



Program Statement

OPI: HSD/HPB
NUMBER: P6360.01
DATE: 1/15/2005
SUBJECT: Pharmacy Services

1. **PURPOSE AND SCOPE.** To guide a broad spectrum of operations in the Bureau pharmacy program.

2. **PROGRAM OBJECTIVES.** The expected results of this program are:

An inmate's access to quality, necessary, cost-effective pharmaceutical care will be provided.

3. **DIRECTIVES REFERENCED**

P4100.04 BOP Acquisitions Manual (5/19/04)
P4500.04 Trust Fund/Warehouse/Laundry Manual (12/15/95)
P6010.02 Health Services Administration (1/15/05)
P6013.01 Health Services Quality Improvement Program (1/15/05)
P6027.01 Health Care Provider Credential Verification, Privileges, and Practice Agreement Program (1/15/05)
P6031.01 Patient Care (1/15/05)
P6090.01 Health Information Management (1/15/05)
P6340.04 Psychiatric Services (1/15/05)
P6541.02 Over-the-Counter Medications (11/17/04)

21 CFR Chapter II, Part 1300

4. **STANDARDS REFERENCED**

a. American Correctional Association 4th Edition Standards for Adult Correctional Institutions: 4-4378 (M), 4-4379 (M), 4-4397 (M), 4-4401 (M), and 4-4402

b. American Correctional Association 3rd Edition Standards for Adult Local Detention Facilities: 3-ALDF-4E-17 (**M**), 3-ALDF-4E-12-1 (**M**), 3-ALDF-4E-18, 3-ALDF-4E-39, 3-ALDF-4E-42, and 3-ALDF-4E-43

5. **STAFFING.** Each institution will maintain a pharmacy directed by a professionally and legally qualified pharmacist and staffed by a sufficient number of trained personnel, in keeping with the size of the institution and the scope of medical services provided.

Consultant/contract pharmacists, if used, will provide the Health Services Administrator (HSA) with a written monthly report of pharmacy activities. The HSA will maintain this report on file.

6. **STANDARDS OF OPERATION.** Each institution will provide space, equipment, and supplies for the professional and administrative functions of the pharmacy to promote patient safety through the proper storage, preparation, dispensing, and administration of drugs.

a. The Chief Pharmacist will maintain up-to-date reference materials (computer-accessible or print), specifically:

- (1) Drug Information reference (e.g. Facts and Comparisons, American Hospital Formulary Service, MicroMedex, etc.);
- (2) Pharmacology/Pharmacotherapeutics reference (e.g. Goodman/Gilman's, Applied Therapeutics, Harrison's Internal Medicine, Dapiro);
- (3) Drug Interactions;
- (4) Drug Information for Patients; and
- (5) Internet access in the pharmacy.

b. Equipment in the pharmacy will include at least:

- (1) Adequate computer equipment including GroupWise access;
 - The Chief Pharmacist will be the owner of the institution pharmacy mailbox with proxy rights to a designee for leave purposes.
- (2) A refrigerator dedicated to and appropriately labeled, for the storage of medications and biologicals;
- (3) Adequate lighting and ventilation;
- (4) A sink with running water;

- (5) A system to monitor temperature control that meets compendia/Food and Drug Administration (FDA) standards. Medications are considered distressed and must be discarded if temperature controls are not maintained over a 48 hour time frame.
 - There must be either daily temperature control documentation or an electronic temperature control system that alerts staff to values outside standards.
- (6) The Bureau Correctional Institution Pharmacy System (CIPS) computer software system.

c. Key Control And Accountability. Only pharmacy staff (pharmacists and pharmacy technicians) and the off-shift duty provider will have keys to the pharmacy. Only the Chief Pharmacist and/or pharmacist-designee(s) will have access to the main stock of controlled substances.

- The key ring for the off-shift duty provider will have a key to the pharmacy, but not to the pharmacy storeroom or any key which would allow them access to main stock medications.
- Access to the controlled substances sub-stock is limited to the staff member who is responsible for the shift inventory of sub-stock. This staff member will sign the "sub-stock inventory certification sheet" for each shift.
- Each institution will develop local procedures for conducting the sub-stock shift inventory.
- The use of automated medication administration cabinets (e.g. SureMed, Pyxis) negates the need for shift inventories and proof of use (disposition) sheets for controlled substances, needles, and syringes.

7. PROCEDURES AND OPERATIONAL PRACTICES. The Chief Pharmacist will develop and maintain written procedures and operational practices pertaining to pharmaceutical services, in concert with the medical staff and, as appropriate, with representatives of other disciplines.

a. Pharmacy and Therapeutics (P&T) Committee. The Clinical Director (CD) will establish a Pharmacy and Therapeutics (P&T) Committee that will meet at least quarterly. Membership of the P&T Committee will be defined in institution policy and will

include, at a minimum, representatives from the medical (physician), psychiatric (if available), pharmacy, dental, and nursing staff, as well as Health Services Administration.

(1) **Meetings.** The required minimum agenda for this committee meeting includes:

- Determine what drugs on the National Formulary will be available locally;
- Determine what strengths and dosage forms will be available locally;
- Determine if any drugs on the National Formulary should be restricted further (i.e. designated as "Pill Line");
- Discuss and evaluate errors in prescribing, dispensing, and administering medications in the institution;
- Discuss and evaluate Adverse Drug Reactions that occur in the institution;
- Approve Drug Use Evaluations (DUEs) used in the institution;
- Review DUE data and track problems over time;
- Review changes in the National Formulary;
- Present drug information;
- Recommend that a "Request for Addition to Formulary" be completed for a specific drug; and
- Discuss Quality Improvement measures.

(2) **Minutes.** Local P&T Meeting minutes will be made available to all institution health services staff. An electronic copy of the minutes will be sent to the BOP Chief Pharmacist within 30 days of the end of the quarter. Institution P&T Committee Meeting minutes will contain:

- Date of meeting;
- List of attendees;
- Reading and acceptance of previous minutes;
- Policy and Procedure Review;
- Review of past issues;
- Formulary issues;
- Investigational drugs;
- Drug related research projects;
- Monitoring and enforcement activities;
- Medication recalls;
- Medication errors;
- Adverse drug reactions and monitoring;
- Quality Improvement activities;
- Pharmacy interventions;
- Floor stock medications;

- Drug Utilization Review;
- Completed DUEs;
- DUE proposals; and
- Overall and specific pharmaceutical cost trends.

b. **National Drug Formulary.** Each institution will use the Bureau's National Drug Formulary. The National Formulary will be issued following the publication of the National Pharmacy and Therapeutics and Formulary Meeting Minutes.

Authorization for use of items not in the national formulary must be requested from the Medical Director through the BOP Chief Pharmacist, using the "Non-Formulary Drug Authorization" form (BP-S802).

- The form will be completed and sent to the Chief Pharmacist for each medication order requesting a non-formulary item.
- The completed "Non-Formulary Drug Authorization" form will be sent electronically upon receipt of this module from the pharmacy software vendor.
- Emergency requests may be made by phone.
- The institution pharmacy will maintain a copy of all approved and disapproved non-formulary requests. The original will be filed in section 6 of the Health Record.
- Prescribing a formulary medication against a restriction placed on it during the National P&T meeting requires a non-formulary drug authorization unless otherwise stated in the formulary.
- A new non-formulary request is not required for intra-system transfers who previously had a non-formulary medication approved. The approved form, located in Section 6 of the Health Record, will be copied and retained in the pharmacy of the current institution.

The "Request for Addition to Formulary" form (BP-S804) must be used to request a drug item be added to the National Formulary. This form should be routed through the local P&T Committee and then sent to the BOP Chief Pharmacist.

- All requests will be reviewed at the annual National Pharmacy and Therapeutics (P&T) Meeting.

- Recommendations for formulary deletions, restrictions, etc., must also be submitted on this form.

Updates to the National Formulary will be published regularly following National P&T review. Comments and suggestions should be directed to the BOP Chief Pharmacist.

Unless indicated as a non-substitutable product (i.e. negative formulary), proprietary (brand) names are used as examples for identification purposes only. All institutions will use the least expensive A/B rated generic when possible. "Dispense as Written" (DAW) orders will be processed as a non-formulary medication order and must include appropriate justification from the prescriber.

The institution P&T Committee may use a local formulary based on the National Formulary.

- A local formulary can only be more restrictive than the National Formulary. Medications may not be added or restrictions removed.
- Local formularies will be made available to all of the institution's health services staff and consultants.

c. **Training and Education.** Pharmacy personnel will participate in relevant education programs, including orientation of new employees, in-service, and outside continuing education. The institution Chief Pharmacist will maintain participation documentation.

All health care providers performing pill line, physicians, and pharmacy technicians will complete pharmacy orientation as part of the Health Services Orientation. These staff will have documentation in their credentialing file indicating they have completed the Pharmacy Services Orientation, before beginning work in the Pharmacy.

- After completing this orientation, these providers can **administer** medication doses, or **distribute** medication orders to inmates, but they cannot **dispense** medication orders.

d. **Patient Safety.** The institution Chief Pharmacist will ensure there are written procedures in place for patient safety and the control, accountability, and distribution of drugs. These procedures will be reviewed/revised annually, as necessary, and are subject to local negotiation.

- All drugs will be labeled adequately, including the addition of accessory or cautionary statements, and the expiration date, if appropriate.
- Discontinued and outdated drugs and containers with worn, illegible, or missing labels will be returned to the pharmacy for proper disposition.

e. **Dispensing Medication Orders.** Before a medication order is dispensed, a pharmacist will review it prospectively for the following:

- drug/drug interactions;
- drug/disease interactions;
- drug/food interactions;
- therapeutic duplications;
- over use/under use;
- allergies;
- therapeutic appropriateness;
- appropriate dose;
- appropriate route of administration;
- duration of therapy;
- adverse drug reactions;
- proper laboratory monitoring;
- appropriate clinical outcomes; and
- provide the final check of the medication order to ensure it contains the correct drug.

The label will contain the correct directions and patient information pursuant to the medication order. Proper cautionary statements will be included on the vial.

Any items which are changed must be documented in the Health Record justifying the need for the change.

A practitioner with "independent status" (i.e. physician or pharmacist) must check each medication order before it is dispensed to the patient, ensuring the appropriate prospective review has been completed.

- Although dentists have "independent status" they are not allowed to dispense as a majority of medications fall outside the scope of their practice.
- Health care providers, such as MLPs, EMTs, nurses, medical technicians, and pharmacy technicians do not have independent status. As such, health care providers will not be assigned Pharmacist duties.

- (1) In order to satisfy these requirements during evenings and weekends, each institution will use a "drug administration cabinet". This may be as sophisticated as a Pyxis Medstation, a Meditrol, or a Documed Station, or as simple as a locked, metal cabinet in the urgent care room, or a designated area in the pharmacy.
 - This cabinet will contain a limited number and supply of urgently needed drugs that are commonly used after hours in the institution.
 - These drugs should be in single dose or single day packages but in some cases may be in a three day supply to ensure coverage for weekends and holidays.
 - These medications will be pre-labeled with standard directions and the name and strength of the drug.
- (2) When the after-hours health care provider needs to give an inmate a medication, the following options will be used.
 - (a) The inmate may be placed on pill line to be administered single doses of the prescribed medication until a medication order can be dispensed.
 - (b) The health care provider may access the off-shift drug administration cabinet, remove a pre-packaged container, and:
 - write the inmate's name and number;
 - the date;
 - the provider's name;
 - the expiration date on the package; and
 - distribute it to the inmate.
 - (c) A medication order will be written for the pharmacist to review retrospectively.
 - (d) A log book will be maintained for the off-shift medication cabinet, to record drugs and doses that are distributed from the cabinet. The log book will contain:
 - date;
 - time;

- inmate name;
- register number;
- drug;
- amount dispensed; and
- provider's signature.

- (e) Where an automated medication distribution system is used as the drug administration cabinet, the distribution/administration report will provide documentation of these occurrences in lieu of the log book.
- (f) The next working day, the pharmacist will:
- enter the order into the pharmacy computer;
 - review the order retrospectively;
 - fill the order for the amount written less the dose(s) distributed or administered by the health care provider;
 - provide a "final check" of the medication order; and
 - dispense the completed order to the inmate.
- (g) The practice agreement for MLPs will state specifically they may access the drug administration cabinet and pill line stock. **Pill line stock will not be bulk stock containers.** Local procedures will specify the system in use at each institution. Pill line stock may include:
- unit-dose packaging appropriately labeled;
 - medication order labeled vials with a seven to 30 day supply of the inmate's medication;
 - heat-sealed blister cards filled or checked by the pharmacist; and
 - automated medication administration cabinets (e.g. Pyxis Envoy).
- (h) Non-pharmacist health care providers will not have access to bulk stock packages that would permit them to actually dispense a medication order or administer doses.
- The only exception to the above is described in Section 9.c.

- (3) Inmates transferring to other institutions in/out of the Bureau will have their medications listed on a Medical Summary of Federal Prisoner/Alien in Transit (BP-S659) form, which is delivered in a timely manner to the pharmacy for processing.

f. **Inspections.** The Chief Pharmacist or designee will conduct at least quarterly inspections of all areas where medications are dispensed, administered, or stored. The Chief Pharmacist will maintain a record of quarterly inspections for at least two years.

g. **Drug Monitoring.** The Chief Pharmacist will provide drug monitoring services keeping with each patient's needs, FDA and manufacturer recommendations, and practices recommended through drug information references.

8. DEA CONTROLLED SUBSTANCES

a. **Applicability of Federal Law.** Drug Enforcement Administration (DEA) controlled substances are drugs and drug products under jurisdiction of the Controlled Substances Act of 1970 and are divided into five schedules (I, II, III, IV, and V).

- Nothing in this chapter will be construed as authorizing or permitting any person to engage in any act that is not authorized or permitted under existing federal laws, or that does not meet regulations published in the most recent edition of Title 21, Chapter II, of the Code of Federal Regulations (21 CFR, Part 1300 to end).

Application for a new or renewed registration number under the Controlled Substances Act includes the following procedures.

- (1) To obtain an initial DEA registration number, each Chief Pharmacist will complete and forward a New Application for Registration form (DEA-224), to the BOP Chief Pharmacist for certification.
- For renewal, Form DEA-224a will be sent to the Central Office, Attn: Chief Pharmacist, BOP, 320 First Street NW, Washington, DC 20853 for certification (there is no cost for new or renewal registration).
 - The BOP Chief Pharmacist will verify fee exemption status.
 - The phone number for DEA registration and renewal is 1-800-882-9539.

- (2) "Registration Classification" on Form DEA-224 will be checked as "hospital/clinic." There will be only one official registration number for each Bureau institution.
- (3) The DEA registration number will be used only for official federal business.
- (4) The BOP Chief Pharmacist will forward the certified form to the DEA, which will send the new or renewed registration number to the institution.
- (5) The institution Chief Pharmacist will complete and submit these forms. At institutions without a pharmacist on staff, the HSA will retain this responsibility.

b. **Responsibility.** The Chief Pharmacist will be the responsible authority for all DEA controlled substances. The main stock will be kept locked and stored in a vault or safe to which only the Chief Pharmacist and/or pharmacist designee(s) has the combination or keys.

- The HSA will ensure that a duplicate set of keys or combinations of all vaults and safes in the HSU will be sealed in separate envelopes, plainly marked with contents, and filed in the Warden's or security officer's vault or safe.
- The Chief Pharmacist or designee must be present for any inventories, inspections, searches, or shakedowns of the storeroom, vaults or safes.
- The Chief Pharmacist will ensure that all combinations or locks to main stock vaults or safes storing DEA controlled substances are changed:
 - (1) At transfer, reassignment, or termination of applicable HSU administrative or pharmacy personnel, or
 - (2) When unusual circumstances dictate increased internal control measures.

c. **Purchasing/Receiving.** Purchase orders for controlled substances will be prepared by a designated employee without the knowledge or assistance of inmates.

- Controlled substances will be stocked in single-dose packaging when available.

- The Chief Pharmacist will establish a proper system of security for their receipt.
- d. **Records.** The pharmacist will maintain adequate main stock records for each controlled substance. Headings will indicate:

- sub-stock unit;
- date;
- record number/P.O. number;
- quantity received;
- quantity issued to sub-stock; and
- balance on hand.

Sub-stock records address the administration of medication on medical/nursing units or on pill line. Sub-stock will have records maintained for proof of use for each DEA controlled substance on hand. Each proof of use sheet will contain:

- name and strength of drug;
- date issued;
- amount issued;
- pharmacy control number;
- department location (if applicable);
- date and amount returned;
- date and time of administration;
- name and number of inmate;
- dosage administered;
- corresponding medication order number (CIPS);
- signature of person administering; and
- balance on hand.

The completed proof of use sheet will be returned to the pharmacy, and kept with controlled substances records.

At the start of each shift, staff will conduct a complete DEA sub-stock inventory in accordance with local procedures. If the inventory is not correct, staff will attempt to resolve the differences immediately.

- The staff member discovering the discrepancy will write a memo to the Chief Pharmacist explaining the event.
- If the discrepancy is not resolved, the Chief Pharmacist or designee, will notify the HSA, to ensure that its possible cause(s) is identified.
- For institutions using a computer driven medication station, the pharmacist will generate sub-stock discrepancy reports daily.

- The pharmacist will review and sign these reports and file them with the controlled substance main stock records.

The staff member completing the sub-stock inventory certification sheet will return it to the pharmacy. The pharmacist will review and retain the forms for two years prior to the last federally mandated biennial inventory. The change of shift record will include:

- date and time of the count;
- signature of off going and oncoming staff; and
- exact quantity of all controlled substances on hand in that sub-stock at that time.

The use of automated medication administration cabinets (e.g. SureMed, Pyxis) negates the necessity for shift inventories, proof of use sheets, and disposition sheets for DEA controlled substances, needles, and syringes.

All inventories and listings in the controlled substance records will be exact using tablets, capsules, vials, etc., not in units of bottles or other bulk measurements.

When a Chief Pharmacist permanently departs from an institution, he/she and the oncoming Chief Pharmacist (or the acting Chief Pharmacist or the HSA) will complete an immediate inventory of:

- main stock controlled substances;
- perpetual inventory;
- purchase orders;
- federal order forms;
- receivers; and
- invoices.

When a newly selected Chief Pharmacist arrives at an institution, he/she and the HSA will complete a similar inventory immediately.

Controlled substances in sub-stocks are to be used for administration only. Any dispensing of controlled substances will be accomplished through main stock.

e. **Security.** The DEA, per 21 CFR Part 1301.72, requires safeguarding and accounting for all controlled substances.

- Main stock controlled substances will be stored in a vault or safe.
- Sub-stock controlled substances will be stored in a stationary, approved steel cabinet with two separately key-locked steel doors, a safe with a keyed padlock, or an automated medication cabinet (e.g., SureMed, Pyxis).
- When a controlled substance requires refrigeration, the medication must be secured in a locked refrigerator or in a locked drawer within the refrigerator.

f. **Biennial Inventory.** The Controlled Substances Act requires each registrant to make a complete and accurate record of all controlled substance stock on hand every two years. The Chief Pharmacist will complete the biennial inventory on the date mandated by federal law (May 1 of odd-numbered years for institutions registered before May 1, 1971; for institutions registered after May 1, 1971, every two years on the date of the initial inventory).

The actual taking of the inventory will not vary more than four days from the biennial inventory date. The Chief Pharmacist will maintain the inventory with the controlled substances records. The inventory record must:

- (1) List the registrant's name, address, and DEA registration number;
- (2) Indicate the date and time the inventory is taken (i.e., opening or close of business);
- (3) Be signed by the person or persons responsible for taking the inventory;
- (4) Be maintained at the location appearing on the registration certificate for at least two years prior to the last federally mandated inventory;
- (5) List the name of each controlled substance;
- (6) List the dosage form and unit strength of each controlled substance;
- (7) List the number of units in each container of each controlled substance;
- (8) List the number of each container of each controlled substance;

(9) Separate Schedule II controlled substances from all others; and

(10) Include main stock and all sub-stocks.

g. **Additional Auditing Requirements.** Corrected or amended medication orders may not be processed for controlled substances. A new medication order will be written.

Any record keeping error will be corrected by the person who made the error by drawing one line through the error, writing an explanation directly below, and initialing. Errors may not be "blacked out."

(1) **Theft or Loss.** Any incident of theft or loss must be documented by the individual discovering it. A copy of the documentation will be sent to the Chief Pharmacist for review and filing. The Chief Pharmacist will in turn send a memo to the HSA, with a copy to the Warden. The Warden will notify the DEA via DEA Form 106.

In accordance with 21 CFR 1301.76(b), the DEA Form 106 must contain:

- (a) Name and address of the facility;
- (b) DEA Registration Number;
- (c) Date of the theft;
- (d) The fact that the local police department was notified;
- (e) The type of theft;
- (f) A list of the symbols or cost code (if any) used by the facility; and
- (g) A list of the controlled substance(s) missing.

The report is made in triplicate. The pharmacy keeps the original copy, and forwards the other two copies to the Regional DEA Office.

(2) **Controlled Substances Inventory Team.** The HSA will designate, in writing, a Health Services supervisor as Chair of the Quarterly Controlled Substances Inventory Team. The Controlled Substances Inventory Team will consist of the chair and at least one other supervisor.

- The Chief Pharmacist will be a technical advisor and will be present during the inventory, but may not be a team member.

- The team will conduct a quarterly count of all main stock controlled substances.
- Each team member will then sign the Quarterly Controlled Substance Audit Team Certificate form to be filed with the controlled substance records. A copy of this form does not need to be sent to the BOP Chief Pharmacist.
- This count may be done at anytime within the time frame of the quarter.

(3) **Quarterly Report.** At the end of each quarter, the Chief Pharmacist will complete a Quarterly Report for Narcotics and other Controlled Substances inventory form. An electronic copy will be submitted to the BOP Chief Pharmacist within 30 days of the end of the quarter. Each quarterly report will reflect the usage pertaining to the following dates (variance from these dates will not be allowed):

- 1st Quarter = October 1 to December 31
- 2nd Quarter = January 1 to March 31
- 3rd Quarter = April 1 to June 30
- 4th Quarter = July 1 to September 30

h. **Disposal.** The Chief Pharmacist or designee will dispose of controlled substances when necessary, in the manner prescribed by the DEA in 21 CFR 1307.21.

This disposal will be accomplished in one of two methods:

- (1) Request from the Special Agent-in-Charge at the Regional DEA Office, in writing, that permission be granted for the facility to self-dispose of controlled substances; or
- (2) By transfer to a DEA approved vendor that is certified to dispose of controlled substances.

9. DISPENSING AND ADMINISTRATION

a. Definitions

- (1) **Administration** is defined as providing one dose of medication to be applied or consumed immediately.
- (2) **Dispensing** is defined as placing multiple doses in a properly labeled container for use over a period of

time, i.e., filling a medication order. Dispensing is the act of prospectively reviewing the medication order as described in Section 7.e.

- Only pharmacists may dispense medications.

(3) **Distribution** is defined as physically handing a filled medication order or OTC (over-the-counter) product to an inmate. Any health care provider who has completed the Pharmacy Training and Orientation Program can distribute or administer medications.

b. **Prescribing Restrictions.** All DEA controlled substances, psychiatric medications, and other medications restricted to "physician use only" by the BOP National Formulary prescribed by a MLP must be countersigned by a staff physician before the medication order may be processed and dispensed.

- Local policies will address a process of review in the absence of a full time physician.

c. **Options During the Absence of the Pharmacist.** During periods when a pharmacist is not available (e.g. annual refresher training, CME, etc.) one of the following options will be used:

- **Contracting (Amend Existing Contract).** Incorporate a requirement for pharmacist back-up coverage in the comprehensive medical contract.
- **Contracting (Establish Separate Contract).** Contract with a firm that is capable of providing temporary pharmacist services using open market procurement procedures or existing Federal Supply Schedules (FSS). The Bureau of Prisons Acquisition Policy (BPAP), Part 37, stipulates various requirements relating to using private sector temporary services. The Chief Executive Officer and Regional Director must approve a written justification prior to the acquisition.
- **Interagency Agreements.** Establish an interagency agreement with another government agency (e.g., VA or DOD) to provide pharmacist coverage on an "as needed" basis.
- **TDY Within the Bureau.** Arrange/plan for TDY pharmacist assistance from another Bureau institution with more than one pharmacist.

- **Use PHS Officers from Outside the Bureau.** Secure TDY assistance from PHS officers assigned to other government agencies. (The institution needing the pharmacist is responsible for travel, lodging, and per diem.) The BOP Chief Pharmacist can help identify pharmacists in this category **or** use a PHS inactive reserve corps officer through the BOP-PHS liaison and the PHS Inactive Reserve Coordinator.
- **Obtain the Services of a Second Pharmacist** for larger institutions, particularly those with a satellite camp or FDC. In this situation, pharmacy hours of operation could be extended, vacations, training, and sick leave covered, and quality services can be maintained.

Physicians are responsible for diagnosing and treating patients and may only dispense medications in emergency situations. All of the above options must be actively pursued and exhausted. Institutions without the services of a pharmacist for more than three days will contact the Medical Director for guidance.

d. **Administration.** To ensure that medications are actually consumed at pill line, the following procedures will be followed.

- The pharmacist or pharmacy technician will prepare a CIPS-generated Medication Administration Record (MAR) sheet for use at pill line.
- The person administering the medication will identify each inmate by examining two forms of identification (e.g. photo ID, DOB, registration number, name, etc.) of anyone who arrives to receive medication.
- The inmate will swallow the dose of medication and the water while being observed directly by the staff member.
- The inmate will then show the empty dose cup and water cup to the person conducting pill line before disposal.
- The inmate will be asked to open his/her mouth to show that the medication has not been "cheeked" before leaving the window.
- Medications should not be removed from their packaging or labeling until being administered.

- The administration of medication should be documented in the MAR after it is completed.
- When an inmate refuses to take a prescribed pill line or inpatient administered medication, or is a "no-show," that decision will be documented on the MAR.

Unless local institution security requirements dictate otherwise, medication dispensing will be in light-resistant, moisture-resistant vials and not plastic bags.

e. **DEA Controlled Substances.** The physician or dentist will initiate or countersign the medication order in the health record which will include:

- controlled substance;
- DEA number;
- strength;
- directions; and
- duration of therapy.

Health Services staff may accept a verbal order, but the physician or dentist must countersign the verbal order within 24 hours or by the close of the next workday.

Schedule II controlled substance orders will be valid for 72 hours only (with the exception of detox medications). Schedule III, IV, and V orders may be written for not more than 30 days.

- An exception to this requirement is when DEA controlled substances are used for seizure disorders unless otherwise restricted in the BOP National Formulary. Then, medication orders can be written for up to 180 days.
- All orders for controlled substances used for hypnotic purposes will be valid for not more than seven days.
- All orders for substances (Schedule II - V) used in cases of chronic or terminal illness resulting in unremitting pain not likely to abate in the short term and drugs used for narcolepsy or ADHD will be valid for up to 30 days.
- All such orders must be supported by on-going documentation in the health record or inpatient record.

Accountability. Consistent with 21 CFR, Part 1300, Section 1304.4, the Chief Pharmacist will maintain all records pertaining to purchase, administration, inventory, and audits for at least two years prior to the most recent federal biennial inventory. These records will be kept in a vault, safe, or other secure area. No other items may be stored with DEA controlled substances or their records.

- Daily, the pharmacist will generate a CIPS controlled substance report. The report will be maintained with other controlled substance documentation in accordance with DEA regulations.

Controlled substances that are damaged, expired, or retrieved from inmates through R/D will be segregated in the safe from other controlled substances.

- A separate "Outdate & Confiscate" log will serve as an inventory as long as the medications are in the facility.

Ordinarily, all DEA controlled substances taken by mouth will be crushed or administered in liquid form. Pharmacy staff will issue crushed medication in single dose packaging already crushed.

f. **Restricted Drugs.** Restricted drugs are defined as non-DEA controlled drugs that may be abused or those that require Directly Observed Therapy (DOT). Ordering, prescribing, dispensing, and accounting for restricted medications will be in accordance with local and Bureau procedures.

The Chief Pharmacist will ensure that medication is not subject to excessive exposure to heat, light, and moisture.

All restricted drugs to be taken by mouth will be administered in single doses, and swallowed in the presence of an employee to ensure that the medication is ingested, in accordance with the procedures outlined in Section 9.d.

g. **Medication Orders.** A medication order is any medication a health care practitioner orders for a patient. A health care practitioner will reevaluate each medication order prior to writing a renewal order.

- All medication orders for chronic care medications are valid for no more than 30 days with five refills totaling 180 days (**except for controlled substances unless used for seizure control and other medications specifically restricted by the BOP National Formulary**).
- When available, the Prescriber Order Entry (POE) will be used to prescribe and process all medication orders. This does not negate the need for the pharmacist to have access to the patient's health record.
- Local CIPS data will be backed up each work day.

All institutions will have a system(s) in place for ensuring medications not picked up by inmates are logged into the CIPS computer system along with documentation in the inmate health record.

The distribution of drug samples within the institution is prohibited.

A staff physician will review and cosign orders written by consultant physicians.

- The pharmacy department will have a means to identify the signatures of all staff practitioners authorized to prescribe.

When an inmate is hospitalized, undergoes surgery, or is transferred from outpatient to inpatient status, or inpatient to outpatient status, current drug orders are to be discontinued automatically.

- Local procedures will determine automatic stop orders for drugs in other circumstances. (Stop order dates for DEA controlled substances are addressed in Section 9.e.)

All medications arriving with inmates through receiving and discharge as new commitments will be given to the Chief Pharmacist or designee.

- The Chief Pharmacist will dispose of all DEA controlled substances in a manner prescribed by the DEA.
- Pharmacy staff will dispose of all other medications according to local procedures.

- During the intake screening process, health care staff will determine the need for any medication orders. The Pharmacy will ensure that adequate supplies are on hand prior to disposal. These medications, if appropriate, will be administered on pill line until the pharmacy is able to obtain the drug(s).
- An inmate may retain medications prescribed by another Bureau institution if they are not otherwise restricted by policy (e.g. controlled substance).

h. Medications for Inmates in Special Housing Units (SHU).

Every workday, the Chief Pharmacist will obtain a list of all inmates placed in a SHU during the previous 24 hours (e.g. SENTRY, Operations Lieutenant). Using this list, the pharmacist will issue current medication(s) and ensure the MAR is available for administration of all restricted medications during SHU rounds.

- Local procedures will be developed and negotiated to retrieve the inmate's confiscated medication. Health Services staff will determine if the medication should be administered or redistributed to the inmate, if appropriate.
- Local policies and procedures will stipulate the medication(s) and amount (number of days) an inmate in SHU may maintain in their cell.
- Under no circumstances will medication be locked up with the inmate's property, thrown in "hot trash," or distributed or administered to an inmate by anyone other than a health care provider.

i. Psychiatric Medication. Refer to Program Statement on Psychiatric Services for procedures on obtaining informed consent, non-compliance, and patient counseling.

Informed consent will be obtained and documented before dispensing or administering psychiatric medication. Ordinarily, the prescribing physician will be responsible for obtaining the informed consent.

- Psychiatric medication for a current DSM Axis III diagnosis does not require an informed consent (e.g. amitriptyline for trigeminal neuralgia or headache disorder), but does require routine patient counseling procedures.

(1) **Continuity of Care.** All institutions will have a system(s) in place for ensuring continuity of care for all inmates receiving psychiatric treatment. This system will include:

- Review of psychiatric history prior to incarceration;
- Review of psychiatric treatment prior to intra-system transfer;
- Monitoring compliance with psychiatric medications; and
- Maintaining documented informed consent in the health record.

(2) **Non-Compliance.** All institutions will have a system(s) in place for timely notification of noncompliance. Such notification will be made to the CD and other relevant mental health staff, such as the Chief of Psychology, treating staff, or contract psychiatrist.

- At Psychiatric Referral Centers (PRCs), the treating psychiatrist and Chief Psychiatrist will be informed of any noncompliance issues.

j. **OTC Medications.** See the Program Statement on Over-the-Counter Medications.

k. **Outdated Medications.** The Chief Pharmacist will maintain adequate records and procedures to ensure that outdated medications are not used.

- Expired medications must be stored separately.
- Expiration dates will be the last day of the month unless otherwise specified.
- Local procedures will be written for disposal of expired medications.

When multi-dose vials of injectable medications are opened, the expiration date will be regarded as the manufacturer's expiration date as long as aseptic technique is used, unless otherwise stated by the manufacturer in the package labeling.

l. **Hormone Maintenance Drugs.** Refer to the Program Statement on Patient Care.

m. **Investigational/Experimental Drugs.** Refer to the Program Statement on Patient Care.

10. MEDICATION ERRORS

a. Definitions

- (1) A **medication error** is a dose of medication that deviates from the physician's order as written in the inmate's health record or from the expected standard of care, or institution policy and procedures.
 - With the exception of errors of omission, the patient must actually receive the drug for the incident to be classified as a medication error.
- (2) A **potential error** is a mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention, by another health care provider or the inmate, before actual medication administration.
 - Documentation of instances in which an individual has prevented the occurrence of a medication error will help identify system weaknesses and reinforce the importance of multiple checks in the medication use system.

b. **Types of Medication Errors.** Based on the American Society of Health Systems Pharmacists (ASHP) Guidelines, medication errors will be categorized as follows:

- **Prescribing Error.** An incorrect drug selection (based on indicators, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rates of administration, or instructions for using a drug product ordered or authorized by a physician (or other legitimate prescriber). This includes illegible medication orders that lead to errors that reach the patient.
- **Omission Error.** The failure to administer an ordered dose to a patient before the next scheduled dose, if any.
- **Wrong Time Error.** Administration of a medication outside a predefined time interval from its scheduled administration time.

- **Unauthorized Drug Error.** Administration to the patient of medication not authorized by a legitimate prescriber for the patient.
- **Improper Dose Error.** Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the inmate.
- **Wrong Dosage Form Error.** Administration to the patient of a medication in a different dosage form than ordered by the prescriber (e.g., intramuscular instead of intravenous).
- **Wrong Drug-Preparation Error.** Medication incorrectly formulated or manipulated before administration.
- **Wrong Administration Technique Error.** Inappropriate procedure or improper technique in the administration of a drug.
- **Deteriorated Drug Error.** Administration of a medication that has expired or for which the physical or chemical dosage form integrity has been compromised.
- **Monitoring Error.** Failure to review a prescribed regimen for appropriateness and detection of problems, or, failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.
- **Compliance Error.** Inappropriate patient behavior regarding adherence to a prescribed medication regimen.
- **Other Medication Errors.** Any medication error that does not fall into one of the above predefined categories.

c. **Applicability and Procedures.** Listed below are the required elements of the institution's Medication Error Program. The Pharmacy Technical Reference Manual (TRM) should be used as a reference for the institution program.

- The monitoring and reporting of medication errors will be conducted in a **blame-free** manner and focus primarily on systems and continuous quality improvement activities rather than on individuals.

(1) **Organizational Responsibilities.** Sufficient personnel must be available to perform tasks adequately and a suitable work environment must exist for preparing drug products.

- Lines of authority will be clearly defined for medication ordering, dispensing, and administration.

A formal Drug Use Evaluation (DUE) program will be integrated and coordinated with the overall institution Quality Improvement Program (QIP). The institution's QIP will include monitoring, evaluation, and resolution of problems in the area of quality and appropriateness of patient care services the pharmacy department provides.

- Pharmacists and others responsible for processing medication orders will have routine access to appropriate clinical information and patients (including medication, allergy and hypersensitivity profiles; diagnoses; pregnancy status; and laboratory values) to help them evaluate the appropriateness of medication orders.

Pharmacists will maintain medication profiles for all patients, both inpatients and ambulatory patients, who receive care at the institution. This profile will include adequate information to allow monitoring of the following:

- medication histories;
- allergies;
- potential drug interactions and Adverse Drug Reactions (ADRs);
- duplicate drug therapies;
- pertinent laboratory data; and
- other information.

The Pharmacy Department must be solely responsible for procuring, distributing, and controlling all drugs used within the organization.

- The preferred administration method is the unit dose drug distribution and control system.

- Comprehensive policies and procedures that provide for efficient and safe distribution of all medications and related supplies to patients will be established.
- Except in emergencies, all sterile and non-sterile drug products will be dispensed from the pharmacy.
- The storage of non-emergency floor stock medications on the nursing units or in other patient care areas will be limited to OTCs and stat dose quantities of selected drugs.
- Only abbreviations approved in the Program Statement on Health Information Management may be used.

The telephone number of the local **poison control center** will be displayed prominently in the pharmacy and readily available in areas where medications are dispensed/administered.

The pharmacy department, in conjunction with nursing, risk management, QIP, and the medical staff, will conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence.

(2) **Prescriber Responsibilities.** Prescribers will evaluate the patient's total status and review all existing drug therapy before prescribing new or additional medications.

- Prescribers will be familiar with the medication use system in place within the institution (e.g., the formulary system, DUE programs, allowable delegation of authority, procedures to alert nurses and others to new drug orders, standard administration times, and approved abbreviations).

Medication orders written in the health record and inpatient record, must be complete and will include:

- drug name;
- route and site of administration;
- dosage form;
- dose;
- strength;
- frequency of administration;

- duration of therapy; and
- prescriber's name.

In some cases, a dilution, rate, and time of administration should be specified.

Prescribers will write legible medication orders. An illegible handwritten order will be returned to the prescriber and regarded as a potential error.

Medication orders will include specific instructions rather than using non-standard or ambiguous abbreviations. Specific instructions help differentiate among intended drugs.

- Medication orders will include standard nomenclature, using the drug's name. Avoid locally coined names (e.g., Dr. Doe's compound); chemical names; unestablished abbreviated drug names; acronyms; and apothecary or chemical symbols.
- Always use a leading zero before a decimal expression of less than one (e.g., 0.5 ml).
- A terminal zero will not be used (e.g., 5.0 ml).

Ordinarily, verbal orders will be reserved for emergency situations. When it is impossible for the provider to write the order, the following must occur:

- The health care provider will read the order back to the prescriber to confirm it.
- The health care provider receiving the verbal order will write the order in the patient's health record.
- The prescriber will confirm the order by signing the chart entry within 24 hours or the next working day.

- (3) **Pharmacist Responsibilities.** Pharmacists will participate in drug therapy monitoring and DUE activities to help achieve safe, effective, and rational use of drugs.

Pharmacists must be familiar with the medication use system in place within the institution, including:

- the formulary system;
- DUE programs;
- allowable delegation of authority procedures;
- procedures to alert health care providers and others to new drug orders;
- standard administration times;

Each institution will have a local policy outlining procedures to be followed for "hold" orders.

Before dispensing medications in non-emergency situations, the pharmacist will review an original copy of the written medication order. Pharmacists will have a system for self-checking the reading of medication orders, labeling, and dosage calculations.

- When possible, for high risk drug products, all work should be double checked by another member of the pharmacy staff (e.g., injectable/IV admixtures, cancer medications).

Pharmacists will dispense medications in ready-to-administer dosage forms whenever possible. Pharmacists will ensure timely delivery of medications to the patient care area after receipt of the orders.

- If medications doses are not delivered or therapy is delayed pending resolution of a detected problem (e.g., allergy or contraindications), the pharmacist will inform the health care staff of the delay and the reason.

Pharmacy staff will review medications that are returned to the department. Such review processes may reveal system breakdown or problems that resulted in medication errors (e.g., omitted doses and unauthorized drugs).

c. Monitoring and Managing Medication Errors. The staff member identifying the error will report potential and actual medication errors on the Medication Error form (BP-S795). The electronic version of this form will be used when available.

- (1) Physician notification will be made when clinically indicated.

The Medication Error form will be submitted to the institution Chief Pharmacist who will report this information to the QIP Coordinator.

- (2) The QIP coordinator will furnish a copy of the Medication Error Report or a summary of all reports, to the HSA.
- (3) After reviewing the available information, the HSA, Clinical Director, and Chief Pharmacist may determine that immediate intervention (e.g. further education) is necessary to prevent further repeats of the same or similar error, rather than wait on the conclusions of the P&T Committee.

Medication Error Severity Ratings

Level 0	No medication error occurred (<u>potential errors rated Level 0</u>))
Level 1	An error occurred that did not result in patient harm
Level 2	An error occurred that resulted in the need for increased patient monitoring, but no change in vital signs and no patient harm
Level 3	An error occurred that resulted in the need for increased patient monitoring with a change in vital signs but no ultimate patient harm, or, Any error that resulted in the need for increased laboratory monitoring
Level 4	An error occurred that resulted in the need for treatment with another drug or an increased length of stay
Level 5	An error occurred that resulted in permanent patient harm (sentinel event)
Level 6	An error occurred that resulted in patient death (sentinel event)

The QIP coordinator and the Chief Pharmacist will meet at least quarterly to review the forms collected, analyze, and classify the errors, and prepare a Medication Error Review Summary (BP-S796) to report at the P&T Committee.

- This summary will not identify those making the error by name.
- An electronic copy of this summary will be sent to the BOP Chief Pharmacist for informational purposes.

The P&T Committee will suggest process improvements that result from the review. Suggestions may include:

- Conducting organizational staff education;
- Making recommendations for staffing levels;
- Revising policies and procedures, or
- Changing facilities, equipment, or supplies.

d. **Error Resolution.** All errors will be reviewed and researched by the QIP coordinator or Chief Pharmacist.

- The P&T Committee will research errors for correctable administrative and clinical issues and report medication errors in the meeting minutes.

In the large majority of cases, one or more of the following actions are appropriate:

- Error discussion;
- Staff training; and
- Local peer review. (Refer to Program Statement on Credentialing, Privileging and Practice Agreements)

Reviews should focus on the improvement of performance by recognizing errors and developing a plan to minimize future errors.

- A Focus Review Team should evaluate errors resulting in permanent patient harm or death (e.g. sentinel events).

11. **ADVERSE DRUG REACTION REPORTING AND DRUG RECALL.** The Health Services Division participates in adverse reaction reporting programs sponsored by the Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS).

- Institutions will use the Adverse Drug Reaction Monitoring and Prevention Program outlined in the Pharmacy TRM.
- Drug product defects will be reported in accordance with the FDA drug product problem reporting program.
- A drug recall procedure that can be implemented readily, including provisions for documenting results, will be initiated.
- Adverse Drug Reactions and drug recalls will be reported in the institution P&T Minutes.

12. RELEASE/TRANSFER MEDICATION. When an inmate is transferred to a CCC, up to a 90 day supply of current medication will be provided pursuant to a new medication order. The number of days supplied will be determined on a case-by-case basis, dependent upon clinical justification and release planning for the inmate (i.e., insurance, Medicaid, Aids Drugs Assistance Programs (ADAP) availability).

- Unless properly justified, a minimum of 30 days supply of chronic medications will be provided.
- Inmates requiring DEA controlled substances may be considered for transfer to a CCC after institution staff consult with the Community Corrections Manager (CCM) to determine if the respective CCC can accommodate the inmate's special medication needs.

An inmate releasing from custody will be provided a 30 day supply of medication. The medication, with directions, will be given to the releasing officer as indicated by local procedure.

- All release medications will be dispensed in an approved child-resistant container unless waived by the inmate or clinically justified (e.g. disability, etc.).

All intra-system transfers will be provided with a minimum seven day supply of all clinically necessary medications as noted on the Medical Summary of Federal Prisoner/Alien in Transit form (BP-S659) .

- On a case-by-case basis, additional medication may be necessary en route to the next institution, with consideration given to length of time, mode of travel, and availability of medication at the next institution.
- All DEA controlled substances and other items subject to abuse will be restricted to minimum quantities.
- An inmate brought in from another Bureau institution (intra-system transfer) may use medication at the receiving institution in accordance with local policy.

A copy of the Medical Summary of Federal Prisoner/Alien in Transit (BP-S659) form may be used to transcribe current medications.

13. **PRIME VENDOR CONTRACT.** The national contracts for medications and pharmaceutical products are **mandatory**. All institutions will order from these contracts, which are applicable for Federal Supply Schedule (FSS), General Services Administration (GSA), and Blanket Purchase Agreement (BPA) contract pharmaceutical items.

- If the items are identified on the computer database as non-contract items, normal procurement procedures will be used; i.e., purchase from FSS, mandatory source, or open market.

The Chief Pharmacist will implement the prime vendor contract at the institution. Procedures for delivery and receipt of medications will be developed locally in conjunction with the warehouse.

- Questions that cannot be resolved by the Prime Vendor regarding the contract will be directed to the BOP Chief Pharmacist.
- The Chief Pharmacist will ensure institution compliance with the Prime Vendor Procedural Guide. A current guide can be obtained from the Prime Vendor.

Mandatory national contracts exist for selected medications listed in the National Formulary. In these cases, institutions **must** use only the specified brand of the product under contract, when available.

- In order to receive the beneficial contracted price, no institution is authorized to vary from this requirement.

All medications indicated for treatment or manifestations of HIV and AIDS will be listed separately on a purchase order under project number **84-U** if purchased from a vendor **other than** the Prime Vendor. HIV/AIDS medications purchased from the Prime Vendor will use the project number designated to their respective region:

NER	73L	MAR	74L
SER	75L	SCR	76L
NCR	77L	WXR	78L

Medications used to treat Hepatitis C Virus (HCV) infection, such as Interferon Alfa 2B, Interferon Alfa con-1, and ribavirin, will be ordered using project number **31-J**.

Medications other than those to treat HCV or HIV/AIDS will be ordered from the Prime Vendor using the following project number designated to their respective region:

NER	72I	MAR	73I
SER	74I	SCR	75I
NCR	76I	WXR	77I

14. NEEDLES AND SYRINGES. The HSA or designee will be responsible for the control of needles and syringes. The importance of proper control and use cannot be overstated.

- **All** unused needles and syringes in sub-stocks will be inventoried on each medically staffed shift. For institutions using computer driven medication stations (e.g. SureMed or Pyxis) for needle and syringe accountability, the shift inventories and disposition sheets are not required.
- Local procedures will specify responsibility for conducting the inventory.
- The time the inventory is conducted will be documented.

The only exceptions to the shift inventory requirement are properly sealed emergency carts or kits or the automated medication cabinets (e.g. SureMed or Pyxis).

- Each institution will develop a policy for inventorying sealed carts on a quarterly basis.

When a discrepancy is noted, a thorough search will be conducted by the finder of the discrepancy, after attempting to resolve the discrepancy, for the missing item(s).

- The finder will report all unresolved discrepancies immediately to the HSA and the Operations Lieutenant.
- After the search, a written memorandum to the HSA and Operations Lieutenant will be prepared by the finder explaining the details.

Local procedures will identify the party responsible for storing needles and syringes. **All** unused sub-stock needles and syringes will be stored in a separate locked cabinet or drawer, within a room locked at all times when staff are not present.

- All main stock inventories of sterile needles and syringes will be stored in a secure area, and have a perpetual inventory.
- Each facility will have suitable storage space.

The HSA will ensure a Certificate of Disposition for Control of Needles and Syringes is provided for all areas accountable for these items. The HSA will also ensure local procedures indicate responsibility for requisition of needles and syringes and for recording additions to and uses of inventory.

- Each area of use will have an individualized inventory.
- For institutions using a computer driven medication station, the Activities Report will take the place of the Certificate of Disposition.

The practitioner using or obtaining new supplies of needles and syringes will subtract or add, as appropriate, from the inventory.

- The employee using the needle or syringe will designate on the form the patient's name or reason that the item(s) was used, and sign for the item(s), indicating date and time.
- Employees will not handle disposed/contaminated syringes, needles, scalpels, and other accountable items to conduct a physical count.
- Staff may check out needles/syringes in small quantities for specific indications (e.g. lab, insulin line). All unused needles/syringes will be returned to stock or sub-stock.

Needles and syringes obtained from main stock will be added to the sub-stock inventory and the new totals brought forward. Sub-stock needles and syringes will be requested from main stock via a requisition form.

- Under no circumstance will needles and syringes be stored with controlled substances.

The Certificate for Disposition for Control of Needles and Syringes will be collected by the HSA. This documentation will be retained for two years.

- The HSA will review and maintain each form for spot-check inventories of used needles and syringes.

15. PATIENT COUNSELING. The Chief Pharmacist will develop written procedures to address patient counseling by a pharmacist. Physical plant considerations will be factored into this plan. All inmates, whether in the parent institution, SHU, or a satellite facility, will be provided information on their medication. Patient counseling will comply with federal and state regulations.

- This information may take the form of a written medication information sheet and/or oral counseling. Every effort should be made to provide oral counseling when possible.
- Written medication information sheets may be those developed by Bureau pharmacists or those available from pharmacy software program.
- Oral counseling may be done at the pharmacy window, a designated counseling area, or the inmate's cell always being mindful of patient confidentiality.
- The patient counseling will also consider literacy and primary language.

The opportunity for oral counseling by a pharmacist will be offered when new medication is distributed. If not logistically possible, local procedures will provide an avenue for inmates to request counseling.

Patient information to be furnished with new medication orders may include:

- Name of the Drug;
- Indications;
- Dosage Instructions;
- Significant or common Adverse Effects;
- Drug-drug or Drug-food interactions;
- What to do if a dose is missed; and
- Special instructions (i.e. take with food, will discolor urine, etc.)

It is not necessary to furnish patient counseling for each medication refill. However, this provides the pharmacist with an excellent opportunity to check on patient compliance, drug effectiveness, and adverse drug reactions.

Patient information for OTC drugs dispensed by a pharmacist may be on a sheet with other OTC products, and made available in the Health Services Unit.

16. **CHRONIC MEDICATION/SUMMARY SHEET.** The chronic medication/summary sheet is filed under the problem list in Section 2 of the health record. The chronic medication/summary sheet lists current medications.

- Each institution will determine the appropriate format to meet this requirement (i.e., computerized pharmacy records available to the prescriber, etc.).

17. **METHADONE.** The regulations on purchasing, prescribing, and storing of methadone vary depending on the clinical reason for its use. There are currently only three approved uses for methadone within BOP institutions. These uses are:

- Treatment of opiate addicted pregnant inmates;
- Detoxification of opiate addicted inmates; and
- Treatment of severe pain.

a. **Treatment/Detoxification.** Title 42 CFR 8 requires that any healthcare facility using methadone for detoxification or maintenance of opioid addicted patients must have an accredited behavioral health program in order to maintain a valid license for the use of methadone. The responsibility for opioid treatment centers falls under the Substance Abuse and Mental Health Services Administration (SAMHSA).

There are several options available to institutions regarding the use of Methadone.

- (1) Institutions may participate in the DEA Narcotic Addiction Treatment Program by obtaining a methadone license. This license allows institution physicians to treat narcotic addicts with a tapering or withdrawal schedule of methadone for an extended period.
 - Inmates will not be maintained on methadone with the exception of pregnant inmates.

Institutions which have a methadone license must store bulk stock methadone in a separate safe from that used to store other controlled substances.

- Methadone ordered under this license may only be used for detoxification purposes. It may not be used for other diagnoses (e.g. pain management).
- All records pertaining to purchasing, prescribing, and administering must be stored separate from other controlled substance records.

- If the institution chooses this method, an application to SAMHSA must be submitted.
 - If the institution chooses to maintain a methadone license the Chief Pharmacist will be responsible for the accreditation process. The institution will be responsible for the corresponding fee.
- (2) For institutions without a methadone license, the DEA allows physicians to prescribe methadone for up to 72 hours, in an emergency, to narcotic addicts.
- The medication order may not be extended or renewed for that individual under any circumstances.
 - This 72 hour window allows for rapid tapering when an inmate coming into the institution has been maintained on methadone in the community.
 - In this instance, the main stock of methadone may be stored with other controlled substances.
 - Documents pertaining to purchase, prescribing, and administering do not have to be stored separately from other Schedule II controlled substances.
- (3) A contract with a local methadone clinic may be pursued to supply methadone for detoxification. All institutions which do not have a methadone license and could conceivably receive a pregnant female on methadone will have a contingency plan, such as this, in place.
- Any pregnant female arriving at the institution on methadone needs to be maintained on methadone until the baby is delivered.
 - Detoxification should be done after delivery. The CD will seek guidance from the BOP Medical Director.
- (4) Institutions may choose non-methadone alternative detoxification protocols either after the 72 hour window explained in subsection 2. above or upon receipt of the inmate.

b. **Treatment of Pain.** Bureau physicians may prescribe methadone for inmates with severe pain for an extended period. The procedures for prescribing methadone for pain are the same as those described in 9.e.

- When prescribed for severe pain, methadone may be purchased without a methadone license.
- Bulk stock methadone may be stored with other controlled substances.
- Documents pertaining to purchase, prescribing, and administering do not have to be stored separately from other Schedule II controlled substances. However, they must be "readily recoverable."
- Ensure that medication orders for methadone clearly indicate the use for severe/chronic pain in the health record to avoid any confusion or problems during a DEA audit.
- Institutions with a methadone license are not allowed to order methadone used for pain under the methadone detoxification license. These inventories must be kept completely separate.

18. **URGENT CARE CARTS.** An adequate supply of urgent care drugs will be maintained in the pharmacy and in designated areas. The Chief Pharmacist is responsible for all medications located in the urgent care carts and kits, and for the inspection procedures used.

- Approved DEA controlled substances may be maintained on urgent care carts and will be inventoried by pharmacy staff at least quarterly or whenever the urgent care cart seal is broken.
- Information regarding supplies and medication for the urgent care carts, based on the level of emergency care provided, is available from the BOP Chief Pharmacist.

/s/
Harley G. Lappin
Director