PURCHASING AND INVENTORY

A. INTRODUCTION

The Department of Corrections utilized a department formulary system which each institution is to utilize.

The Consultant Pharmacist of Record or Pharmacy Manager is responsible for maintaining and procuring all drugs within the pharmacy or institution. Sufficient stock to provide efficient day-to-day operations shall be maintained. However, the use of the prime vendor eliminates the need for excessive stock levels and shall be utilized whenever possible. The Consultant Pharmacist of Record or Pharmacy Manager is expected to demonstrate prudent fiscal responsibility in ordering and maintaining the pharmacy inventory.

B. POLICY AND PROCEDURES

The Consultant Pharmacist of Record or Pharmacy Manager shall develop specific procedures for ordering and maintain the drug inventory. Procedures shall be coordinated through the Chief of Pharmaceutical Services and shall include:

- 1. A policy specifically establishing guidelines for separating the ordering, receiving and approval process and designating staff that perform those functions. Separate staff is required for each of these functions.
- 2. Establishment of a computerized system, at dispensing pharmacies only, to determine ordering needs on a regular basis. All dispensing pharmacies should do computerized purchase order and utilize a want list only for special orders.
- 3. Institutions with a non-dispensing pharmacy, Institutional Modified IIB, are to utilize approved stock lists utilizing stock level ordering points. These stock lists order forms are to be faxed to the assigned regional pharmacy for approval and ordering.
- 4. Procedures for utilizing the contract system for routine ordering include:
 - a. Prime vendor computerized ordering
 - b. Other state contract resources available through MYFLORIDAMARKETPLACE.
- 5. Establishment of a procedure to obtain medications from a local pharmacy or hospital for immediate and after-hours emergency purchases including:

- a. The Consultant Pharmacist of Record, Pharmacy Manager or on-call Pharmacist must approve the purchase of any urgent non-stocked medication deemed necessary for the welfare of the patient.
- b. Prescriptions purchased from the local pharmacy or hospital shall be kept to a minimum amount of medication, usually no more than a three-(3) day supply. Institutional staff are required to pick up the medication from the local pharmacy or hospital.
- c. The HSA at the institution is responsible for obtaining the invoice/receipt from the local pharmacy.
- 6. Procedures for receiving and processing the drug orders include:
 - a. Checking orders actually received against vendor invoices.
 - b. Utilizing vendor stock labels as appropriate.
 - c. Preparing and/or signing the receiving report.
 - d. Submitting invoice(s) to the assigned regional pharmacy and business office as appropriate.
 - e. Maintaining files as appropriate.
- 7. A procedure for handling computerized receiving reports shall be established at each dispensing pharmacy.
- 8. Procedures for the ordering of controlled substances including maintaining copies of invoices in a separate file and use of D.E.A Form 222 for Class II substances.
- 9. Procedures for an every four (4) month (tri-annual) physical inventory of the dispensing pharmacy as coordinated with Chief of Pharmaceutical Services Director and Health Services Director. These inventories will be completed in February, the last working day in June, and in October.

B. SAMPLE MEDICATIONS

There will be no medication samples allowed in the pharmacies or institutions.

C. DRUG STORAGE

Drugs stored within the confines of the pharmacy or institution shall be under the supervision of the Pharmacy Manager or Consultant Pharmacist of Record.

All drug storage areas shall have posted forms or other written documentation indicating the date that the area was checked for expired medications and by whom. These checks must be no less frequent than every three (3) months. This documentation shall be posted for viewing by proper personnel. The expired or damaged drug shall be removed and separated. These drugs shall be stored in a separately designated area so as to be identified, and the distribution and administration of such drugs shall be prevented. Expired dispensing pharmacy stock medications shall be removed from the computerized inventory. A printout of all such transactions shall be made.

All medication storage areas will have proper storage conditions, including sanitation, temperature, light moisture, ventilation, segregation and security.

Refrigerators used for the storage of medications must be maintained at a temperature between 36° F and 46° F.

The Consultant Pharmacist of Record shall record the monthly inspections of the drug storage areas on the form DC4-771A, *Consultant Pharmacist Monthly Inspection*.

Controlled substances shall be stored under double lock or in a safe with accountability ensured as outlined in appendix B (see Disbursement of Controlled Substances section).

Locked storage areas or locked medication carts shall be provided for all medications, syringes, and needles.

Drugs for external use shall be stored separately from internal and injectable medications.

D. RETURN/DISPOSAL OF DRUGS

All medications confiscated from inmates by security or medical staff shall be documented on an appropriate form DC4-551, *Medication Destruction Log* to include inmate name, date, name of medication, amount of medication, and initials of person confiscating the medication. These items shall be not returned to the dispensing pharmacy. The medications shall be stored separately in a quarantined area until disposed of. These medications shall be disposed of by approved methods. No adjustments to inventory are necessary for these already dispensed items.

For dispensing pharmacy overstocked, expired or damaged stock medications; a computergenerated form shall be used as the written documentation. The medications are entered under transaction posting in the CIPS pharmacy computer system and when all medications are entered a printout of the action is to be done. The printout is to be signed by the Pharmacy Manager and filed.

Overstocked, damaged and outdated drugs shall be disposed in the following manner:

1. Returnable Stock

The Pharmacy Manager or Consultant Pharmacist of Record or designee shall return any overstocked or outdated drugs to the vendor, or manufacturer for credit. A letter requesting return authorization for exchange or credit shall be written, if appropriate. Appropriate return forms shall be filled out and copies shall be maintained in the pharmacy. Adjustments to the inventory shall be made in accordance with the computer processing procedures outlined in this technical instruction and filed within the pharmacy. A copy shall be maintained so that credit can be confirmed.

2. Non-returnable Stock

The Pharmacy Manager, Consultant Pharmacist of Record, or designee shall properly dispose of stock medications that cannot be returned for credit, through a reverse distributor. A report on the value of drugs returned to the reverse distributor will be provided to the Chief of Pharmaceutical Services.

- 3. Controlled Substances
 - a. Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.
 - b. Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 "Registrants Inventory of Drugs Surrendered" (effective 8/31/2014), herein incorporated by reference, available at <u>http://www.flrules.org/Gateway/reference.asp?No=Ref-03998</u> or http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction requires that a copy of the completed and witnessed Form DEA 41 be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction. The medication shall then be placed in a tamperproof hazardous pharmaceutical waste container until disposed of by a Hazardous Pharmaceutical Waste company or a Reverse Distributor.
 - c. In lieu of D.3.b., destruction may be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction. The medication shall then be placed in a

tamperproof hazardous pharmaceutical waste container until disposed of by a Hazardous Pharmaceutical Waste company.

- d. In lieu of destruction on the premises as outlined in subsections (2) and (3) above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.
- e. For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2), F.A.C., must be followed.

A report on the value of drugs surrendered will be provided to the Chief of Pharmaceutical Services.

E. DRUG RECALLS

All drugs recalled by the manufacturer or the FDA shall be promptly removed from the institutional drug distribution system.

The Pharmacy Manager or Consultant Pharmacist of Record shall have a binder or file with all recall notices and each notice shall be signed and dated as to the status of the recalled pharmaceutical.

The drug and amount of recalled drug must be processed by using the transaction posting option in the CIPS pharmacy computer system, if appropriate.

Drugs recalls are classified by the FDA according to the degree or urgency involved in removing the product from the market.

CLASS I- A situation in which there is reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.

CLASS II- A situation in which the use of, or exposure to, a product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote.

CLASS III- A situation in which the use of, or exposure to, a product is not likely to cause adverse health consequences.

CLASS I and II Recalls- As soon as recall information is received from the manufacturer or FDA, the Pharmacy Manager or Consultant Pharmacist of Record shall determine if the drug is stocked or has ever been stocked in the institution. If the drug is stocked or has been stocked in the past, the Pharmacy Manager or Consultant Pharmacist of Record shall notify the Chief Health Officer and the Nursing Supervisor and shall, with their assistance, check all drugs storage areas in the institution. Any recalled medications stocked in the institution shall be immediately removed from the stock and shall be segregated until proper disposition. Records of drug recalls shall be maintained by the Pharmacist.

CLASS III Recall- When Class III recall information is received by the pharmacy, the Pharmacy Manager or Consultant Pharmacist of Record ensure that all drug storage areas are checked for the drug and the drug is removed and segregated until proper disposition. The Pharmacist shall notify the Chief Health Officer and the Nursing Supervisor, if appropriate, (verbally or in memo form) of the actions taken. Records shall be maintained by the Pharmacy Manager or Consultant Pharmacist of Record.

In the event all lots of a drug are recalled and a patient is receiving the drug, the physician shall be notified of the recall and shall make the necessary changes in therapy. If a patient has been issued medication which has been recalled and the lot number cannot be determined, the medication shall be considered to be under recall and shall be withdrawn from use. The recalled drugs shall be returned to the vendor for credit as directed by the recall.

F. DRUG QUALITY

The Pharmacy Manager, Consultant Pharmacist of Record or designee shall be responsible for maintaining an adequate inventory and for removing all outdated and recalled drugs from inventory. All outdated or recalled drugs will be kept separately from active inventory, returned to the manufacturer/vendor when possible, properly disposed, or returned to the department's contracted reverse distributor for credit. Outdated controlled substances will be separated from active controlled drug inventory and surrendered as previously indicated. Proper conditions of temperature, sanitation, light, and humidity shall be maintained in the pharmacy, as well as refrigeration (where needed) for temperature sensitive drugs. Proper security of all pharmacy inventory and equipment must be maintained at all times.

Adequate containers for the separation and disposal of glass, plastic, metal, and other items destined for trash removal shall be maintained in the pharmacy.

All refrigerators that contain pharmaceuticals shall be equipped with a thermometer and must be maintained from 36° F to 46° F (61N-1.013 F.A.C.).

G. PHYSICAL INVENTORY: DISPENSING PHARMACIES

A physical inventory is to be performed three times a year in February, the last working day in June, and October.

The tri-annual pharmacy inventory is to be conducted by the end of the month. The inventory will be counted in increments to the nearest estimated $1/4^{\text{th}}$ of a bottle. If assistance is needed, please coordinate through the Chief of Pharmaceutical Services .

The following procedures for conducting the inventory shall be forwarded:

- 1. Print beginning drug inventory.
- 2. Do a physical inventory of items in the pharmacy; estimate to nearest 1/4th of a bottle. Enter the quantity on hand on the printed drug inventory sheet. If the item is not stocked, the quantity should be zero (0).
- 3. Adjust inventory amounts and pricing information in the computer using the drug adjustment function in the CIPS pharmacy software.
- 4. Print and send a drug adjustment reports to the Chief of Pharmaceutical Services.
- 5. Print and save an ending drug inventory.
- 6. It is departmental policy that a complete inventory of narcotics be completed yearly in the month of June. This inventory should be kept on file and the results of the inventory shall be emailed toto the Chief of Pharmaceutical Services. Remember that this count includes narcotics in stock, in any nursing area or cart, and all expired narcotics awaiting disposal.

Information to be contained in drug record maintenance field:

Drug Name (shall reflect how item is dispensed) example: 120ml, 15gm, bottle or tube, etc. NDC Number (or bar code for OTC) D.E.A. Class (controlled substances) GPI Code Drug Type Allergen(s) Package Size (must compare to cost) Cost per Unit (must compare to package size) Vendor (prime vendor or direct) Price Schedule (there is only one price schedule).

A copy of the inventory will be stored at the pharmacy.

- 7. In addition to the three complete inventories, a weekly inventory will be performed on all brand name anti-retroviral, all brand name atypical anti-psychotics, all brand-name SSRI'S, interferons, and other select medication of high dollar value.
- 8. The Pharmacy Manager is to notify the Chief of Pharmaceutical Services of any medication whose inventory is off by 100 units, comparing actual count versus computerized quantity, and include a reason as to why.

H. EMERGENCY MEDICATIONS

The Consultant Pharmacist of Record of each institution is to ensure that there is an adequate supply of emergency medications available as required by HSB 15.03.22, *Medical Emergency Care Plan and Guidelines*.

I. INVENTORIES OF CLOSED PHARMACIES

- 1. On the date of closing, the Chief of Pharmaceutical Services and/or designee will conduct a manual count of the inventory. This count will be put in writing by listing the medication name, size of package, quantity on hand, and price (by package size) of the medication.
- 2. A copy of the completed inventory will be shipped with the medication to the receiving pharmacy. Another copy will be sent to the Chief of Pharmaceutical Services.
- 3. The receiving pharmacy will open the container(s) and verify the contents.
- 4. Receiving pharmacy staff will complete a manual inventory of the container(s) contents.
- 5. Receiving pharmacy staff will compare the inventory of what was received against the shipping inventory.
- 6. Any discrepancies will be reported to the Chief of Pharmaceutical Services for resolution.
- 7. Receiving pharmacy staff will place the medication into stock and make all necessary adjustments to the computerized inventory.