PHARMACY SERVICES

A. OVER-THE-COUNTER MEDICATIONS

Each institutional Pharmacy and Therapeutics Committee / Pharmacy Services Committee shall establish an approved list of over-the-counter (OTC) medications to be used in nursing sick call that can be issued by approved medical staff to inmates for personal use. These medications must be properly labeled to meet Sections 499.001—499.067, F.S.(Florida Drug and Cosmetic Act).

OTC medication shall be issued using the DC4-683 series, *Protocol services* and dorm medication procedures (Procedure 406.001, *Provision and Use of Over-the-Counter Medications*) unless the prescriber deems it medically necessary for the inmate's welfare to use the legend drug prescribing procedures.

Non-legend medications with therapeutic value prescribed by practitioners and labeled by the Pharmacist are considered legend drugs.

Non-legend medications used in sick call by the nursing staff or housing officers are considered over-the-counter (OTC) drugs and are to be handled as such. These OTC medications are to be ordered per HSB 15.14.04.

1. The ancillary institutions shall order all pharmaceuticals from their assigned pharmacy. Each institution shall set up guidelines for each area within the ancillary institutions where pharmaceuticals are stored.

2. The guidelines shall include:

    a. List of pharmaceuticals in each area within the institution.

    b. The stock level within each area.

    c. An order form shall be compiled and sorted in alphabetical order by use of word processing software.

3. Each area in which OTC medications are stored must have a system of inventory control. An inventory/ordering sheet shall be formatted to include the name of medication, the stock levels as determined by the Consultant Pharmacist/Pharmacy Manager, the amount on hand, and the amount ordered. These inventory/order sheets shall be used to enter data for drop shipping via the wholesaler.

    All OTC medications issued directly to inmates must be properly labeled with the standard over-the-counter cautions and warnings as directed by the Food and Drug Administration (FDA). Improperly labeled medications shall not be issued.

B. LOST/STOLEN MEDICATIONS

Refills for lost or stolen medications may be dispensed only upon an oral or written notification from the prescribing physician. The Pharmacist, in acute situations and upon verification of a physician and patient relationship, may dispense a three-day emergency supply for the continuation of therapy as described in the Florida Statutes. This shall be documented in the medical record on DC4-714B, *Physician's Order Sheet,* or DC4-714C, *DEA Controlled Substances Physician's Order Sheet*, and the prescriber shall be notified. Single-dose procedures shall be followed in case of repeated incidents or in situations that may bring harm to the inmate or jeopardize security within the institution. Security shall be informed of all lost or stolen medication by filling out an incident report DC6-210, *Incident Report*.

C. MEDICATION FROM OTHER PROVIDERS AND/OR INSTITUTIONS

1. Prescriptions from other approved and licensed providers within the department may be issued to inmates.

2. Medications from other institutions shall be examined by the medical staff and noted in the medical record DC4-701, *Chronological Record of Health Care.* These medications may not be relabeled. If relabeling is necessary, a new prescription shall be written and dispensed according to statutes.

    a. The medical staff shall inspect the:

        1) Labeling information to ascertain if the information on the label reads the same as that in the medical record.

        2) Contents of the container to ascertain if the contents of the container are the same as stated on the label and if the contents are in good condition.

    b. The information shall be documented in the medical record. (DC4-701, *Chronological Record of Health Care*)

3. If the receiving medical staff cannot identify outside medication (or medication from other providers) and subsequently determines that the inmate should not have medication on his/her person, such medication shall be single dosed until it can be verified by the Pharmacist or authorized by a Physician.

D. SELF/SINGLE-DOSE ADMINISTRATION OF MEDICATION

1. All medications may be self-administered with the exception of controlled substances, muscle relaxants, injectables, , all antiretroviral medications (can be KOP within six (6) months of EOS date), most psychotropic medications, specific Pharmacy Services

Committee designations and anti-TB medications except as noted in HSB 15.03.18, Identification and Management of Latent Tuberculosis Infection (LTBI) and Tuberculosis Disease.

2. Single dosing shall be used by the prescribing practitioner for inmates who may cause harm to themselves (or others) or inmates who are noncompliant; or in other appropriate medical situations in which single dosing is in the best interest of the institution and/or inmate.

3. Psychotropic medication shall be dispensed in solid dosage forms unless otherwise indicated by the prescribing provider. Most psychotropic medications shall be single dosed. The prescribing practitioner or agent shall indicate the use of liquid dosing on the DC4-714B, Physician's Order Sheet, or DC4-714C, DEA Controlled Substances Physician's Order Sheet, if it is determined that a liquid is required.

4. Each dose of medication administered shall be recorded on DC4-701A, Medication and Treatment Record (MAR). The MAR shall be present when single-dose medication is administered. Each patient shall be properly identified prior to drug administration.

E. ADVERSE DRUG REACTIONS

Each Consultant Pharmacist (with the help of the risk management section) shall establish procedures for nursing and pharmacy personnel when a patient experiences a known adverse drug reaction.

The procedures shall include:

1. Notification of physician

2. Appropriate action for severe reactions

3. A reporting system which utilizes risk management forms DC4-690A, *Occurrence Report* and DC4-550, *Quality-Related Event Report*.

F. MULTIDOSE VIALS AND/OR CONTAINERS

Each institutional Consultant Pharmacist shall develop procedures to ensure that contaminated or deteriorated parenteral drug products are not utilized. The Department of Corrections' institutions shall adhere to the following guidelines:

1. Multi-dose injectable vials/containers shall be dated and initialed when opened. Current community standards allow multi-dose vials to be used for 28 days unless the following conditions exist:

    a. Literature indicates that the parenteral has a period of stability of less than 28 days.

b. The manufacturer's stated expiration date, including reconstituted products, is less than 28 days.

c. During the 28-day period, contents of the vial fail to pass a visual inspection as described below.

Any multi-dose vial/containers found opened and not dated shall be considered to be more than 28 days old and shall be properly destroyed. Non-dated containers shall be noted on the consultant pharmacist report DC4-771A, *Consultant Pharmacist Monthly Inspection*, if found on these monthly inspections.

Outdated multi-dose vials (more than 28 days after opening) shall be properly disposed. Those medications to be disposed shall be entered on a medication disposition log which shall include date, medication, amount of medication to be disposed, and initials of two (2) staff members who disposed the medication.

2. Solutions or suspensions that have visual signs of contamination or deterioration shall not be administered to patients. Turbidity, cloudiness, solid impurities, crystal formation, color changes, or changes in viscosity may all be signs of deterioration or contamination. Products suspected of deterioration or contamination shall be returned to the pharmacy for examination and/or destruction. All containers used for multidose functions shall be dated and initialed when opened. The pharmacy unit may supply labels to nursing areas for this purpose.

G. MEDICATION STOP ORDERS

Each institutional Pharmacy Services Committee shall establish automatic stop orders on any medication orders not indicating a specific number of doses or specific time periods.

The time limits for stop orders shall not exceed the following:

Controlled substances	72 hours
Antibiotics	7 days
Other medication	7 days

The specific stop orders and a procedure for notifying the prescribing practitioner shall be included in the institutional pharmacy policy and procedure manual.

H. CONTROLLED SUBSTANCES

A controlled substance is any substance named or described in Schedules I through V of Section 893.03, F.S.

Each Consultant Pharmacist and Pharmacy Manager shall develop specific procedures for handling controlled substances in the institution or Community Pharmacy in accordance with Chapter 893, F.S. These procedures must meet state and federal regulations and shall include the following:

1. Record Keeping (Reference Chapter 893, F.S.)

    a. An annual inventory must be conducted and kept on file. The Department of Corrections policy is for this to be conducted in June of each and every year. The inventory shall be reconciled with the computer inventory system for dispensing pharmacies. The Department of Corrections requires an annual inventory that must be dated and signed by the Consultant Pharmacist and filed in a file marked Biannual Inventory. Community pharmacies must also conduct an annual inventory of controlled substances which is to be signed, dated, and stored as previously indicated.

    b. A perpetual inventory of all controlled substances stored in the pharmacy must be kept by the Consultant Pharmacist, Pharmacy Manager or designee. Access shall be limited and stock stored under double lock or in a safe. This inventory record shall clearly show dates of all receipts and disbursements. It shall also show from whom it was received and to whom it was dispensed.

    c. Copies of invoices, receiving reports, and prescriptions of all controlled substances must be filed in the pharmacy and kept readily retrievable. Destruction, loss, or theft records must also be maintained in the pharmacy.

    d. D.E.A. (Drug Enforcement Agency) Form 222 must be completed and filed in the pharmacy for all Schedule II drugs purchased within the pharmacy or transferred to the pharmacy from other institutions.

    e. ALL NURSING PROOF-OF-USE CONTROLLED SUBSTANCE SHEETS MUST BE RETURNED TO THE INSTITUTIONAL NURSING SUPERVISOR FOR VERIFICATION AND STORAGE WITHIN TWO (2) WORKING DAYS.

2. Disbursement of Controlled Substances

    The instructions for dispensing and administering controlled substances within the Department of Corrections must be complied with unless the Chief of Pharmaceutical Services has given a written exception to this policy.

    Only controlled substances listed in the State Drug Formulary can be dispensed and / or administered to inmates serviced by the Department of Corrections unless an approved drug exception DC4-648, *Drug Exception Request* request is on file.

    Controlled substances can only be administered or dispensed pursuant to a valid prescription/order as stated in Chapters 465 and 893, F.S.

    Controlled substances must be stored in double-locked areas only. Schedule I substances also must be stored in a “substantially constructed” locked cabinet per the DEA regulations. 21 C.F.R. § 1301.75(a).

Each controlled substance issued must be added to DC4-781E, *Narcotic Accounting Log* by the nursing staff at the receiving institution responsible for the controlled substance. The DC4-781E, *Narcotic Accounting Log* must be properly numbered and dated if issued for individual prescriptions or dated if issued to floor stock. A Pharmacist shall complete the controlled substance issue records.

Each inmate who is administered a controlled substance must have a DC4-701A, *Medication and Treatment Record (MAR)* properly issued and filled out by the nursing staff.

All dispensing pharmacies will utilize two systems for monitoring the controlled substances dispensing procedure. One shall be a manual system and the other shall be a computerized system.

The manual system will contain separate sections for each controlled substance in the institutional pharmacy inventory. Each item must have documentation for all transactions dealing with that drug. The items shall be in the same order and have the same listing as the Controlled Substances on Hand Report as generated by the computer system. A log must contain a perpetual inventory, starting balance, prescription number or issuing number for physician's orders, date issued, amount issued, ending inventory, amount received, invoice number, date received or issued, and signature of the dispensing Pharmacist.

The computerized system will monitor the manual system. The computerized system must have an up-to-date perpetual inventory. The controlled substance logs must be completed on each day that a controlled substance is dispensed. Each transaction must be processed using the pharmacy computer system. The ending computerized controlled substance inventory must be the same as the manual system.

The Pharmacy Manager, with another pharmacist, shall (on a monthly basis) verify the correct count of controlled substances in the Community Permitted pharmacies using both the computer system and the manual system. The Chief of Pharmaceutical Services will be supplied with a current computerized Controlled Substance on Hand Report. Any discrepancies will be noted on the manual entry and corrected in both systems. All major discrepancies shall be reported to the Chief of Pharmaceutical Services and other parties as appropriate. The Consultant Pharmacist shall verify the correct count of controlled substances at each nursing area of Institutional Permitted Pharmacies on a monthly basis.

The administering nurse must document the date and time of each administrated dose on a DC4-701A, *Medication and Treatment Record (MAR)* and on DC4-781E, *Narcotic Accounting Log*. The nursing staff must return each daily DC4-781E to the nursing supervisor within two working days. If the DC4-781E,

Narcotic Accounting Log is not returned within two working days, a risk management report DC4-690A, *Occurrence Report* shall be filed. If the controlled drug account record forms are missing, the CHO, Nursing Supervisor, and Consultant Pharmacist shall assume joint responsibility in ensuring that proper action is taken. If, in the professional judgment of the Consultant Pharmacist or dispensing Pharmacist, a dose(s) is missing or drug diversion has occurred, the Warden, Chief Health Officer, Nursing Supervisor, Chief of Nursing Services, Chief of Pharmaceutical Services, the Department of Health Medical Quality Assurance, Regional Director of Nursing, Regional Medical Director, and the Drug Enforcement Administration must be notified. It is mandatory to identify ALL licensed persons on that shift, not just the person that is assigned the keys (only one person is to be assigned the controlled substance keys) and to note each applicable license number. Reference F.S. 893.07(5)(b) for notification requirements to local law enforcement of theft or significant loss.

On the back of DC4-781E, *Narcotic Accounting Log*, there must be space for the documentation of all wasted drugs, missed doses, or any discrepancies or inconsistencies in the administration of that dose. The Consultant Pharmacist must check, verify, and store such information in the pharmacy for four years.

All institutions that dispense controlled substances within the Department of Corrections must follow this procedure.

Any questions relating to the Department's Controlled Substances Procedures should be directed to the Chief of Pharmaceutical Services .

3. Stock

All controlled substances will be stocked in unit-dosed form when available. Such controlled substances will be stored and administered pursuant to institutional policy and procedures as outlined in Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.

4. Dropped Pills and Unsecured Syringes

Each institution shall develop a policy and procedure for properly identifying and disposing of any controlled substance dropped on the floor or otherwise contaminated. A policy shall also be developed for the identification and disposal of controlled substances which are found stored outside manufacturer requirements, i.e., opened tab on carpujects; such policy shall include notification of the Consultant Pharmacist. If drug diversion is suspected, the previously noted people must be notified.

For instructions regarding the disposal of controlled substances, see appendix C.

I. DATA ENTRY AND MEDICATION ISSUING REQUIREMENTS OF THE BOARD OF PHARMACY

1. Each pharmacy must have separate filing systems for institutional prescriptions/orders and community prescriptions/orders. Those orders for the institution where the pharmacy is located must be filed separately from those prescriptions written for offsite institutions in that off-site institution prescriptions are issued under the community permit and those for the institution are issued under institution II permit. A prescription/order file for medications shall be issued under the institutional permit and one for the community permit. End-of-sentence
2. prescriptions are issued under the community permit and shall be filed accordingly.

3. Stock items or line order items for onsite institutions are to be entered into the computer. Computer prescription labels are not to be placed on the packaging of these items (due to the prescription number on the label).

4. Emergency stock items will be invoiced to the –off site institution. The invoice will contain (at the top of the page): the institutional name, address, and DEA number. Listed just below will be the name, address, and DEA number of the receiving institution, if applicable. The invoice will contain the middle portion of the prescription label and such is to be filed at the receiving institution as other invoices are filed. A copy of the invoice is to be kept in a file that shows where the medication is sent. A separate invoice must be prepared for controlled substances and must also be filed separately at the sending and receiving institution.

5. Each pharmacy shall maintain a pharmacist signature logbook with the date, Pharmacist initials, and Pharmacist signature. The log is to be signed by all Pharmacists who work on any given day. Each page of the log will have a statement that attests that the information entered into the data processing system that day has been reviewed by the Pharmacist and is correct as entered. This statement will be at the top of each page. All signature logs must be kept for four (4) years. With the implementation of signature logs, daily logs will no longer be required.

   Board of Pharmacy inspectors shall be provided with a printout of issues (prescriptions) at any given site. Daily logs are not to be printed because these combine fills on the institutional permit with fills on the community permit. These logs also provide information on line ordered medications that are considered invoiced transactions. A report can be printed for any transaction requested. For example, if an inspector requests information on prescriptions filled for an institution during the time period of May 1, 2003, to July 1, 2003, a Drug Utilization Report would be printed which lists all issued items that would affect the request for information about that institution. The process for this report would be a drug utilization report:

   List pharmacy code in beginning and ending pharmacy
   Click on facility desired

GPI selection: all categories
Formulary selection: all drugs
Patient selection: all drugs
Sex selection: all
Facility selection: page break on facility change
Drug cost selection: script acquisition cost
Script cost selection: print cost
Sort 1 selection: patient name
Sort 2 selection: drug name
OTC selection: all
Location groups selection: do not use
KOP selection: all
Detail selection: print details without subtotals
Press OK: print report

5. A complete backup of the computer system shall be performed on a daily basis at Central Office.

J. ESSENTIAL INFORMATION FOR BOARD OF PHARMACY INSPECTORS

Each institution that has a modified II-B permit is required to have the following:

1. A file for all controlled substance invoices
2. A file for legend medication invoices
3. A file for all consultant pharmacist reports
4. A file with all quarterly Pharmacy and Therapeutics Committee and Continuous Quality Improvement Program meeting minutes
5. The Department of Corrections Drug Formulary
6. A file for all approved stock medications
7. A file and display of the following:
    a. The modified II-B permit
    b. DEA license, if applicable
    c. Consultant Pharmacist license
8. The institutional pharmacy policy and procedure manual
9. A file for annual controlled substance inventory
10. Quality-related events summary file using DC4-550 as a reference

K. REFERENCE GUIDES

The following reference guides are recommended:

1. AHFS Drug Information American Society of Health-System Pharmacists
   Customer Service Department
   7272 Wisconsin Ave.
   Bethesda, MD 20814
   Phone: 866-279-0681 Fax: 301-657-1251
   www.ashp.org

2. Drug Facts and Comparisons

   111 West Port Plaza, Suite 450
   St. Louis, Mo. 63146
   Phone: 1-800-223-0554
   www.factsandcomparisons.com Access to the laws and rules governing the practice of pharmacy in the State of Florida.