pharmacy personnel will ensure that a signature card is generated, containing the statement: "I request non-childproof closures for all medications prescribed for me", is completed, signed and dated by the patient. Signature cards shall include the date, printed name of the patient, initials of the pharmacy staff assisting the patient and shall be maintained at the pharmacy location until the patient permanently leaves the area or has not used the facility within one year of the original date of the signature card. The patient's CHCS profile shall be annotated in the Pharmacy Patient Comment (PPC) to reflect the patient's request.

- i. Refills. Prescriptions (except for controlled substances, see Chapter 10-B-4.c.) may be refilled when authorized by the prescriber. The maximum quantity of medication authorized for refills shall be for up to a one (1) year supply of medication. No prescriptions shall be refilled after more than one (1) year from the date it was written. **PRESCRIPTIONS SHALL NOT BE REFILLED FROM THE CONTAINER LABEL.** Verification of an ongoing prescription order shall be verified in the CHCS system before a refill is dispensed to the patient.
- j. Non-prescription Medication Program. CG regional practice sites are encouraged to establish non-prescription medication programs under the following guidelines:
  - (1) CG regional practice sites/sickbays with assigned 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 CG RPE or supporting IDHS. Units electing to offer the CG non-prescription drug will obtain authorization through the HSWL SC Pharmacy Officer and will verify that they will operate within the established CG non-prescription program guidelines.
  - (2) All CG regional practice sites/sickbays shall make condoms available to beneficiaries even if the location does not elect to offer the CG non-prescription medication program. Condoms shall be made available to beneficiaries under the age of 18 years unless specifically forbidden by law.
  - (3) Items available shall be limited to those medications specifically identified (authorized) in the CG non-prescription medication program (Figure 10-A-1). Practice sites may elect to offer a limited selection of authorized products to their patients, but shall NOT add unauthorized products (even if the product is classified as over-the-counter in the retail sector). All products must be dispensed in the manufacturer's FDA approved packaging with the mandated instructions and warnings. Locally packaged items are not authorized.
  - (4) A beneficiary family shall be limited to a maximum of two (2) items per week from the CG non-prescription medication program.

- (5) Items shall be available ONLY during normal operating hours of the pharmacy or the sickbay.
- (6) Pharmacy or sickbay personnel shall monitor the non-prescription medication program for perceived overuse/abuse. Individuals suspected of this misuse shall be referred to a medical provider for assessment and may have access to this privilege terminated.
- (7) The CG non-prescription medication program items shall not be dispensed to pregnant patients or non-active duty beneficiaries under 18 years of age. Local flight surgeons shall determine which of the program's products may be acquired by aviation personnel.
- (8) Regional practice sites offering the CG non-prescription medication program will maintain monthly statistics for the quantity of items provided to beneficiaries. This figure shall be separated from regular pharmacy workload statistics and will not be tallied as a part of the practice site's number of prescriptions. The quantity of items provided on the non-prescription medication program will be an additional statistic provided to the health service administrator (HSA). Only those prescription medications that have been dispensed by written prescription orders shall be counted in the practice site's total number of prescriptions. Once non-prescription medications forms have been collected and tallied, the request forms may be shredded, except for those requests for products containing pseudoephedrine, which will be retained for three (3) years.
- (9) To receive an item from the CG non-prescription medication program, 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, and is not taking blood thinners.
- (10) Individuals suspected of returning for medication for a non-resolving problem shall be referred to a medical provider for evaluation. In addition, beneficiaries requesting medical advice that in the opinion of the pharmacy or sickbay personnel is beyond their expertise shall be referred to the medical provider.
- (11) The log sheet or request form shall contain the current date, patient's name and quantity of the item(s) received. For medication containing

pseudoephedrine, in addition to the above required items, the patient address shall be included on the designated log sheet or request form.

- (12) Pharmacy personnel shall ensure positive control and a tracking mechanism for any items on the CG non-prescription medication program list, containing pseudoephedrine. Pharmacy personnel shall ensure that all beneficiaries, requesting any items on the non-prescription medication program, containing pseudoephedrine have signed the request form prior to dispensing. These request forms shall be segregated from the other non-prescription medication program request forms and maintained in the pharmacy for a period of three (3) years.
- (13) Funding for independent duty HS (IDHS) assigned units that will offer the CG non-prescription medication program shall acquire funding of the products from their district regional practice's AFC-57 account.
- (14) Figure 10-A-1 provides a sample form for the non-prescription medication program with a current list of authorized items.

- k. At larger regional practice sites where a night locker/locked cabinet is utilized and, in such situations when the pharmacy is closed, a medical or dental officer, or other authorized person, shall dispense medication(s) only from the locked vehicle, which contains pre-packaged medications in limited supply for "after-hours" dispensing. The locked cabinet shall contain a small supply of medications that are typically required to treat acute medical conditions. Prescriptions generated from sources outside of the CG practice site shall not be filled after regular pharmacy operating hours. In these situations, patients will be advised of alternative resource availability.
- l. A sign shall be posted outside of the pharmacy practice site in a highly visible location stating "Please inform our pharmacy staff if you are breast feeding or may be pregnant."
- m. Pharmacies shall adhere to the TRICARE guidance of the mandated dispensing of generic medications.
- n. Drug samples are not authorized at CG regional practice sites/sickbays.
- o. For guidance on pharmaceutical gifts, the CG Ethics Program can be found in Standards of Ethical Conduct, COMDTINST M5370.8 (series), specifically Chapter 2-C.

7. Labeling.

- a. Requirements. A label will be prepared for each prescription dispensed to individuals and will be securely affixed to the container prior to dispensing. The label or appropriate auxiliary labeling will show as a minimum:
  - (1) Facility identity, including the pharmacy address and telephone number.
  - (2) Consecutive identifying number.
  - (3) Prescribers name.

- (4) Definitive, concise directions to the patient.
  - (5) Drug name and strength.
  - (6) Quantity dispensed.
  - (7) Patient's first and last name.
  - (8) Inked initials of person preparing the prescription label and the person double checking the prepared prescription.
  - (9) The legend "KEEP OUT OF THE REACH OF CHILDREN" on all prescription labels.
  - (10) Date prescription filled.
  - (11) Refill status.
  - (12) Expiration date for prepared and compounded prescriptions (e.g. liquid antibiotics, dermatologic products, etc.).
  - (13) 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).
  - (14) Necessary supplemental or auxiliary labels.
- b. Directions on labels. 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. Generic names. Medicinal preparations compounded or packaged in the pharmacy for subsequent issue will be identified and labeled with the full generic name. The manufacturer's name, lot number, and expiration date, if any, will be shown on the label.
  - d. Multiple Dose Injectables. All multiple dose injectable vials shall be dated upon opening. The expiration date will be reflected as twenty-eight (28) days from the opening of the product, except in situations where the manufacturer's product information indicates a shorter expiration date.
8. Drug Stock.
- a. Source of medications. The Defense Logistics Agency (DLA) 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, HSWL SC negotiated purchase agreements, etc.) may be used when medication is unavailable or the price/service advantages are determined

to be the most cost effective procurement method for the regional practice site.

- b. Nutritional/Herbal/Dietary Supplements/Medications and Performance Enhancing Substances. Scientific information (quality and production control, adverse effects, drug interaction, side effects) regarding these products are often times scanty or nonexistent. Many of these products have interactions with other medications in unpredictable ways, The possible/potential side effects from these agents are difficult to predict, occur with irregularity, interact differently in any body system and may affect the central nervous system, cardiovascular system, vision, balance, mood, behavior, learning and cognitive ability. Active duty personnel are required to be operationally ready, stand watch/post, and/or perform special duties. Due to the active duty personnel requirement to remain alert with full senses and reasoning capabilities, active duty members may neither possess, use, nor purchase (via any venue) herbal supplements, dietary products, or alternative health care substances banned or not approved by the FDA for sale or use in the United States. 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. CG regional practice health care sites shall not purchase or dispense "herbal supplements" or "dietary supplements". Patients should inform their healthcare providers if they are taking any type of "supplement" to avoid potential drug interactions. Aviators and flight crew members shall follow guidance provided in the Coast Guard Aviation Manual, COMDTINST M6410.3 (series), Chapter 7. Commands can contact the RPE or the HSWL SC Pharmacy Officer for additional guidance.
- c. Separation of dosage forms. For the storage of any medications stocked in the regional practice site pharmacy/sickbay, external use medications shall be separated from internal use medication and ophthalmic medications shall be separated from otic medications. Caustic acids such as glacial acetic, sulfuric, nitric, concentrated hydrochloric, or oxalic acid shall not be issued or stored in regional practice pharmacy/sickbays, 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. Refrigerated items. Pharmaceuticals requiring refrigeration shall be stored within proper refrigeration equipment which meets the USP criteria for pharmaceutical storage. Refrigerators shall be installed with alarms and constant temperature monitoring and recording devices and shall be connected to an emergency power supply to protect refrigerated medications in the event of an electrical malfunction or power surge. Temperature readings will be checked and recorded twice daily. Temperatures which register outside the acceptable storage range will be immediately reported to the RPE, the HSA (if ashore) or the Executive Officer (if afloat). Refrigerated medications will be stored and maintained at a temperature between 36-46 degrees F. The HSWL SC Pharmacy Officer can be contacted for further guidance on resources for obtaining refrigerators and temperature monitoring devices. Vaccines shall not

be stored in the same refrigerator used to store food as the potential increased access to the (food) refrigerator compromises the stable temperature environment for the vaccines. Additionally, the potential hazard of vaccines contaminated by food spill or spoilage could compromise the vaccine.

Additional guidance can be found at:

<http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html#temperatures>

- e. Room Temperature items. Medications that are identified as requiring storage at room temperature will be maintained within a temperature range of 59-77 degrees F.
  - f. Hazardous substances. Store flammable drugs according to accepted fire safety regulations. Additional information regarding hazardous materials can be found at: [http://www.uscg.mil/directives/ci/6000-6999/CI\\_6260\\_31B.pdf](http://www.uscg.mil/directives/ci/6000-6999/CI_6260_31B.pdf).
  - g. Doors. 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 key lock or cipher lock to remain secured at all times.
  - h. Shelf Life Extension program. When eligible drugs are listed on the DoD FDA Shelf Life Extension Program (SLEP), the regional practice site's identified drug "to be tested" shall be removed from stock and labeled with project number until the results are received. Upon result notification, items shall be marked with FDA approval labels, which will contain the new expiration date and the medication shall be returned to stock. In the event that the medication expiration date is not extended, the drug shall be forwarded to the reverse distribution company for credit or disposal. The SLEP program determines the eligible medications that will be tested and are based upon the enrolled medications submitted by the SLEP participants.
  - i. Poison antidotes. The regional practice site pharmacy shall maintain, in the prominent practice site areas, an adequate supply of emergency medications and poison antidotes (the National Poison Control Center telephone number is 1-800-222-1222). Containers for these items shall be closed with break-away seals to prevent the unreported removal of items. The outside of the container shall display an inventory product list, including expiration dates.
9. Credit return program (Reverse Distribution Program). Regional practice site pharmacies/sickbays shall establish a credit return program through an approved pharmaceutical returns vendor that accepts expired pharmaceuticals and disposes of them in accordance with federal law. The company shall coordinate and issue refunds from the respective manufacturers of the returned products directly to the practice site's prime vendor account and the prime vendor will issue it as available credit for the specific practice site location. Expired medications not accepted by the returned goods vendor shall be disposed of as biohazard waste. DLA currently has an established contract with several reverse distribution or returned goods vendors. Participating facilities shall select from one of the contracted vendors, following guidance as provided by DLA. Prior to transfer of

medications to the returns vendor, pharmacy personnel shall ensure that a printed inventory of all returned pharmaceuticals will be prepared and retained at the pharmacy location BEFORE the pharmaceuticals are removed from the practice site location. Quarterly at the next scheduled PTC meeting, the RPE shall review returned pharmaceuticals data for trends that may indicate a need to modify inventory levels or ordering practices and make recommendations to the committee. If controlled substances are included in the pharmaceutical returns, pharmacy personnel shall ensure appropriate documentation has been completed, signed and retained (e.g., Requisition And Invoice/Shipping Document, Form DD-1149 and Perpetual Inventory, Form NAVMED 6710).

10. Pharmacy and Therapeutics Committee (PTC).

- a. This is a mandatory advisory committee in all CG regional practice site health care facilities and will include all practice sites within the respective district, which have assigned medical officer and shall meet quarterly in a face-to-face, video or teleconference. The PTC will be conducted centrally as a function of the Regional Practice for that district and each clinic in the district will participate in the meeting. The committee is composed of, but not limited to, the following members and will constitute a quorum: the Senior Medical Executive (SME) or representative, the Senior Dental Executive (SDE) or representative, the Regional Pharmacy Executive (RPE), the Regional Practice Manager (RPM) or representative, and one representative from each clinic within the district. HSAs are strongly encouraged to attend. The chairman will be the SME and the RPE will be the secretary.
- b. The committee is an advisory group on all matters relating to the acquisition and use of medications. Recommendations made are subject to the approval of the SHSO. The basic responsibilities of this committee are to:
  - (1) Use of the Department of Defense (DoD) Basic Core Formulary (BCF) will be the basis for the regional practice site formulary.
  - (2) The regional practice site pharmacy's formulary will include medications and protocols as designed in the CG Standardized Health Services Allowance List (HSAL) formulary.
  - (3) The regional practice site pharmacy formulary shall not include items based primarily on civilian prescriber demand.
  - (4) Prevent unnecessary therapeutic duplications of formulary products.
  - (5) A review of all non-formulary items the pharmacy procures and dispenses will be conducted. To meet this requirement, the regional practice PTC will review:
    - (a) A list of all regional practice site pharmacy formulary items not currently in the DoD BCF.
    - (b) 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 regional practice site'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 deemed necessary.
  - (10) Reviews any adverse reaction or product quality reports (VAERS or MEDWATCH).
  - (11) Monitors compliance with HIPAA privacy and security mandates.
- c. Documentation for upcoming PTC meetings will be forwarded to the RPE in the first month of each quarter for inclusion to the PTC agenda, which will be prepared and forwarded to the SHSO for approval prior to the meeting. The PTC meeting will be conducted in the second month of each quarter. Minutes of the meeting will be prepared and forwarded to the SHSO for approval by the end of the third month of the quarter and then returned to the RPE for retention and uploaded to the CG's online CG Portal Microsite. A copy of the minutes will be forwarded to the regional practice manager.
  - d. Quality Improvement Implementation Guide (QIIG) #5, Pharmacy and Therapeutics Committee provides additional guidelines.

Figure 10-A-1

CG REGIONAL PRACTICE SITE NON-PRESCRIPTION MEDICATION PROGRAM

USCG (may insert name of practice site or location here)

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 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.

\_\_\_\_\_ I will inform the pharmacy staff if the person for whom this medication is intended has high blood pressure, cardiac problems, diabetes, thyroid problems, is taking blood thinners.

Signature: \_\_\_\_\_

Printed name: \_\_\_\_\_ Date: \_\_\_\_\_

Address:(Required only for products containing Pseudoephedrine)

\_\_\_\_\_  
\_\_\_\_\_

NOTE: Items listed may be available.

- |  |   |
|--|---|
| <input type="checkbox"/> Acetaminophen 325mg tabs, #50             | <input type="checkbox"/> Cetylpyridinium Anesthetic Loz, 30gm     |
| <input type="checkbox"/> Acetaminophen 80 mg chewable tabs, #30    | <input type="checkbox"/> Guaifenesin 100mg/5ml syp., 120ml        |
| <input type="checkbox"/> Acetaminophen 160mg/5ml liq., 120ml       | <input type="checkbox"/> Guaifenesin 100mg/DM 5mg/5ml syp., 120ml |
| <input type="checkbox"/> Antichap, Lipstick                        | <input type="checkbox"/> Diphenhydramine 25mg caps #24            |
| <input type="checkbox"/> Liquid Antacid, 150ml                     | <input type="checkbox"/> Diphenhydramine 12.5mg/5ml liq., 120ml   |
| <input type="checkbox"/> Ibuprofen 200mg tabs, #24                 | <input type="checkbox"/> Bacitracin oint., 15gm                   |
| <input type="checkbox"/> Ibuprofen 100mg/5ml soln., 120ml          | <input type="checkbox"/> Analgesic Balm, 30gm                     |
| <input type="checkbox"/> Pseudoephedrine 30mg tabs, #24            | <input type="checkbox"/> Clotrimazole Topical crm 15 gm           |
| <input type="checkbox"/> Saline Nasal Spray, 45ml                  | <input type="checkbox"/> Hydrocortisone 1% crm, 15 gm             |
| <input type="checkbox"/> Pseudoephedrine 30mg/5ml liq., 120ml      | <input type="checkbox"/> Tolnaftate powder, 45gm                  |
| <input type="checkbox"/> Brompheniramine/Phenylephrine soln, 120ml | <input type="checkbox"/> Male Condoms                             |

B. Controlled Substances.

1. General.

a. Controlled substances, as used here, are defined as.

- (1) 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 CO or Pharmacy and Therapeutics Committee determine to have significant abuse potential.

b. CG authorized uses for controlled substances are one of the following.

- (1) Medicinal purposes.
- (2) Retention as evidence in legal or disciplinary actions.
- (3) Other uses CG Regulations specifically authorize.

c. Controlled substances not authorized.

- (1) Amphetamines for fatigue management or performance enhancement (go-pills).
- (2) Ephedra derivatives, including ephedrine.
- (3) Controlled substances for weight loss, including human chorionic gonadotropin (HCG).
- (4) Schedule I (or CI) drugs.
- (5) Alcoholic beverages.

d. Quantity Definitions. Due to the potential for abuse and associated audits required, and the DoD Pharmaceutical Prime Vendor ordering advantage, CG regional practice site pharmacies 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 Regional Practice Manager (RPM).
- (2) In the absence of a Pharmacy Officer, RPM shall designate the Health Services Administrator (HSA) as the CSC.
- (3) Medical and Dental Officers may not serve as alternate CSCs, which avoids a possible conflict of interest.

- (4) Temporarily assigned personnel shall not serve as CSCs or alternates.
  - (5) Under United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series), Chapter 6-2-3-A-(6), the XO 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 inventory audit of all controlled substances is required whenever the CSC is changed. Documentation of this type of audit will be forwarded, signed and retained as every controlled substance audit (Chapter 10-B-2-b-1-b). At the time of this change in designation and subsequent inventory audit, all keys should be transferred and/or combination locks changed.
- b. Unit Controlled Substance Audits.
- (1) Controlled Substance Audit Boards (CSAB). Each regional practice site pharmacy 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 RPM. 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 regional practice site operations.
    - (b) The CSAB shall conduct monthly audits of controlled substances at regional practice sites (quarterly on afloat sickbays) and submit the report to the RPM for signature within 5 working days. The RPM will review the report, sign it, make a copy for their records upload the report to the CG Portal Microsite and then forward the signed original CSAB report to the pharmacy for retention. The regional practice site pharmacy will retain for three (3) years.
    - (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 Monthly Report for Narcotics and Other Controlled Drugs, Form CG-5353 or CHCS generated controlled substance vault report.
    - (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 the 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, Form CG-5353 or the CHCS generated

controlled substance vault report form. 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 CG 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 Monthly/Quarterly Report for Narcotics and Other Controlled Drugs, Form CG-5353 or CHCS generated controlled substance vault report shall be maintained on file locally in the pharmacy and will be labeled "FOR DEA BIENNIAL INVENTORY" at the top of the form.

### 3. Drug Enforcement Administration (DEA) Registration.

- a. DEA registration is required for those CG regional practice site pharmacies with Prime Vender (PV) ordering capability. Purchase of controlled substances from commercial sources is prohibited unless approved and procured by the Regional Pharmacy Executive (RPE) of the practice site. Sickbays shall not register with the DEA unless in-house physician services are provided. The regional practice site's Drug Enforcement Agency Registration, Form DEA-244A, shall be forwarded to the HSWL SC Pharmacy Officer as the approving authority for "fee exempt" status for processing of the regional practice site DEA certificates.
- b. The HSWL SC shall forward the Drug Enforcement Agency Registration, Form DEA-244A to the DEA, providing a copy to the originating regional practice site pharmacy. The DEA will issue the registration directly to the practice site.
- c. In the case of DEA renewals, (FACILITY RENEWALS ONLY--NOT INDIVIDUAL PROVIDERS), do not complete. Send the entire renewal application to the HSWL SC Pharmacy Officer via traceable means (e.g. DHS authorized Commercial Carriers FedEx or UPS), who will electronically complete and submit the renewal application. For questions regarding renewal

of clinic DEA certificates, contact the HSWL SC Pharmacy Officer for further guidance.

4. Reporting Theft or Loss. 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 shortage of one (1) to two (2) tablets/capsules from 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 discrepancy. Immediately, upon discovery of ANY discrepancy the HSWL SC Pharmacy Officer will be notified for guidance.
  - a. If discovered during the course of a monthly CSAB, a designated command member shall contact the HSWL SC Pharmacy Officer, discuss the circumstances of the discrepancy, and request guidance for further action. The HSWL SC Pharmacy Officer will advise the RPM and SHSO in writing or by e-mail of the guidance provided. Should the HSWL SC Pharmacy Officer determine an investigation is warranted, the HSWL SC Commanding Officer (CO) shall appoint one or more members to investigate the discrepancy. The HSWL SC CO 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 regional practice site's proper chain of command, shall notify the HSWL SC Pharmacy Officer and request guidance for further action. Guidelines as indicated in Chapter 10-B-4-a. may be followed, if warranted.
    - (1) Finding of the investigational review shall be forwarded to the HSWL SC Pharmacy Officer.
    - (2) The HSWL SC Pharmacy Officer shall determine if the discrepancy warrants further action or DEA notification via Report of Theft or Loss of Controlled Substances, Form DEA-106. A copy of all Report of Theft or Loss of Controlled Substances, Form DEA-106 reports submitted to DEA shall be sent to Commandant (CG-11).
5. Procuring, Storing, Transferring, and Disposing of Controlled Substances.
  - a. Procurement.
    - (1) Regional practice site pharmacies shall procure controlled substances from the DLA prime vendor source. CG vessels shall obtain authorized controlled substances through their respective RPE.
    - (2) Schedule I controlled substances and alcoholic beverages are prohibited and shall not be procured or stocked in CG health care facilities
    - (3) Upon receipt, controlled substances shall immediately be placed in the custody of the designated CSC. The invoice shall be reviewed and compared against the requisition, verifying receipt of all products and quantities listed on the invoice. The CSC shall acknowledge receipt by

signing and dating the invoice. Controlled substance procurement documents shall be maintained in the pharmacy for three (3) years.

b. Storage.

- (1) Controlled substances shall be stored in an all-purpose GSA Class V safe. Chapter 11 of the Physical Security and Force Protection Manual, COMDTINST M5530.1 (series), offers in-depth guidance regarding storage of Controlled Substances.
- (2) For CANA (Diazepam 10mg Auto Injectors) acquisition and storage, required quantities are often too bulky to feasibly store in Class V safes. Therefore, storage in a secured locked cabinet in a controlled access and temperature controlled area is authorized. For field deployments, CANA is authorized to be stored in a secured portable container under the control and custody of the unit's CO or the designated CSC in a controlled access area. CANA must be stored between 59-86 degrees F. If this temperature cannot be maintained, a log must be maintained, indicating storage temperature and conditions with regular readings entered. Disposition of CANA shall be documented on the Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, Form 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 Requisition and Invoice/Shipping Document, Form DD-1149. Regional practice site pharmacies and sickbays are required to include CANA as a part of its Controlled Substance Audits.
- (3) Afloat units may use existing "built in" containers to store controlled substances. Such "built in" units shall be secured at all times with positive control.

c. Transfer.

- (1) Controlled substances may be transferred between CG and other government facilities using the Requisition and Invoice/Shipping Document, Form 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 Requisition and Invoice/Shipping Document, Form DD-1149 for three (3) years.
- (3) When the transaction cannot be completed face-to-face, documentation will be completed and then send the entire renewal application to the HSWL SC Pharmacy Officer via traceable means (e.g. DHS authorized

Commercial Carriers FedEx or UPS). The shipment document shall be maintained by the issuing unit until a signed copy of the Requisition and Invoice/Shipping Document, Form DD-1149, is returned.

- (4) A copy of the Requisition and Invoice/Shipping Document, Form DD-1149, shall be sent to the regional practice site's RPE.

d. Disposal.

- (1) Expired, contaminated, excessive, inadequately labeled, damaged or otherwise unusable controlled substances shall be properly labeled, isolated in the Controlled Substance Safe from usable and in-date items and included in the next shipment of pharmaceutical returns goods for credit or destruction. Pharmacy personnel will acquire a signed and dated inventory summary from the returns goods vendor prior to the transfer of returned controlled substances.

6. Prescribing Practices.

- a. Authorized (Active Duty) prescribers (see Chapter 10-A-2-a). are exempt from registration under provision of 21 CFR 1301.25. The officer's social security number may be used in lieu of a DEA or NPI registration number when prescribing medications dispensed at the regional practice site pharmacy. This 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. Signatures

- (1) All prescriptions for controlled substances shall be signed by a medical or dental provider. For medical provider prescriptions generated in PGUI or by POE and signed electronically in the CHCS system, the pharmacy staff will generate a duplicate pharmacy label of the ordered controlled substance, placing it on a prescription blank and the patient will sign and date the back of the prescription as designated in Chapter 10-B-6-b-(4). If no medical or dental provider is assigned at the regional practice site/sickbay, the prescription shall be signed by the senior health services department representative and countersigned by the XO.
- (2) All schedule II controlled substance prescriptions written by midlevel providers (i.e. Physician Assistants or Nurse Practitioners) shall be countersigned quarterly by their supervising Medical Officer.
- (3) 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. Recommended is made that the patient observe the amount dispensed during the course of the second (dual integrity) count or at time of dispensing.

c. Quantities and Refills.

- (1) Controlled substances shall be prescribed in minimal quantities consistent with proper treatment of the patient's condition. Controlled substance prescriptions generated from a source other than the CG regional practice site may only be honored for formulary items at the practice site where a registered pharmacist is available and at the discretion of the pharmacist.
- (2) Out-of-state controlled substance prescriptions may be dispensed if, in the professional judgment of the RPE, the prescription appears legitimate. These prescriptions should invoke special scrutiny by the RPE/registered 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, prescriptions will not be accepted more than 30 days after the date the prescription was written.
- (4) Schedule II prescriptions shall be limited to a maximum of 30 day supply. The only exception shall be medication for Attention Deficit Disorder (ADD) where quantities may be dispensed in up to a 90 day supply. Refills are not permitted on Schedule II drugs.
- (5) Schedule III, IV, and V prescriptions shall be limited to 30-day quantities with up to five refills within a 180 day period and only when 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). Prescriptions generated at sources outside of a CG regional practice facility shall only be honored for these quantities, at the discretion of the pharmacist. Patients shall be informed of this quantity or refill limitation at the time of the initial prescription presentation, allowing the patient the opportunity to have the prescription(s) filled elsewhere.
- (6) Controlled prescriptions shall not be commonly filled until the patient, for whom it is intended, is available to pick up the medication. This should also include refills. However, if a pharmacy's workload is such that in the opinion of the Pharmacist it is in the best interest to maintain pharmacy flow, refill of controlled substances may be completed in advance as long as the pharmacy personnel ensures positive and secured control until the patient picks up the medication. These refills shall be bagged and/or sealed in such a way to ensure tamper resistance. Additionally, they shall be housed in a central location such that at the end of the day, those controlled prescriptions not picked up shall be returned to the narcotics safe for storage.

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 (3) years after which they may be destroyed by shredding.
- (5) All controlled prescriptions shall be posted on Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, Form NAVMED 6710/5 at the time of each transaction. A physical back count of the opened container from which the prescription was dispensed will be conducted to verify the remaining balance. The prescription shall then be diagonally lined across and initialed by the pharmacy staff member completing the transaction.

### C. Forms and Records.

1. General. Records shall be maintained for certain procedures conducted within all CG regional practice site locations. 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. Regional practice site providers shall write prescriptions on the DoD Prescription blank, Form DD-1289 or equivalent, when chart prescribing, PGUI or POE is not available.
  - b. All prescriptions shall be filed in one of three files:
    - (1) All non-controlled drug prescriptions;
    - (2) Schedule II prescriptions; and,
    - (3) Schedule III, IV, and V prescriptions.
  - c. Prescriptions will be written in black or blue ink, indelible pencil, or typewritten must 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 controlled prescriptions are written, 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 and distinct directions to the patient are required on all prescriptions. Expressions such as "take as directed," "label," etc. are NOT allowed.
    - (5) Prescriber's legible, legal signature (initials not permitted) with printed or stamped name and professional discipline (MD, DO, DMD, DDS, PA, HS2, etc.). When CG provider order entry or PGUI entry is utilized, electronic signature satisfies this requirement
    - (6) All additional requirements when prescribing controlled substances:
      - (a) Patients complete address.
      - (b) Prescriber's SSN, DEA or NPI number.
      - (c) NOTE: Alterations on prescriptions for CII controlled substances are prohibited.

- d. Multiple prescription forms, such as Poly Prescription, Form NAVMED 6710/6 or Prescription Limited, Poly, Form NAVMED 6710/10, which are intended for use when prescribing a number of non-controlled drugs for one patient, are authorized.
  - e. Maintenance of all prescriptions on file, including all “prescription logs” related to chart prescribing is required for three (3) years, after which they may be destroyed by shredding.
  - f. The pharmacy shall have readily retrievable access to the patient’s medical information, including provider’s current patient visit entry, patient’s current medications, age, allergies, weight, etc., when preparing and dispensing prescriptions.
3. Quality Control Forms. 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 provides clearly definable material sources (manufacturer’s name, lot numbers, and expiration dates), procedures used, intermediary and final checks by supervisory personnel, and labeling.
4. Controlled Drug Forms.
- a. Narcotic and Controlled Drug Inventory-24 Hours, Form NAVMED 6710/4. This record shall be maintained at CG regional practice site locations, providing inpatient care.
    - (1) The Narcotic and Controlled Drug Inventory-24 Hours, Form 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 Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1 received from the pharmacy during each watch shall be entered. The serial numbers of completed Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1 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 Narcotic and Controlled Drug Inventory-24 Hours, Form NAVMED 6710/4.
  - b. Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1.
    - (1) Upon receipt of a properly completed prescription requisition, a separate Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1

shall be prepared by the pharmacy for each Schedule II through Schedule V drug, and any other drug which requires control procedures.

- (2) All Narcotic and Controlled Drug Account Records, Form NAVMED 6710/1 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 Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1 shall be inserted in back of the current record. The serial number of the new Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1 shall be entered on the Narcotic and Controlled Drug Inventory-24 Hours, Form NAVMED 6710/4.
- (5) The heading for each Narcotic and Controlled Drug Account Record, Form 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 on the Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1.
  - (a) All amounts will be recorded in Arabic numerals. If 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 Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1. Such statements shall be signed and witnessed by two (2) health service providers.
  - (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 Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1.
  - (e) Deteriorated drugs shall be returned to the pharmacy for disposal.

- (f) The completed Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1, along with the counter-type dispenser, shall be returned to the pharmacy.
  - (g) Monthly, the pharmacy shall report all Narcotic and Controlled Drug Account Records, Form NAVMED 6710/1 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 RPE 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 Narcotic and Controlled Drug Inventory-24 Hours, Form NAVMED 6710/4 in the first section and individual Narcotic and Controlled Drug Account Record, Form NAVMED 6710/1 in the latter sections.
  - (2) The senior HS shall remove all filled Narcotic and Controlled Drug Inventory-24 Hours, Form NAVMED 6710/4 over three (3) months old from the Narcotic and Controlled Drug Book and return them to the pharmacy.
- d. Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, Form NAVMED 6710/5. Separate Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, Form 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, Monthly Report For Narcotics and Other Controlled Drugs, Form 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 Monthly Report For Narcotics And Other Controlled Drugs, Form CG-5353. If software is not consistently available, prepare a separate Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, Form 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, the source will be entered.
  - (5) Recipient. Enter “pharmacy” for receipts. Enter regional practice site or patient name, as appropriate, for expenditures.

(6) Narcotic and Controlled Drug Account Records, Form NAVMED 6710/1 Returned. The date the Narcotic and Controlled Drug Account Records, Form 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. Obtain DEA forms from the nearest DEA office. Consult with the regional practice site's RPE for more information.
- b. Prescription Blanks. Prescription blanks DoD Prescription, Form DD-1289 can be found at the following web site:  
<http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm>

D. Drug Dispensing Without a Medical Officer.

1. General. 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 Regional Pharmacy Executive (RPE).
2. Child-Resistant Containers. Prepackaged OTC products shall be issued in their original container. For vessels, limited quantities of prescription drugs may be issued in labeled plastic zip-lock bags and retained by the patient 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. However, these bags must be inserted in a child resistant container with proper labeling when removed from the vessel.
3. Controlled Substances.
  - a. 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.
  - b. An officer (usually the XO), designated by the CO, shall serve as the Controlled Substance Custodian (CSC) and keep in a separate locked compartment, all bulk un-issued controlled substances, alcohol, or items otherwise controlled. The CSC shall always maintain positive control of the keys or combination. The CSC 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, COMDTINST M5000.3 (series) and this Manual.
  - c. The CSC or the designated Sickbay/Medical personnel shall retain the keys or combination to the working stock storage area while on duty. When relieved, they shall deliver the keys to their relief or to a responsible person designated by local instructions. A copy of the combination of a safe, if used, shall be sealed in an envelope and deposited with the CO.
  - d. COs may authorize temporary deviations from the controls established in this Chapter due to operational and/or emergency situations.
  - e. Controlled Substance Audit Board (CSAB) at these units (e.g., Cutters) shall be conducted at least quarterly by two disinterested members. CSAB shall also be conducted when there is a change in designation of the CSC and when there is a permanent change in Sickbay/Medical personnel. Chapter 10.B. provides detailed instructions regarding CSAB.

4. Formulary. Health Services Technicians on independent duty corpsmen (IDHS) shall maintain drug formularies consisting of:
  - a. Standardized Health Services Drug Formulary items.
  - b. Health Services Allowance List Afloat requirements.
  - c. Chronic medications prescribed by a physician for active duty members currently assigned to the duty station.
  - d. Other drugs the HS has been authorized in writing by the DMOA to stock for their active duty members. A copy of the DMOA's written approval of these medications will be forwarded to the RPE for review, approval and acquisition. The review will ensure compliance with the DoD Basic Core Formulary.
5. Non-Prescription Medication Programs. Sickbays are encouraged to operate a non-prescription medication program as described in Chapter 10-A-6-j of this Manual. HSs shall contact their RPE for guidance and additional support.

