

CHAPTER 10

PHARMACY OPERATIONS AND DRUG CONTROL

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CHAPTER TEN – PHARMACY OPERATIONS AND DRUG CONTROLSection 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 [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. 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. Senior Health Services Officer (SHSO)/Regional Practice Director (RP DIR). The SHSO/RP DIR 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). In addition, all regular assigned pharmacy

personnel shall 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 CG health services team and therefore enhance CG mission support. For clinics without a Pharmacy Officer or "C" School Trained Pharmacy Technician on site, as training tabs permit, units must send a qualified health services technician to pharmacy "C" School or all prescriptions must be double checked by a pharmacy "C" School trained technician or by a privileged medical provider for product and labeling accuracy prior to dispensing. In addition, appropriate patient counseling will be provided prior to the dispensing of medication. Information regarding alternate pharmacy sources, such as Tricare Mail Order Pharmacy, Civilian Retail Pharmacy Network or a Department of Defense Military Treatment Facility will be provided to direct eligible beneficiaries to alternative points of service. Information for enrollment and how the Tricare Mail Order Pharmacy Program operates can be found at www.tricare.mil/mybenefit and clicking on the "prescription" tab found at the top of the page. When providers issue a prescription to be filled at an alternative location, they shall note the medications prescribed in the comments section of the PGUI/POE notation and provide the patient with a written prescription on a DD-1289 or equivalent prescription blank. Prescriptions should not be entered in the "MED" tab of the PGUI as this will prevent the prescription from being filled at an alternative point of service. Clinics will be advised they shall ensure pharmacy technicians receive pharmacy "C" school training in order to provide the highest quality pharmaceutical service and ensure patient and medication safety to our beneficiaries. Facilities are advised the availability of a Pharmacy Officer or a "C" school trained technician is a risk management tool. Many medications have a narrow therapeutic index, especially those for pediatric and elderly patients, placing considerable responsibility upon a non-pharmacy "C" school trained pharmacy technician, the SHSO, the CG Health Care System, and ultimately the safety of the patient.

- f. Pharmacy Officer Oversight. Pharmacy Officer collateral duty oversight shall be provided for all clinics 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) 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.
- (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 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.
- (l) 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 HSWL SC Quality Improvement 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. Pharmacies shall 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 a period of three years after which they may be destroyed. Ensure messages include initial, date of review, and action taken.
- (o) Submit a report of the content and frequency established by HSWL SC
- (p) QIIG 45, Collateral Duty Pharmacy Program provides additional guidelines.

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) HSs may prescribe drugs listed in the Standardized Health Services Technician Drug Formulary, COMDTINST 6570.1 (series). While performing isolated duty at LORAN stations 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 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 CG, authorized by their service to write prescriptions in practicing their profession
- b. Non-clinic issued prescriptions. Prescriptions by uniformed service or civilian medical and dental officers/providers, other than CG, shall be honored whenever possible and only at CG clinics where a registered pharmacist or pharmacy officer is physically present. For example, DoD prescription policies (TRICARE) shall be observed to the fullest extent possible within the scope of the primary care nature of CG 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 CG 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 CG pharmacies.
- 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 Pharmacist is available. Clinic formularies are to be based on DoD Basic Core Formulary (BCF) guidelines and the prescribing habits of the providers assigned to that clinic.
- (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 clinic for specialty care: Patients shall be advised by their referring CG provider/clinic that prescriptions written by the consulting provider may be filled at the CG clinic pharmacy location where the consultation was generated, at a DoD Military Treatment Facility (MTF) pharmacy, or at a Tricare Retail Network Pharmacy. After completing the consult appointment, patients shall return to their referring CG provider with a consultation brief to maintain continuity of care and assess a treatment plan. If medications prescribed by the consulting provider are not on the referring CG clinic pharmacy’s formulary and the patient prefers to obtain the medication at this location, the CG provider will review the consulting provider’s brief and determine if a medication on the formulary may be an appropriate therapeutic substitute. If not, the CG provider shall generate a CG special order medication request to be presented at the CG clinic pharmacy for procurement. The request shall also be submitted for review at the next Group Practice Pharmacy and Therapeutics Committee (PTC) meeting.
- 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 prescriber is assigned to the facility, 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 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. CG clinics

may agree amongst themselves to honor another CG clinic's Physician Assistants' or Nurse Practitioners' 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 in the best interest of the patient's care. Faxed prescriptions for controlled/narcotics will not be accepted. CG clinics without a Pharmacy Officer will not accept faxed prescriptions.
- 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 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.
- 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 professional practice and the ethics of the prescriber.
- h. Cosmetic conditions. Prescriptions for medications to treat cosmetic conditions (baldness, wrinkles, etc.) and for weight loss will not be honored nor shall medications for these conditions be stocked at CG facilities.
- i. Prescriptions for animals. Prescriptions for animals other than Government owned shall not be filled.
- j. Physician Assistant. 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]."

- k. Responsibility of prescribing facility. 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 DEA or National Provider Identifier (NPI) number, date of prescription).
 - l. Special order medications. Providers are tasked with the cost effective use of medications. The DoD Basic Core Formulary (BCF) serves as the basis of all CG clinics' formulary. Pharmaceuticals ordered that are not on the clinic formulary are 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 Group Practice 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 DEA or NPI 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. 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 clinics and sickbays, patient medications will be ordered by utilizing the Chronological Record of Care, SF-600 or when appropriate an Emergency Care and Treatment, 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, SF-603A. For controlled prescriptions written by Dental Providers, a single hard copy of the prescription (e.g., DD-1289) is required as well. For medical providers utilizing PGUI or POE an additional 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 MEDMAN Chapter 10-B.6.b.4.

b. Procedures.

- (1) Document in subjective, objective, assessment, and plan (SOAP) format the patient visit on a Chronological Record of Care, SF-600 or Emergency Care and Treatment, 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 and unapproved acronyms 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.
- (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 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 outside the continental United States (OCONUS) for greater than 180 days will be advised and 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 staff 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, SF-600 and all members will initial in ink to signify who prepared the

- (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) In addition to the SF-600, Chronological Record of Care or SF-558, Emergency Care and Treatment entry, written prescriptions are required for all prescriptions (including controlled substances) when a prescription must be taken to another pharmacy for dispensing. When controlled substance prescriptions are processed in-house, separate documentation shall be maintained and filed appropriately (i.e., CII file and CIII-V file) in the pharmacy by the pharmacy staff.
- (8) 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. Pharmacy personnel shall ensure DEERS eligibility with every visit.
- (9) At clinics where a Pharmacy Officer/Pharmacist is available, the Pharmacy Officer/Pharmacist should make a significant effort to ensure all prescriptions are double-checked by a pharmacist. At clinics where the Pharmacy Officer/Pharmacist is unavailable, the RPE may allow a "C" school trained Pharmacy Technician to prepare and dispense prescriptions, double checked by either another "C" school trained technician or a pharmacy technician who is Watchstander qualified. At clinics where neither a pharmacist or "C" school trained Pharmacy Technician is available, a Pharmacy Technician Watchstander may prepare and dispense prescriptions, after the prescriptions have been double-checked by a medical provider. In cases where neither a pharmacist, "C" school trained Pharmacy Technician, or Pharmacy Technician Watchstander is available, ashore CG units shall instruct patients to have their prescriptions dispensed by either a civilian pharmacy, a Military Treatment Facility Pharmacy or through the

TRICARE Mail Order Pharmacy; afloat CG units staffed by CG IDHS Corpsmen shall be exempt from the double-check prescription requirement (but are required to complete requirements to become a Pharmacy Technician Watchstander through their RPE; however if a Medical Officer (MO) is aboard, the IDHS corpsman shall have prescriptions double-checked by the MO.

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 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 from other sources. CG provider order entry is utilized, electronic signature satisfies this requirement.
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. Prescription verification. Except for approved OTC program items, the pharmacy/sickbay will dispense all stocked items only on receiving a properly written, verified prescription. If pharmacy staff receives an illegible prescription or questions its authenticity, dosage, compatibility, or directions to the patient, staff shall obtain clarification from the prescriber before dispensing the medication(s). In the case of outside prescriptions, the Pharmacist is the only authorized pharmacy staff to contact an outside provider for clarification of a prescription.
 - c. Medication recall. Clinics/Sickbays shall have a system (computerized, written, etc.) in place to ensure they can retrieve prescriptions in case of a product recall, segregate recalled product until receipt of further guidance on disposition, and make appropriate notification based on the recall level.
 - d. Adverse medication reaction reporting. Clinics shall submit all pertinent patient adverse reactions or product quality problems on the FDA MEDWATCH system on FDA Form 3500. Obtain MEDWATCH forms and information from the FDA at 1-800-FDA-1088 or at www.fda.gov. 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 for submitting, via fax, a completed copy to Commandant (CG-1121) at (202) 475-5172, ATTN: Epidemiologist and to HSWL SC (OM).

- e. Patient identification. When dispensing medication, the dispenser shall identify the patient through a military identification card and ensure his or her DEERS eligibility, via CHCS and particularly on new outside prescriptions presented to the pharmacy for filling.
- 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/cder/Offices/ODS/medication_guides.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 Group 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 Group Practice Quality Improvement Focus Group meeting.
- h. Medication containers. Child-resistant containers shall be used to dispense all prescription legend medications except for sublingual nitroglycerin tablets, which are dispensed in the original packaging. 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. In the case where a particular patient is requesting all of his/her prescriptions be conventional (non-child resistant) closures, pharmacy shall ensure a signature card containing the statement: "I request non-child proof closures for all medications prescribed for me" is completed and signed by the patient. Signature cards shall include date, printed name of patient, and initials of pharmacy personnel and shall be maintained at the pharmacy until patient permanently leaves the area or has not used the facility within one year of original date of signature card. Patient's CHCS profile shall be annotated in Pharmacy Patient Comment (PPC) to reflect the request
- i. Refills. Prescriptions (except for controlled substances-see 10-B-4.c.) may be refilled when authorized by the prescriber. 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

- j. Non-prescription Medication Program. CG clinics are encouraged to establish non-prescription medication programs under the following guidelines:
- (1) CO of CG 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 CG Pharmacist or supporting Independent Duty HS. Units electing to offer a nonprescription drug program shall request authorization through HSWL SC, and verify that they will operate within the guideline.
 - (2) All CG 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, sick bay or facility.
 - (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 Administrator. Once collected, request forms may be shredded and disposed. Over the counter medication forms that contain pseudoephedrine will be retained for 3 years. 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) Pharmacy personnel shall ensure positive control and tracking mechanism for any items on the OTC list containing pseudoephedrine. Pharmacy personnel shall ensure that all beneficiaries, requesting any items on the OTC containing pseudoephedrine, have signed the request form prior to dispensing. These request forms shall be segregated from the other OTC request forms and maintained in the pharmacy for a period of three years, after which they may be destroyed by shredding.

- (15) 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.
- (16) Funding for independent duty HS assigned units (vessel, Sector, etc.) deciding to offer this service shall be from their supporting pharmacy's AFC-57 account.
- (17) Enclosure one (1) provides a sample form for the Non Prescription Medication Program with a current list of authorized items.
- k. 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.
- l. Bulk items for use in the clinic may be issued on authorized prescription forms or locally approved requisition forms.
- m. 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, FDA, CHCS) to provide information to patients when appropriate. Post the MHS Notice of Privacy Practices in an accessible location.
- n. 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.
- o. Drug samples are not authorized at CG facilities.
- p. For guidance on pharmaceutical gifts, the CG Ethics Program can be found in Standards of Ethical Conduct, COMDTINST M5370.8 (series), specifically 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) Definite, concise directions to the patient.
 - (5) Drug name and strength, unless prescriber directs otherwise.
 - (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) Indication of refills.
 - (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, 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. Labeling Medications for Transfer. Drugs issued to clinics for subsequent reissue to outpatients shall bear appropriate pharmacy label with space available to write in the patient's name, prescriber, date issued and prescribing instructions. The pharmacy shall ensure these medications are in FDA approved packaging such as commercially available pre-packed or unit of use bottles.
 - e. Multiple Dose Injectables. All multiple dose injectable vials shall be dated upon opening. The expiration date will be thirty days from the date of opening unless the manufacturer's product information indicates a shorter or longer expiration date.
8. Drug Stock.
- a. Source of medications. 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, HSWL SC 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. 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. Often, these products interact with each other and with prescribed medications in unpredictable ways. The possible/potential side effects from these agents are hard to predict, occur with irregularity, and may be different in any given population. Side effects may be manifested 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. Because active duty personnel are required to remain alert with full use of all senses and reasoning powers, 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 in CG health care facilities. CG health care facilities shall not purchase or

dispense "herbal supplements" or "dietary supplements". 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 HSWL SC Pharmacy Officer for further guidance.

- c. Separation of dosage forms. In storage, separate external use medications from internal use medications and ophthalmic and otic preparations. 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. Refrigerated items. Pharmaceuticals requiring refrigeration shall be stored in proper refrigeration equipment that meets the criteria for storing pharmaceuticals requiring specific temperature control/storage process. Refrigerators will be installed with temperature monitoring devices that provides constant temperature recording and shall be connected to an emergency power supply to protect refrigerated medications in the event of an electrical malfunction or power surge. Manual temperature readings will be checked and recorded twice daily. Temperatures that register outside the acceptable storage range will be immediately reported to the RPE, the Clinic Administrator (if ashore) or the Executive Officer (if afloat). The HSWL SC Pharmacy Officer can be contacted for further guidance and information on sources 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 will not provide a 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://www2.cdc.gov/nip/isd/shtoolkit/006Chap5.pdf> or at http://www.methodistmd.org/pdf/pi/PI2_Leb.pdf.
- e. Hazardous substances. Store flammable drugs according to accepted fire safety regulations. Additional information regarding hazardous materials can be found at: http://www.uscg.mil/ccs/cit/cim/directives/CI/CI_6260_21B.pdf.
- f. 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 keylock or cipher lock to remain secured at all times.
- g. Shelf Life Extension program. Remove from stock drugs under testing in the FDA/DoD Shelf Life Extension Program; label them with the project number until results are received. 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.

- h. Poison antidotes. The pharmacy shall maintain, in the pertinent clinic areas, an adequate supply of emergency medications (or kits), poison antidotes, and the National Poison Control Center telephone number (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 post an inventory list with their expiration dates.
9. Credit return program (Reverse Distribution Program). 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 shall 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 several reverse distribution or returned goods vendor. Participating facilities shall select from one of the contracted vendors following guidance as provided by DSCP. Prior to transfer of drugs to the returns vendor, pharmacy personnel shall ensure an inventory of all returned pharmaceuticals is prepared and retained at the pharmacy before the shipment leaves the facility. Quarterly, preferably prior to next scheduled P&T Committee meeting, Pharmacy Officer will review returned pharmaceuticals data for trends that 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 (e.g., DD-1149, Requisition And Invoice/Shipping Document and NAVMED 6710, Perpetual Inventory).
10. Pharmacy and Therapeutics Committee (PTC).
 - a. This is a mandatory advisory committee in all CG health service treatment facilities which have assigned Medical Officers and shall meet quarterly 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 Manager (RM) or representative, and one representative from each clinic within the district. Clinic Administrators 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. Its recommendations are subject to the approval of the SHSO. The basic responsibilities of this committee are to:
 - (1) 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 CG 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 Group Practice and/or P&T committee reviews:
 - (a) A list of all clinic 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 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. Documentation for the upcoming PTC 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 the 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 Manager.

- d. Quality Improvement Implementation Guide (QIIG) #5, Pharmacy and Therapeutics Committee provides additional guidelines.

Figure 10-A-1
CLINIC NON-PRESCRIPTION MEDICATION PROGRAM
USCG (may insert name of clinic 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 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.

_____ 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, or is pregnant.

Signature: _____

Printed name: _____

Date: _____

Address:(Required only for products containing Pseudoephedrine)

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

- | | |
|---|---|
| ___ Acetaminophen 325mg tabs, 50 count | ___ Cetylpyridinium Anesthetic Lozenge |
| ___ Acetaminophen 80 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 |
| ___ Ibuprofen 100mg/5ml, solution | ___ Analgesic Balm, 30gm |
| ___ Pseudoephedrine 30mg tabs, 24 count | ___ Saline Nasal Spray, 45ml |
| ___ Pseudoephedrine 30mg/5ml, 120ml | ___ Clotrimazole Topical cream, 30gm |
| ___ Triprolidine/Pseudoephedrine tabs, 24 count | ___ Hydrocortisone 1% topical cream, 30gm |
| ___ Brompheniramine/Phenylephrine solution, 120ml | ___ Tolnaftate powder, 45gm |
| ___ Guaifenesin 100mg/5ml, 120ml | ___ Calamine Lotion |
| ___ Guaifenesin 100mg/Dextromethorphan 5mg, 120ml | ___ Male Condoms |
| ___ Diphenhydramine 25mg capsules, 24 count | |
| ___ Diphenhydramine liquid, 120ml | |

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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).

d. Quantity Definitions. Due to the potential for abuse and associated audits required, and the DoD Pharmaceutical Prime Vendor ordering advantage, CG 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 CO (Air Stations), Base Commanders, or the HSWL Regional Manager.
- (2) In the absence of a Pharmacy Officer, COs (Air Stations) or Regional Manager (RM) 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 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 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. Unit Controlled Substance Audits.

- (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 CO (Air Stations) or the Regional Manager. 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 CO (Air Stations) or the Regional Manager within 5 working days after the completed audit for signature. The command/Regional Manager will sign the report, make a copy for their files, upload to the online CG Portal Microsite, and forward the signed original back to the pharmacy for retention. The 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, CG-5353.
 - (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 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 Report for Narcotics and Other Controlled Drugs, 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.
- a. 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 the HSWL SC Pharmacy Officer. The HSWL SC Pharmacy Officer is the approving authority for Fee Exempt Status of clinic DEA certificate.

- b. The HSWL SC shall forward the Drug Enforcement Agency Registration Form, DEA-244A to the DEA and provide a copy to the originating unit. The DEA will issue the registration to the unit.
 - c. In the case of DEA renewals, (CLINIC 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); US Postal Service (USPS): 1) Express Mail or 2) Proof of Delivery using Extra Services which are either Certified, Delivery Confirmation, or Signature Confirmation, 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 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 or loss, notify the HSWL SC Pharmacy Officer.
- 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 command in writing or by e-mail of the guidance provided. Should the HSWL SC Pharmacy Officer 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 the HSWL SC Pharmacy Officer and request guidance for further action. Guidelines as indicated in 4.a. above may be followed, if warranted.
 - (1) Review and send to the HSWL SC Pharmacy Officer the findings of the investigation.

- (2) The HSWL SC Pharmacy Officer shall determine if the theft or loss warrants further action or DEA notification via Report of Theft or Loss of Controlled Substances, DEA Form 106. A copy of all Report of Theft or Loss of Controlled Substances, DEA Form 106 reports submitted to DEA shall be sent to Commandant (CG-112).

5. Procuring, Storing, Transferring, and Disposing of Controlled Substances.

a. Procurement.

- (1) Clinics shall procure controlled substances from the DSCP prime vendor source. CG 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 CG 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.

- (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) 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 CO 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 Requisition

and Invoice/Shipping Document, 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. 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, 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, DD-1149 for three years.
- (4) When the transaction cannot be done in person, it shall be done via traceable means (e.g. DHS authorized Commercial Carriers FedEx or UPS); US Postal Service (USPS): 1) Express Mail or 2) Proof of Delivery using Extra Services which are either Certified, Delivery Confirmation, or Signature Confirmation. The Registered Mail Return Receipt (PS Form 3806), or tracking document, shall be maintained by the issuing unit until a signed copy of the Requisition and Invoice/Shipping Document, DD-1149 is returned.
- (5) A copy of the Requisition and Invoice/Shipping Document, DD-1149 shall be sent to the Pharmacy Officer with collateral duty responsibility for the facility.

d. Disposal.

- (1) Expired, contaminated, excessive, inadequately labeled, or otherwise unusable controlled substances shall be destroyed by the CSAB 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. In the case of full or partially full bottle of expired controlled substances, they shall be properly labeled as expired, isolated in the Controlled Safe from usable or in-date items, and included in the next shipment of pharmaceutical returns via the contracted pharmaceutical returns good vendor.

Pharmacy personnel shall document return of controlled items via Requisition and Invoice/Shipping Document, DD-1149 as well as documents as required by the returned goods vendor.

- (2) If any controlled pharmaceutical is dropped or damaged, it shall be recovered, isolated, and stored, with adequate labeling to identify the contents, and labeled as "To be Destroyed by CSAB", in the controlled pharmaceuticals safe until the next CSAB at which time it shall be destroyed by the audit board in accordance with 10.A.8. and 10.B.5.d.(1) above.

6. Prescribing Practices.

- a. Authorized (Active Duty) prescribers (see 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. 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. 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 have the patient annotate the back of the prescription as designated in Chapter 10.B.6.b.(4). If none is assigned, the prescription shall be signed by the senior health services department representative and countersigned by the XO.
- (2) All schedule II controlled substance prescriptions by Physician Assistant 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.
- (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 done 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 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, 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.

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Section C. Forms and Records

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C. Forms and Records.

1. General. Records shall be maintained for certain procedures conducted within all CG 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. Clinic providers shall write prescriptions on the DoD Prescription blank, 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 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 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. Expressions such as "take as directed," "label," etc. are not adequate directions and 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 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, NAVMED 6710/6 or Prescription Limited, Poly, NAVMED 6710/10 which are intended for use when prescribing a number of non-controlled drugs for one patient, are authorized.
 - e. Maintain all prescriptions on file, including all “prescription logs” related to chart prescribing, for three (3) years, after which they may be destroyed by shredding.
 - f. The pharmacy shall have ready 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 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. Controlled Drug Forms.
- a. Narcotic and Controlled Drug Inventory-24 Hours, NAVMED 6710/4. This record shall be maintained at CG facilities providing inpatient care.
 - (1) The Narcotic and Controlled Drug Inventory-24 Hours, 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, NAVMED 6710/1 received from the pharmacy during each watch shall be entered. The serial numbers of completed Narcotic and Controlled Drug Account Record, 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, NAVMED 6710/4.
 - b. Narcotic and Controlled Drug Account Record, NAVMED 6710/1.
 - (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 CO, requires control procedures.

- (2) All Narcotic and Controlled Drug Account Records, 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, NAVMED 6710/1 shall be inserted in back of the current record. The serial number of the new Narcotic and Controlled Drug Account Record, NAVMED 6710/1 shall be entered on the Narcotic and Controlled Drug Inventory-24 Hours, NAVMED 6710/4.
- (5) The heading for each Narcotic and Controlled Drug Account Record, 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, 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 Narcotic and Controlled Drug Account Record, 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 Narcotic and Controlled Drug Account Record, NAVMED 6710/1.

- (e) Deteriorated drugs shall be returned to the pharmacy for disposal.
 - (f) The completed Narcotic and Controlled Drug Account Record, 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, 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 CO 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, NAVMED 6710/4 in the first section and individual Narcotic and Controlled Drug Account Record, NAVMED 6710/1 in the latter sections.
 - (2) The senior HS shall remove all filled Narcotic and Controlled Drug Inventory-24 Hours, 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, NAVMED 6710/5. Separate Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, 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, 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, CG-5353. If software is not consistently available, prepare a separate Perpetual Inventory of Narcotics, Alcohol, and Controlled Drugs, 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, as appropriate, for expenditures.
- (6) Narcotic and Controlled Drug Account Records, NAVMED 6710/1 Returned. The date the Narcotic and Controlled Drug Account Records, 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 a pharmacy officer for more information.
- b. Prescription Blanks. Prescription blanks DoD Prescription, DD1289 can be found at the following web site:
<http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm>.

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Section 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 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. 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, CG Regulations, 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 shall maintain drug formularies consisting of:
 - a. Standardized Health Services Drug Formulary items.
 - b. Health Services Allowance List 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 collateral duty pharmacist (RPE) for review and approval. The review will ensure compliance with the DoD Basic Core Formulary.
5. Non-Prescription Medication Programs. Sickbays are encouraged to operate non-prescription medication programs as described in paragraph 10-A-6.j. of this Manual. HSs shall contact their collateral duty Pharmacists for guidance and additional support.