

PHARMACY OPERATIONS

A. RESPONSIBLE PARTIES AND DUTIES

1. The Chief of Pharmaceutical Services is responsible for administering the statewide pharmacy program for the Department of Corrections. These responsibilities include developing and implementing statewide policies and procedures, maintaining bulletins and departmental procedures, consulting with institutional pharmacy and medical staff in developing clinical pharmacy programs, monitoring standards of pharmacy practice in Department of Corrections institutions, assisting in personnel recruitment for pharmacy operations with direct input into the annual evaluation procedures, and other related duties. The Chief of Pharmaceutical Services shall provide clinical and programmatic input on all annual or special evaluations and be provided with prior notification regarding hiring and terminations as set forth in the Department of Corrections Personnel Procedures Manual.
2. The institutional Consultant Pharmacist and /or Pharmacy Manager, with the cooperation of the Chief of Pharmaceutical Services, shall initiate institutional policies and procedures for the efficient and most cost-effective operation for all Board of Pharmacy-permitted institutions for which they are responsible. These procedures shall not be in conflict with any policy or procedure outlined herein. The Consultant Pharmacist, with the support of the institutional Pharmacy Services Committee shall govern the professional operations of the institutional pharmacy.

The Consultant Pharmacist and / or Pharmacy Manager shall be responsible for comprehensive institutional pharmacy services that shall include, but not be limited to:

- a. Compounding and dispensing pharmaceutical substances.
- b. Ordering, receiving, storing, and securing all classes of drugs.
- c. Maintaining adequate reference materials concerning drugs.
- d. Maintaining equipment and inventory to provide quality pharmacy services including a clean and orderly pharmacy area.
- e. Providing information to medical staff and patients regarding drugs, drug interactions, side effects, etc. In-services shall be scheduled yearly with members of the health services team.
- f. Consulting with prescribing practitioners (MDs, APRNs, DDSs, etc.) and inmates regarding dosage, frequency, administration, adverse effects, and interactions of drug products.
- g. Developing and/or maintaining an updated computerized institutional pharmacy policy and procedure manual or policy and procedures manual for institutions. Updates will be completed on a yearly basis.

- h. Ensuring the institutional Pharmacy and Therapeutics Committee / Pharmacy Services Committee meetings and any other such related committees are conducted as required.
- i. Maintaining full security of the pharmacy and confidentiality of records.
- j. Maintaining adequate computer records of purchases, requisitions, and issues of all pharmaceuticals within the institution.
- k. Properly supervising all auxiliary personnel in the operation of the pharmacy.
- l. Participating in the institutional quality management programs as a member of the Quality Management Committee to assess that the quality and appropriateness of services provided by pharmacy staff shall be monitored and evaluated, and any identified problems shall be resolved. Shall ensure that a quarterly Quality Improvement Program meeting is conducted.
- m. Developing a stock level inventory system for all storage areas within the institution and for the ancillary institutions that are assigned to each major institution.
- n. Providing monthly consultant pharmacist reports, of institutions that were deficient in any category, to the Chief of Pharmaceutical Services within ten (10) working days of the following month in which the consultant report was completed. The consultant reports shall be completed via DC4-771A, *Consultant Pharmacist Monthly Inspection*.
- o. Providing reports to the Chief of Pharmaceutical Services within one business day of medication loss or theft, a wrong dose being issued, medication given to the wrong individual, and excessive wasting or use. This report should be a summary of the event and any action taken. Such report shall be sent via e-mail with the name and DC number of the inmate involved and a brief descriptive paragraph of the incident. These reports are in addition to the risk management program reports DC4-690A, *Occurrence Report* [patient injury report] and administrative quality monitoring report [AQM] that are also required for these occurrences.
- p. Maintaining a drug profile system for inmates to assist in the monitoring of drug therapy, potential interactions, interferences, and incompatibilities on drug abuse. Any irregularities shall be resolved with the prescribing practitioner and, when appropriate, the nursing staff.
- q. Taking reasonable action to ensure that all medication errors and adverse drug reactions are reported immediately on form DC4-550, *Quality-Related Event Report* in accordance with written procedures and Rule 64B16-27.300, F.A.C.

- r. Developing a quality assurance program to monitor personnel qualifications, training, performance, equipment, and facilities.
3. License Requirements— Pharmacies shall be licensed as required by section 465.018 or 465.019, F.S.
 - Institutions with dispensing pharmacies on premises shall have;
 - Class II institutional Permit and be operated under the direction of a duly licensed Consultant Pharmacist
 - Community pharmacy Permit operated under the direction of a Designated Pharmacy Manager.
 - Institutions who do not have prescriptions dispensed on the premises require a modified class II-B institutional license operated under the direction of a duly licensed Consultant Pharmacist.

B. HOURS OF OPERATION

Community Pharmacies will provide pharmacy services at a minimum of 40 hours per week, five days a week, or as allowed by Florida Statutes, unless an appropriate supervisor approves an alternate workweek. When a Pharmacist is absent from the pharmacy for leave, illness, or official business, arrangements will be made by the Pharmacy Manager with consultation with the Chief of Pharmaceutical Services to provide pharmacy services which meet legal requirements either on site or from an outside pharmacy. The names, addresses, and telephone numbers of the Consultant Pharmacist, pharmacists and on-call pharmacists shall be posted in the pharmacy and all appropriate health services areas so that medical staff may contact him/her in the event of an emergency.

The contract relief services shall be used only if other Department of Corrections pharmacists are not available to cover.

C. ACCESS TO THE PHARMACY AND DISTRIBUTION OF KEYS

Access to the pharmacy shall be limited to authorized personnel as determined by the institutional Consultant Pharmacist and/or Pharmacy Manager. The procedures for access to the institutional pharmacy shall be developed by the Consultant Pharmacist and shall comply with Florida Statutes.

1. COMMUNITY PERMITTED PHARMACIES

Current community permitted pharmacies are Region I Pharmacy, Region II Pharmacy (located on site at Union CI) and Lowell CI Pharmacy (located on site at Lowell CI).

The outer pharmacy door shall be secured using a two-lock system (dead bolt and knob keyway). All Pharmacists shall have both keys. The pharmacy technicians shall have one key (working or knob keyway) for entry into the pharmacy (after

the Pharmacist has arrived) and can enter and exit the pharmacy unencumbered during the working day when a Pharmacist is on the premises. Any controlled substance that is locked within the pharmacy must use a different key system.

Pharmacist Keys—The Pharmacist key ring will include both keys used to enter the pharmacy. The Pharmacist key ring may also include any institutional keys as determined by the Warden of the institution. The Pharmacy Manager and/or lead Pharmacist will determine which pharmacist key ring will contain the pharmacy controlled substance stock key, if applicable. If pharmacist keys are to be turned in to the control room at the end of the workday, these keys are to be locked in a clear Plexiglas box. The only keys to the Plexiglas box will be in control of the Pharmacist or Pharmacy Manager.

Technician Keys—The technician key ring will contain only one key (knob key) for entry into the pharmacy. In the case of an institution having only one lock for entry into the pharmacy, the technician key ring will not have that key assigned. The technician key ring may contain any other institutional keys as determined by the Warden of the institution.

A community permitted pharmacy may not be entered unless there is a pharmacist on site.

In the event of an emergency, i.e., a fire, flood, or break-in, the Pharmacy Manager (in conjunction with the Health Services Administrator) shall be notified by phone immediately. The institutional Pharmacy Manager shall develop procedures for securing the area until his/her arrival. The procedures shall be part of the pharmacy policy and procedure manual and security operations must be provided with a copy.

2. INSTITUTIONAL PERMITTED PHARMACIES

a. CLASS II INSTITUTIONAL PHARMACY

RMC Pharmacy

The outer pharmacy door shall be secured using a two-lock system (dead bolt and knob keyway). All Pharmacists shall have both keys. The pharmacy technicians shall have one key (working or knob keyway) for entry into the pharmacy (after the Pharmacist has arrived) and can enter and exit the pharmacy unencumbered during the working day when a Pharmacist is on the premises. Any controlled substance that is locked within the pharmacy must use a different key system.

Pharmacist Keys—the Pharmacist key ring will include both keys used to enter the pharmacy. The Pharmacist key ring may also include any institutional keys as determined by the Warden of the institution. The Pharmacy Manager and/or lead Pharmacist will determine which pharmacist key ring will contain the pharmacy controlled substance stock key, if applicable. If pharmacist keys are to be turned in to the

control room at the end of the workday, these keys are to be locked in a clear Plexiglas box. The only keys to the Plexiglas box will be in control of the Pharmacist or Pharmacy Manager.

Technician Keys—The technician key ring will contain only one key (knob key) for entry into the pharmacy. In the case of an institution having only one lock for entry into the pharmacy, the technician key ring will not have that key assigned. The technician key ring may contain any other institutional keys as determined by the Warden of the institution.

At RMC Pharmacy, Institutional Class II pharmacy, security shall have one key (security key or dead bolt) on the accessible key ring and the charge nurse shall have one key (working or knob keyway) on the charge nurse's key ring that is passed from shift to shift.

The only person that has statutory authority to enter the RMC pharmacy (Institutional Class II) after hours (after a valid physician drug order is received and documented by the nursing staff) is the charge nurse (Chapter 465.019 [2][b], F.S.). The charge nurse shall notify the security station, which will issue the security/dead bolt key to a second nurse, and both parties will open and enter the pharmacy (each using an assigned key). The charge nurse shall be assigned the knob keyway and second nurse shall be assigned the dead-bolt key.

The charge nurse entering the pharmacy after hours must sign DC4-797R, *After-Hour Access to Pharmacy Log*, and each entry must be witnessed by the second nurse. A log must be kept of all entries into the pharmacy. Each entry into this log must include: the date and time, inmate name and DC number, the name, amount, and dosage of the medication that was removed, the nurse's signature, and the security person's signature. After-hour entry into the pharmacy shall be for emergency situations only (inmate care). This procedure shall not be used to replenish nursing floor stock or other routine procedures. Only a single dose of a medicinal drug may be obtained. The replenishment of floor stock is handled by the stock/level inventory ordering system as described in appendix C.

The institutional Consultant Pharmacist/Pharmacy Manager shall develop specific procedures for after-hour access by the charge nurse. These procedures shall provide for a pharmacy sign-out log and witnessed entry. A log must be kept of all entries into the pharmacy, any pharmaceuticals that are removed for the purpose intended, and the patient/inmate name for the intended pharmaceutical. The procedures must comply with Board of Pharmacy Rules.

In the event of an emergency, i.e., a fire, flood, or break-in, the Consultant Pharmacist/Pharmacy Manager (in conjunction with the Health Services Administrator) shall be notified by phone immediately.

The institutional Consultant Pharmacist shall develop procedures for securing the area until his/her arrival. The procedures shall be part of the institutional pharmacy policy and procedure manual and security operations must be provided with a copy.

Narcotic keys are to be assigned to one nurse per shift. Only one nurse is to have access to the narcotic cabinet per shift. At the beginning and end of each shift, an inventory of the narcotics cabinet is to be conducted and noted using DC form: DC4-781E.

3. MODIFIED INSTITUTIONAL II B / Class II Institutional PERMITTED PHARMACIES

Modified Institutional II B and Class II Institutional permitted pharmacies allow facilities to stock legend medications for administration by nursing staff or dispensing by a licensed clinician when appropriate.

Legend stock medications (which have the statement Caution: Federal law prohibits dispensing without a prescription or Rx Only which require a physician's order and are stored outside the central pharmacy), covered under the institutional pharmacy license, shall be accessed only by licensed nursing staff, prescribing providers or assigned staff. The procedure for doing such shall be written by the Consultant Pharmacist and must comply with Florida Statutes.

In the event of an emergency, i.e., a fire, flood, or break-in, the Consultant Pharmacist (in conjunction with the Health Services Administrator) shall be notified by phone immediately. The institutional Consultant Pharmacist shall develop procedures for securing the area until his/her arrival. The procedures shall be part of the institutional pharmacy policy and procedure manual and security operations must be provided with a copy.

Narcotic keys are to be assigned to one nurse per shift. Only one nurse is to have access to the narcotic cabinet per shift. At the beginning and end of each shift, an inventory of the narcotics cabinet is to be conducted and noted using DC form: DC4-781E.

D. COMMUNITY FACILITIES (WORK RELEASE CENTERS)

All prescriptions at Community Facilities / Work Release Centers will be dispensed as "Keep on Person" (KOP). Prescriptions at Community Facilities / Work Release Centers are exempt from the Single Dose / Direct Observed Therapy requirements of HSB 15.14.04 App B (D).

Prescribing clinician will document that the inmate meets clinical criteria for the inmate to keep prescriptions as KOP.

An inmate transferred to a community facility shall be provided with a month's supply of routine or maintenance medications which may be refilled if necessary. This is to assure continuity with the inmate's medication regimen. An inmate who is on work release and

who demonstrates an inability to defray the cost of medication will be referred to the Regional Medical Director for a determination of service delivery. In all cases, every effort will be made to conduct an individual inquiry and to provide reasonable accommodation by utilizing the designed major facility as a medication regimen source.

E. WORK CAMPS AND ROAD PRISONS

Correctional officers may have facility keys to access prescriptions dispensed to inmates who must take medication at prescribed times. The chief of each community facility will be responsible for key control.

Controlled substances or dispensed medications that are assigned single-dosing status may, even after such single dose has been dispensed, be maintained for security purposes by the security staff in the Work Camp/Road Prison. When an inmate is in need of dispensed medication and this conforms to the directions for use on the prescription label, the assigned officer will make the medication available to the inmate for self-administration.

F. INSPECTIONS

The institutional Consultant Pharmacist or designee shall conduct monthly inspections of all areas in the institution and any assigned institution or work camp, etc., where drugs are stored, administered, or dispensed to ensure that proper procedures are in place for drug storage and handling and that there is compliance with HSBs and policy and procedures. This inspection shall be documented on DC4-771A, *Consultant Pharmacist Monthly Inspection*.

All monthly inspections will include a medication administration record review (MAR). This review will be for accuracy and completeness of the MAR. It will include inmate name, DC number, directions, stop dates, times medications are given, medication incompatibilities, allergies listed, and any undocumented missed doses. Any problems found will be documented on DC4-771C, *MAR Review* and reported to the nursing supervisor. Problems identified during these inspections shall be resolved by the Consultant Pharmacist with the cooperation of the Chief Health Officer/ Institutional Medical Director, Nursing Supervisor, and other personnel as applicable. At a minimum, the Consultant Pharmacist must review at least 25% of the Modified Class II B Permitted institution's MARS on a monthly basis. All MARS must then be reviewed if significant problems are noted.

The Consultant Pharmacist/Pharmacy Manager will ensure that all pharmacy areas are checked for expired, damaged, and outdated medications on no less than a quarterly basis. These checks will be documented in writing in a logbook or other recording device and must be available for review. The Consultant Pharmacist or designee shall ensure that all expired or damaged and outdated drugs are removed and separated from the pharmacy inventory stock. Each institution shall establish an institutional pharmacy policy and procedure manual to ensure that the institution meets all pharmacy rules and criteria concerning expired or damaged drugs.

Problems identified for more than two or more consecutive months shall be written in a corrective action plan (CAP) format and monitored by the institutional Pharmacy Services Committee until the problems are corrected. A copy of a dated CAP shall be forwarded to the Warden, Chief Health Officer/ Institutional Medical Director, Regional Medical Director, and Chief of Pharmaceutical Services. The corrected CAP shall be attached to and forwarded with Pharmacy Services Committee minutes to the central office.

G. RECORDS STORAGE

Retention of pharmacy records shall be in accordance with applicable laws, statutes, and regulations.

The minimum time limit required by Section 893.07, F.S., for DEA Controlled Substances records (including invoices, order forms, drug disposal forms, etc.) is two (2) years.

All prescription files shall be kept a minimum of four (4) years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

The following is the Office of Health Services required retention period for pharmacy records:

1. Pharmacist signature logs	four (4) years
2. Computer log reports	four (4) years
3. Purge information hard copies	four (4) years
4. Prescriptions	four (4) years
5. DEA-controlled substance reports	four (4) years
6. Controlled substance inventories	four (4) years
7. Jobber invoices	four (4) years
8. Medication pick-up logs	four (4) years
9. Dorm medication order forms	two (2) years
10. Stock requisition forms	two (2) years
11. Quality-related event summary file	two (2) years
12. Weekly inventories select medication	two (2) years
13. Tri-annual inventories (all forms)	two (2) years
14. Monthly Consultant Pharmacist Inspections	four (4) years

After the designated fiscal year-end inventory, the indicated year's dorm medication order forms and stock requisition forms shall be stored for an additional period of two (2) years and then destroyed, unless otherwise instructed.

H. QUALITY MANAGEMENT PHARMACY SERVICES GROUP/PHARMACY AND THERAPEUTICS COMMITTEE

1. Quality Management Pharmacy Services Committee -Statewide

The Department of Corrections Quality Management Pharmacy Committee//Pharmacy

and Therapeutics Committee members are appointed by the Health Services Director. Voting members shall be representative of medical, mental health and dental disciplines who have prescribing privileges. Ex officio members include pharmacy, nursing and administrative services. This group shall meet a minimum of two times per year.

The group shall be responsible for, but not be limited to, the following:

- a. Establishment and maintenance of a comprehensive departmental drug formulary.
- b. Approval of policies and procedures relating to selection, distribution, handling, use and administration of drugs, and diagnostic testing material.
- c. Evaluation of clinical data concerning new drugs or preparations requested for addition to the formulary.

2. Institutional Pharmacy and Therapeutics Committee/Pharmacy Services Committee

The institutional Pharmacy and Therapeutics Committee/Pharmacy Services Committee members are appointed by the Chief Health Officer/ Institutional Medical Director or Regional Medical Director and shall include representatives from medical, dental, mental health, nursing, and administrative services and shall also include the Consultant Pharmacist who will serve as committee chair. The original copy of the minutes shall be filed in the institution.

The institutional committee shall be responsible for, but not limited to, the following:

- a. Approval of legend stock medication to be used by institutional nursing staff pursuant to a valid practitioner order.
- b. Approval of policies and procedures relating to selection, distribution, handling, use, and administration of drugs and for diagnostic testing material.
- c. Evaluation of clinical data concerning new drugs or preparations for addition to the departmental drug formulary.
- d. Approval of over-the-counter drugs to be used by institutional nursing staff pursuant to the nursing protocols and other clinical guidelines.
- e. Formulation of a corrective action plan (CAP) for problems noted in the pharmacy monthly consultant reports which are not corrected within two (2) months by institutional solutions. The CAP must be

copied to the Regional Medical Director and the Chief of
Pharmaceutical Services .

Establishment of a policy and procedure for obtaining medication in emergency situations or when medication is not delivered in a timely manner. The institution shall set up an emergency purchasing system with a local pharmacy to supply out-of-stock or emergency medication. The committee shall limit the purchase to a three-day supply or a limited quantity to continue therapy to the next delivery time. The purchase shall be restricted to legend drugs (except for insulin).

I. STOCK-LEVEL INVENTORY ORDERING SYSTEM

The Consultant Pharmacist must develop a stock-level inventory and ordering system for each area within the institution that stores pharmaceuticals. The form must list all pharmaceuticals that are authorized to be stocked in each area. The form must list a stock level that is authorized in each area, the amount on hand and amount ordered. The system must provide for routine ordering.

The forms are to be faxed to the assigned regional pharmacy. The assigned regional pharmacy will order the medication from the wholesaler using the drop ship procedure.

The stock level shall be modified to provide a two-week supply of the medication.

The pharmacy and nursing staff shall determine the proper ordering and turn-around times for delivery. The procedure for nursing ordering and receiving must be detailed in a written policy and procedure. These stock-level ordering sheets shall be provided using the Microsoft word- processing software, and a supply of the order sheets shall be kept in the nursing station.