U.S. Department of Justice
Federal Bureau of Prisons

P R O G R A M S T A T E M E N T
OPI: HSD/HPB
NUMBER: 6360.02
DATE: October 24, 2022

Pharmacy Services

/s/
Approved: Colette S. Peters
Director, Federal Bureau of Prisons

1. PURPOSE AND SCOPE

To guide a broad spectrum of operations in the Bureau of Prisons (Bureau) pharmacy program.

a. Program Objectives. Expected results of this program are:

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

b. Summary of Changes

Extensive changes have been made throughout this Program Statement to improve clarity and align with updates to Bureau procedures and provision of medications for Opioid Use Disorder.

Directives Rescinded

6360.01 Pharmacy Services (1/15/2005)

2. DIRECTIVES REFERENCED

P4100.06 Bureau of Prisons Acquisition Policy (7/17/2017)
P4500.12 Trust Fund/Deposit Fund Manual (3/15/2018)
P6010.05 Health Services Administration (6/26/2014)
P6013.01 Health Services Quality Improvement Program (1/15/2005)
P6027.02 Health Care Provider Credential Verification, Privileges, and Practice Agreement Program (10/12/2016)
P6031.04 Patient Care (6/3/2014)
P6090.04 Health Information Management (3/2/2015)
P6340.04 Psychiatric Services (1/15/2005)
P6541.02 Over-the-Counter Medications (11/17/2004)

Statutes
21 CFR Chapter II, Part 1300 Controlled Substances Act

3. STANDARDS REFERENCED

American Correctional Association 5th Edition Standards for Adult Correctional Institutions: 5-ACI-6A-43(M), 5- ACI-6A-44(M), 5-ACI-6C-04(M), 5-ACI-6C- 08(M), and 5-ACI-6C-09(M)

American Correctional Association 4th Edition Standards for Adult Local Detention Facilities: 4-ALDF-4C-36(M), 4-ALDF-4C-38(M), 4-ALDF-4C-39(M), 4-ALDF-4D-15(M), 4-ALDF-4D-17(M), and 4-ALDF-4D-18(M).

TABLE OF CONTENTS

1. PURPOSE AND SCOPE 1
a. Program Objectives. 1
b. Summary of Changes 1
2. DIRECTIVES REFERENCED 1
3. STANDARDS REFERENCED 2
4. ACRONYMS AND DEFINITIONS 4
5. STAFFING 5
a. Hours of Operation 5
b. Options During the Absence of the Pharmacist 5
6. TRAINING AND EDUCATION 6
a. Orientation 6
b. Pharmacist Competency Reviews 6
7. STANDARDS OF OPERATION 6
a. Reference materials. 6
b. Equipment 7
c. Key Control 7
8. PROCEDURES AND OPERATION PRACTICES 7
a. Pharmacy and Therapeutics (P&T) Committee 8
b. National Drug Formulary 8
c. Patient Safety 9
d. Dispensing Medication Orders. 10
e. Technician Check Technician (a.k.a Tech Check Tech) 10
f. Night stock 11
g. Inspections 11
h. Drug Monitoring 12
i. Drug Recall 12
j. Outdated Medications 12
9. CLINICAL PHARMACY PROGRAM 12
a. Patient Counseling 12
10. DEA CONTROLLED SUBSTANCES 13
a. Applicability of Federal Law 13

b. DEA Registration 133
c. Responsibility 14
d. Purchasing and Receiving 14
e. Records 15
f. Sub-stock Inventories 15
g. Discrepancies 16
h. Inventory and Change of Registrant 16
i. Security 16
j. Biennial Inventory 17
k. Additional Auditing Requirements 17
l. Disposal 18
11. ADMINISTRATION, DISPENSING, DISTRIBUTION AND PRESCRIBING 18
a. Prescribing Restrictions 18
b. Administration 18
c. Prescribing DEA Controlled Substances 19
d. Restricted Drugs 20
e. Medication Orders 20
f. Drug Samples 20
g. Intake Medications 20
h. Distribution 21
i. Medications for Inmate Patients in Special Housing Units (SHU) 21
j. Psychiatric Medication 21
k. OTC Medications 22
12. MEDICATION ERRORS 22
a. Definitions 22
b. Types of Medication Errors 22
c. Applicability and Procedures 23
d. Monitoring and Managing Medication Errors 25
13. ADVERSE DRUG REACTION REPORTING 27
14. RELEASE/TRANSFER MEDICATION 27
a. Transfer to Residential Reentry Centers (RRC) or Community-Based Programs 27
b. Release from Custody 27
c. Transfers between institutions and other agencies 27
15. PRIME VENDOR CONTRACT 27
16. NEEDLES AND SYRINGES 28
a. Storage 28
b. Usage 28
c. Sub-stock Inventories 29
d. Discrepancies 29
17. OPIOID USE DISORDER 29
a. Regulations 30
b. Informed Consent 31
18. TREATMENT OF PAIN WITH METHADONE 31
19. URGENT CARE CARTS 31

4. ACRONYMS AND DEFINITIONS

Acronyms

AAAHC	Accreditation Association for Ambulatory Health Care
ADHD	Attention Deficit/Hyperactivity Disorder
ADR	Adverse Drug Reaction
AMDC	Automated Medication Dispensing Cabinet
APP	Advanced Practice Provider
BPA	Blanket Purchase Agreement
BPAP	Bureau of Prisons Acquisition Policy
CD	Clinical Director
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CME	Continuing Medical Education
CPOE	Computerized Prescriber Order Entry
CPPS	Central Processing Pharmacy Services
DATA	Drug Addiction Treatment Act
DAW	Dispense As Written
DEA	Drug Enforcement Administration
DOT	Directly Observed Therapy
EHR	Electronic Health Record
eMAR	Electronic Medication Administration Record
EMT	Emergency Medical Technician
FDA	Food and Drug Administration
FDC	Federal Detention Center
FSS	Federal Supply Schedules
HCV	Hepatitis C Virus
HSA	Health Services Administrator
MAR	Medication Administration Record
MRC	Medical Referral Center
MUE	Medication Use Evaluation
NTP	Narcotic Treatment Program
OTC	Over the Counter
OTP	Opioid Treatment Program
P&T	Pharmacy and Therapeutics
PHS	Public Health Service
PPV	Pharmaceutical Prime Vendor
QIP	Quality Improvement Program
R/D	Receiving and Discharge
RRC	Residential Reentry Center
SAMHSA	Substance Abuse and Mental Health Services Administration
SHU	Special Housing Unit
TDY	Temporary duty

Definitions

- **Administration** is defined as providing one dose of medication to be applied or consumed immediately upon issuance.
- **Dispensing** is the act of prospectively reviewing the medication order as described in Section 8.d. of this Program Statement.
    - Only pharmacists may routinely dispense medications.
- **Distribution** is defined as physically handing a filled medication order or OTC (over-the-counter) product to an inmate patient. Any health care provider who has completed the Pharmacy Training and Orientation Program can distribute or administer medications.

5. STAFFING

Each institution will maintain a pharmacy directed by a professionally and legally qualified pharmacist(s), Pharmacy Technicians(s), Medication Technicians(s), and support staff sufficient in keeping with the size of the institution and the scope of medical services provided.

Medical Care Level 1 Institutions must be staffed by trained Medication Technicians(s).

a. Hours of Operation

- Non-MRCs will normally be day shift, Monday – Friday, excluding holidays.
- All institutions are not normally staffed on holidays, weekends, or beyond 6:00 PM on weekdays without Central Office approval.

b. Options During the Absence of the Pharmacist

During periods when a pharmacist is not able to perform their normal duties (e.g., annual training, continuing medical education, periods of leave, vacancies, or special projects, etc.) one of the following options will be used:

- **TDY Within the Bureau.** Arrange for TDY pharmacist assistance from another Bureau institution with more than one pharmacist, to include bargaining unit pharmacists.
- **Contracting (Amend Existing Contract).** Incorporate a requirement for pharmacist coverage in the comprehensive medical contract.
- **Contracting (Establish Separate Contract).** Contract with a firm that provides temporary pharmacist services using open market procurement procedures or existing Federal Supply Schedules (FSS). The Bureau of Prisons Acquisition Policy (BPAP), Part 37 Services Contracting, stipulates various requirements relating to using private sector temporary services.
- **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.

The use of physicians to cover for pharmacists is not an adequate solution as the roles of each are distinct in healthcare. Physicians are responsible for diagnosing and treating patients and may only dispense medications in emergency situations. All the above options must be actively pursued and exhausted prior to using a physician to provide pharmacist coverage. Institutions without the services of a pharmacist for greater than one business day will contact the Regional

Chief Pharmacist and Regional Health Services Administrator for guidance.

Although dentists and licensed clinical social workers have "independent status," they are not allowed to dispense, as most medications fall outside of their scope of practice. Health care providers, such as APPs, EMTs, Nurses, Medication Technicians, and Pharmacy Technicians, do not have independent status and are not assigned pharmacist-specific dispensing duties.

Institution HSAs and Chief Pharmacists will ensure pharmacists from outside the Bureau complete the following prior to assuming pharmacist responsibilities:

- Electronic health record training.
- Review local pharmacy procedures.

6. 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, or the medical credentialing officer will maintain participation documentation.

a. Orientation

All health care providers performing directly observed therapy (DOT) or medication distribution, such as APPs, Nurses, Pharmacy Technicians and Medication Technicians will complete pharmacy orientation as part of the Health Service Orientation. These staff will have documentation in their credentialing file indicating they have completed the Pharmacy Services Orientation before beginning work in the pharmacy or administering medications. After completing this orientation, these providers can **administer** medication doses, or **distribute** medication orders to inmate patients, but they cannot **dispense** medication orders.

b. Pharmacist Competency Reviews

Pharmacists may have periodic competency reviews.

Focused pharmacy reviews are used when circumstances indicate a need for an onsite review of the institution pharmacy (clinical or administrative) or medication distribution programs, as determined by the Regional Chief Pharmacist, Chief of Clinical Pharmacy Services, or Bureau Chief Pharmacist. These reviews are generally conducted by the Regional Chief Pharmacist but may involve other reviewers deemed appropriate by the Bureau Chief Pharmacist. These reviews are separate and not affiliated with Performance Evaluations.

7. 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. Reference materials.

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

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

b. Equipment

Equipment in the pharmacy will include at least the following:

- Adequate computer equipment including intra-agency email access.
    - The Institution Chief Pharmacist will be the owner of the institution pharmacy mailbox with rights to grant access to additional staff.
- A dedicated and appropriately labeled medical grade refrigerator, regardless of location.
- Adequate lighting and ventilation.
- A sink with running water.
- A system to monitor temperature control that meets compendia/Food and Drug Administration (FDA) standards and Centers for Disease Control and Prevention (CDC) best practices.
    - Temperature monitoring must be continuous, and records must be retrievable to ensure medication viability.
    - Local pharmacy procedures will include processes if temperature range is not maintained.
    - Medications are considered distressed and must be discarded if temperature controls are not maintained within the medication manufacturer specifications.
- Institution Chief Pharmacist or designee ensures medication stored in the institution is not excessively exposed to heat, light, and moisture.
- Access to the Bureau EHR.
- Medical Care Level 4 institutions – hoods and other equipment and rooms meeting current compendia standards to compound intravenous medications. Medical Care Level 3 institutions may have this equipment, if approved by the Central Office.

c. Key Control

Only pharmacy staff (pharmacists, Pharmacy Technicians, Medication Technicians, contractors) or designee will have keys to the pharmacy. Only the Institution 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 and other staff administering medications will have a key to the medication administration area, but not to the pharmacy storeroom or any key which would allow them access to mainstock medications.

8. PROCEDURES AND OPERATION PRACTICES

The Institution Chief Pharmacist will develop and maintain written procedures and operational practices pertaining to pharmaceutical services, in concert with medical staff and, as appropriate, with representatives of other disciplines to include the local Union, when appropriate.

a. Pharmacy and Therapeutics (P&T) Committee
The Clinical Director (CD) will establish a P&T committee that meets biannually in April and October and will review the previous 6 months of data. Membership of the P&T Committee will include, at a minimum, representatives from the medical (physician), psychiatric (if available), pharmacy, dental, quality improvement, and nursing staff as well as Health Services Administration. If working conditions are discussed, union representation should be present per the Master Agreement.

(1) Meetings. The required minimum agenda for this committee meeting includes review of the following:

- Changes in the National Formulary.
- Drugs on the National Formulary available locally.
- Strengths and dosage forms available locally.
- Drugs on the National Formulary that should be restricted further (e.g., designated as DOT).
- Errors in prescribing, dispensing, and administering medication in the institution.
- Adverse drug reactions that occur in the institution.
- Approval of Medication Use Evaluations (MUEs) used in the institution.
- MUE data and track problems over time.
- New or updated drug information.
- Requests for addition to formulary.
- Quality improvement measures.
- Clinical pharmacy outcomes as well as interventions.
- Current DEA registration(s) and expiration dates.
- Non-contract purchases and purchases outside of prime vendor above the micro-purchase limits.
- Overall and specific pharmaceutical cost trends and any medication shortages and recalls affecting the institution.
- Investigational drugs and other medication-related research projects
- Floor stock medications.
- Policy and procedure issues.

(2) Minutes. Local P&T Meeting minutes are made available to all institution health services staff. An electronic copy of the minutes will be sent to the Bureau Chief Pharmacist within 30 days after the meeting. The Bureau Chief Pharmacist will provide a meeting template on the Bureau's Intranet Health Services Chief Pharmacist page. Institution P&T Committee Meeting minutes will contain:

- Date of the meeting.
- List of attendees.
- Reading and acceptance of previous minutes.
- All agenda items listed above.

b. National Drug Formulary
Each institution will use the Bureau's National Drug Formulary. The Formulary is the listing of medications that may be utilized in the Bureau. The listing includes restrictions, if applicable. The National Drug Formulary will be issued following the publication of the National P&T and

Formulary Meeting Minutes. Comments and suggestions should be directed to the Bureau Chief Pharmacist.

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

Authorization for use of items not in the National Formulary or use of medications beyond the listed restrictions must be requested from the Medical Director through the Bureau Chief Pharmacist, using the "Non-Formulary Drug Authorization" process. The process is completed through the EHR.

- 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.
- 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 non-formulary medication orders and must include appropriate justification from the prescriber.

The Medical Services Request for Addition to Formulary form (BP-A0804) must be used to request a drug item to be added to the National Formulary. This form is routed through the local P&T Committee and then sent to the Bureau Chief Pharmacist.

- All requests will be reviewed at the National P&T Meeting.
- Recommendations for formulary deletions, restrictions, etc., must also be submitted using this form.

c. 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.
- Each institution will establish a High-Risk Medication Program. The Institute for Safe Medication Practices defines high risk medications as those that bear a heightened risk of causing significant patient harm when they are used in error. Institutions will identify medications used locally that are potentially high risk and implement mitigation strategies to reduce risk of error. This should also include Look Alike/Sound Alike medications. Mitigation strategies may include:
    - Standardizing the prescribing, storage, preparation, dispensing, and administration of the medications.
    - Improving access to information about these drugs.

- Using auxiliary labels and automated alerts.
- Providing mandatory patient education.

A formal MUE 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.

d. 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.
- Provide the final check of the medication order to ensure it contains the correct drug.

The pharmacist prospective review is documented in the EHR. Any changes to the medication must be documented in the EHR, with justification for the change.

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

e. Technician Check Technician (a.k.a Tech Check Tech).
In certain instances where staffing levels are appropriate, it may be acceptable to have non-pharmacist personnel such as trained Pharmacy Technicians or trained Medication Technicians perform verification of non-judgmental or non-discretionary pharmacy functions. Appropriate instances include:

- Checking unit dose cart fills.
- Checking medications that have been legally repackaged into unit dose form.
- Checking stock prepared for addition to inventory for AMDCs.
- Performing the visual check of the medication to be dispensed.
- Performing verification procedures for an automated dispensing robot (e.g., ScriptPro®).

The processes listed require consultation with and written approval from the Regional Chief Pharmacist. A formal written request from the institution is sent to the Regional Chief Pharmacist and includes current staffing levels and an explanation of the local procedures that

will be in place for this process. The period of approval is limited to one year, after which a renewal must be submitted.

f. Night stock.
A provider with "independent status" (i.e., physician or pharmacist as defined in Section 5.b. of this Program Statement) must check each medication order before it is placed in a drug administration cabinet and distributed or administered to the inmate patient, ensuring the appropriate prospective review has been completed. Non-pharmacist health care providers will not have access to bulk stock packages that would permit them to dispense a medication order or administer doses. The only exception is described in Section 5.b. of this Program Statement.

To satisfy these requirements during evenings and weekends, each institution will use a drug administration cabinet. This may be as sophisticated as an AMDC or as simple as a locked, metal cabinet in the urgent care room, or a designated area in the medication administration area.

- This cabinet will contain a limited number and supply of urgently needed medications that are commonly used after-hours in the institution.
- These medications 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 medication.

When the after-hours health care provider needs to give an inmate patient a medication, the following options will be used:

- The inmate patient may be placed on DOT to be administered single doses of the prescribed medication until a medication order can be dispensed.
- The health care provider may access the off-shift drug administration cabinet, remove a pre-packaged container, and write the inmate patient's name and number, date, provider's name, and the expiration date on the package and distribute it to the inmate patient.
- A medication order will be written for the pharmacist to review retrospectively.
- The distribution of medication from the off-shift drug administration cabinet will be recorded in the EHR.

The next working day, the pharmacist will:

- Review the order retrospectively.
- Fill the order for the amount written less the dose(s) distributed or administered by the health care provider.
- Dispense the completed order to the inmate patient.

g. Inspections
The Institution Chief Pharmacist or designee will conduct at least quarterly inspections of all areas where medications are dispensed, administered, or stored. The Institution Chief Pharmacist will maintain a record of quarterly inspections for at least two years. The Bureau Chief Pharmacist will provide a template that may be used for this purpose. A copy of the documentation will be electronically sent to the Bureau Chief Pharmacist for review within 30 days of the end of each quarter.

h. Drug Monitoring
The Institution Chief Pharmacist will provide drug monitoring services keeping with each inmate patient's needs, FDA and manufacturer recommendations, and practices recommended through drug information resources.

i. Drug Recall
A drug recall procedure that can be implemented readily, including provisions for documenting results, will be initiated.

j. Outdated Medications
The Institution 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 punctured, the beyond use date will be calculated by the current standard set by the United States Pharmacopeia <797> or by the manufacturer's specifications, whichever is sooner.

9. CLINICAL PHARMACY PROGRAM

Each Institution Chief Pharmacist will develop a clinical pharmacy services program to deliver inmate patient medical care consistent with the Program Statement **Patient Care** and institution pharmacy staffing and mission. Guidance for clinical pharmacy services is provided by the Bureau Chief Pharmacist. Institution Chief Pharmacists will report outcome measures to the Bureau Chief Pharmacist each year.

a. Patient Counseling
The Institution Chief Pharmacist will develop written procedures to address patient counseling by a pharmacist. Physical layout consideration will be factored into this plan. All inmate patients, whether in the parent institution, SHU, or a satellite facility, will be provided information on their medication. Patient counseling will comply with federal 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.
- Oral counseling may be done at the pharmacy window, a designated counseling area, or the inmate patient's cell always being mindful of patient confidentiality.
- The patient counseling will also consider literacy and primary language.

Oral counseling by a pharmacist will be offered when a new medication is distributed. If the pharmacist is not immediately available or not physically located inside a particular institution (e.g., satellite camps, administrative units, complexes with pharmacies outside the secure perimeter, non-complex facilities with multiple locations, etc.), local procedures will include a plan for a pharmacist to be available on a routine basis for inmate patient counseling and consultation at each location.

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.
- Special instructions (e.g., 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 the 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.

10. DEA CONTROLLED SUBSTANCES

a. Applicability of Federal Law

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.

b. DEA Registration

Power of Attorney (POA) is required for persons other than the person who signed the current DEA registration to be able to order Schedule II controlled substances (i.e., signing the DEA form 222). DEA POA is granted by the person who signed the current DEA registration. Previous DEA POA forms are void upon departure of the person who has granting authority. Refer to the 21 CFR 1305.5 for further details and POA example. DEA POA forms are kept with other DEA controlled substance records.

To obtain an initial DEA registration number under the Controlled Substances Act, the Institution Chief Pharmacist completes a New Application for Hospital/Clinic Registration form (DEA Form 224). For legal purposes, it is very important Bureau institutions are registered as "hospital/clinic" only. To renew a DEA registration, the Institution Chief Pharmacist completes a Renewal Application for Hospital/Clinic Registration form (DEA Form 224a) or narcotic treatment program (NTP) application (DEA Form 363a). These applications are completed on-line. The contact information for DEA registration and renewal is available at www.deadiversion.usdoj.gov. There is no cost for new or renewed registrations to the Federal Government. The Bureau Chief Pharmacist contact information is entered as the fee exempting official in the appropriate section.

The Institution Chief Pharmacist (DEA registrant) completes and submits the registration. At institutions without a pharmacist, the following staff are responsible for completing the registration in this order of precedence: CD is primary, HSA is secondary, AW is tertiary, and the Warden is quaternary. The position with the highest order of precedence must fill out the registration; it can only move to the next position in cases of staff vacancy.

The institution DEA registration number is used only for official business. Fee exemption is not authorized for personally held DEA numbers regardless of whether they are being newly acquired or renewed.

If individual providers obtain DEA licenses or certifications to prescribe medication for opioid use disorder (OUD) within the Bureau, Health Services Division will provide instructions to those providers. Providers may not use a DEA registration, provided under federal fee-exemption, outside of the Bureau.

Each institution will only have one registration number for controlled substances not used for OUD. One additional DEA registration for NTP may be authorized per institution for Opioid Treatment Programs (OTP) under the guidance of the Bureau Chief Pharmacist. Each Federal Correctional Complex in which all institutions are contiguously located on Federal property maintains only one DEA registration number for the complex. If the Complex's institutions are not located on contiguous Federal property, the Bureau Chief Pharmacist should be contacted for guidance.

c. Responsibility

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

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

d. Purchasing and Receiving

Purchase orders for controlled substances will be prepared by a designated employee without the knowledge or assistance of inmate patients.

- Controlled substances will be stocked in single-dose packaging when available.
- The Institution Chief Pharmacist will establish a proper system of security for their receipt.

e. Records
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.

Consistent with 21 CFR 1304.4, the Institution 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 readily retrievable electronic format. No other items may be stored with DEA controlled substances or their records.

(1) Main stock Records. The pharmacist will maintain adequate main stock records via the current electronic pharmacy system for each controlled substance. Headings will indicate:

- Sub-stock unit.
- Date.
- Record number/Purchase Order number.
- Quantity received.
- Quantity issued to sub-stock.
- Balance on hand.

(2) Sub-stock Records address the administration of medication on medical/nursing units or on DOT. 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 patient.
- Dosage administered.
- Corresponding medication order number.
- Signature of person administering.
- Balance on hand.

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

The use of an AMDC negates the need for proof of use sheets for controlled substances. Controlled substances in sub-stocks are to be used for administration only. Any dispensing of controlled substances will be accomplished through main stock.

f. Sub-stock Inventories

- **For institutions using AMDCs**, a complete sub-stock controlled substance inventory must be completed through the AMDC at least once every seven days. For institutions with higher usage rates, more frequent inventories are recommended.
    - Each institution will develop local procedures for conducting the sub-stock inventory

- **For institutions not using AMDCs**, at the beginning of each shift, a staff member will conduct a complete DEA sub-stock inventory in accordance with local procedures. This staff member will sign the "sub-stock inventory certification sheet" for each shift.
    - Access to the controlled substances sub-stock is limited to the staff member who is responsible for the shift inventory of sub-stock.
    - 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.
        - Exact quantity of all controlled substance on hand in that sub-stock at that time.

The only exceptions to inventory requirements for both of the above instances are properly sealed emergency carts or kits.

g. Discrepancies

Discrepancies may occur for a variety of reasons, and it is important to distinguish between human error and potential misconduct. If the cause of the discrepancy is easily determined, staff will attempt to resolve the discrepancy immediately.

- The staff member discovering the discrepancy will notify the Institution Chief Pharmacist and Health Services Administrator per local procedures.
- For institutions using an AMDC, an institution pharmacist will generate and review sub-stock discrepancy reports daily. At institutions without a pharmacist, the HSA will perform this task.
- Local pharmacy procedures will include processes for addressing unresolved discrepancies.

h. Inventory and Change of Registrant

When a DEA registrant (i.e., Institution Chief Pharmacist) permanently departs from an institution, prior to departure the off-going registrant and the new designated POA will complete an inventory of:

- Main stock controlled substances.
- Perpetual inventory.
- Purchase orders.
- Receivers.
- Invoices.

When a permanently assigned POA/registrant arrives at an institution, he/she and the current POA will complete a similar inventory as soon as practical.

i. Security

The DEA, per 21 CFR Part 1301.71, requires safeguarding and accounting for all controlled substances.

- Main stock controlled substances will be stored in a vault or safe.
- Controlled substances that are damaged, expired, or retrieved from inmate patients

through R/D will be segregated in the safe from other controlled substances.
    - A separate destruction inventory will be maintained if the medications are in the facility.
- Institutions that use methadone for OUD treatment may either store bulk stock methadone in a separate safe from that used to store other controlled substances or stored in the same vault, clearly segregated from other controlled substances as permitted by the DEA.
- Sub-stock controlled substances must be stored in a stationary, approved steel cabinet with two separately key-locked steel doors, a safe with a keyed padlock, or AMDC.
- When a controlled substance requires refrigeration, the medication must be secured in a locked refrigerator or in a locked drawer within the refrigerator.

j. 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 DEA registrant will complete the biennial inventory on the date mandated by federal law. The DEA registrant will maintain the inventory with the controlled substances records.

The inventory records must include:
- The registrant's name, address, and DEA registration number.
- The date and time the inventory is taken (opening or close of business).
- Signature of the person or persons responsible for taking the inventory.
- The name of each controlled substance.
- The dosage form and unit strength of each controlled substance.
- The number of units in each container of each controlled substance.
- The number of each container of each controlled substance.
- Separate Schedule II controlled substances from all others.
- Main stock and all sub-stocks.

k. Additional Auditing Requirements
Corrected or amended medication orders for controlled substances will be completed per Program Statement **Health Information Management**. 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. The DEA registrant will in turn send a memo to the HSA, with a copy to the Warden. The DEA registrant, upon consultation with the Warden will notify the DEA of significant loss, as defined by the DEA, of controlled substances via DEA Form 106. The DEA registrant will maintain a copy of this submission.

(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 Institution 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 Narcotics Audit Team Certificate (BP-A0825) form to be filed with the controlled substance records.
- A copy of this form should be sent to the Bureau Chief Pharmacist.
- This count may be done at any time within the time frame of the quarter.

(3) Quarterly Report by Date Range. At the end of each quarter, the DEA registrant will complete an Inventory Report by Date Range as produced by the pharmacy software for controlled substances to include both main stock and stock to be destroyed (destruction). An electronic copy will be submitted to the Bureau 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.

l. Disposal

The DEA registrant or designee will dispose of controlled substances from the main stock inventory, when necessary, in the manner prescribed by the DEA in 21 CFR 1317. Questions regarding the proper method to dispose of controlled substances should be referred to Regional Chief Pharmacists.

11. ADMINISTRATION, DISPENSING, DISTRIBUTION AND PRESCRIBING

a. Prescribing Restrictions

All medications restricted to "physician use only" by the Bureau National Formulary prescribed by a provider who is not a physician must be countersigned by a staff physician before the medication order may be processed and dispensed. DEA controlled substances used for the treatment of OUD may only be prescribed by an approved and licensed provider (e.g., DATA waived) or a provider practicing within a certified OTP.

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

b. Administration

The following procedures will be followed for directly observed therapy (DOT):

- The person administering the medication will identify each inmate patient by examining two forms of identification (e.g., photo ID, DOB, registration number, name,etc.).
- The inmate patient will swallow the dose of medication and the water while being observed directly by the staff member.
- The inmate patient will then show the empty dose cup and water cup to the person conducting DOT before disposal.
- The inmate patient will be asked to open his/her mouth to show the medication has not

been “cheeked” before leaving the window.
- Medications will be stored in appropriate packaging and clearly labeled until administration.
- The administration of medication will be documented in the eMAR promptly after it is completed.
- When using an AMDC, the individual removing a controlled substance from the AMDC must be the same individual who signs the eMAR except in cases of an emergency.
- When an inmate patient refuses to take a prescribed DOT medication, or is a “no-show,” that decision is documented on the eMAR.
- Ordinarily, all DEA controlled substances taken by mouth are crushed or administered in liquid form.

DOT stock will not be in bulk containers. Local procedures will specify the system in use at each institution. DOT stock may include:
- Unit-dose packaging appropriately labeled.
- Medication order labeled vials with a seven to 30-day supply of the inmate patient’s medication.
- Heat-sealed blister cards filled or check by the pharmacy.
- Automated medication administration cabinets.

c. Prescribing DEA Controlled Substances
The physician or dentist will initiate or countersign the medication order in the health record which will include:
- Controlled substance.
- Strength.
- Directions.
- Duration of therapy.

Health services staff may accept a verbal order, but the physician or dentist must countersign the verbal order by the close of the next business day.

Schedule II controlled substance orders will be valid for 96 hours only. Schedule III, IV, and V orders may be written for not more than 30 days. Exceptions to these time frames include:
- DEA controlled substances used for the treatment of seizure disorders unless otherwise restricted in the Bureau National Formulary, 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.
- Controlled substances (Schedule II - V) used for treatment of OUD or treatment of withdrawal, that are not long-acting formulations, may be written for up to 30 days. Controlled substances that are long-acting formulations used for treatment of OUD may be written for up to 180 days unless otherwise restricted by the Bureau National Formulary.
- All such orders must be supported by on-going documentation in the EHR.

For all inmate patients prescribed a controlled substance who are transferring to a Residential Reentry Center, community-based program, another agency, or releasing from Bureau custody, a hard copy prescription, compliant with DEA regulations, is required. This hard copy prescription is retained by the pharmacy per DEA document storage regulations.

d. Restricted Drugs
Restricted drugs are defined as non-DEA controlled drugs that may be abused or those that require DOT. Ordering, prescribing, dispensing, and accounting for restricted medications will be in accordance with local and national procedures.

All restricted drugs to be taken by mouth will be administered in single doses and swallowed in the presence of an employee to ensure the medication is ingested, in accordance with the procedures outlined in Section 11.b. of this Program Statement.

e. 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. The reevaluation may include a review of relevant documentation of the patient chart or a patient encounter that addresses the medications being prescribed.

- All medication orders for chronic care medications, to include those being used for the treatment for OUD, are valid for no more than 90 day fills with refills totaling 365 days within the limitations outlined in the Bureau National Formulary or elsewhere in this policy. 30-day fills are recommended for DOT medications.
- 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.
- A staff physician will review and cosign orders written by consultant physicians.
- When an inmate patient 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 11.c. of this Program Statement.)

f. Drug Samples
The distribution of drug samples within the institution is prohibited.

g. Intake Medications
All medication arriving with inmate patients through R/D as new commitments will be given to the Institution Chief Pharmacist or designee. An inmate patient may retain medications prescribed by another Bureau institution if they are not otherwise restricted by policy (e.g., controlled substance).

- The Institution 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.
- When an inmate patient enters a facility with medications from the community, the pharmacy will ensure that adequate supplies are on hand prior to disposal. These medications, if appropriate, will be administered on DOT until the pharmacy is able to obtain the drug(s).

h. Distribution

- All self-carry medications provided to inmate patients are documented as distributed to the inmate patient within the distribution module of the EHR.
- Medications received from a remote or central fill pharmacy are documented as received through the packing slip and distribution modules.
- All institutions will have a system(s) in place for ensuring medications not picked up by inmate patients after 10-14 days are returned to stock in the EHR. Medications not picked up by inmate patients at CPPS serviced institutions are returned to the filling pharmacy using the return module of the EHR.
- Unless local institution security requirements dictate otherwise, medication dispensing will be in light-resistant moisture-resistant vials and not plastic bags.

i. Medications for Inmate Patients in Special Housing Units (SHU)

Each institution will develop a procedure (e.g., SENTRY, Operations Lieutenant) to ensure all inmate patients placed in SHU during the previous 24 hours have their current medications available.

- Local procedures will be developed and negotiated to retrieve the inmate patient's confiscated medication. Health Services staff will determine if the medication should be administered or redistributed to the inmate patient, if appropriate.
- Under no circumstances will medication be locked up with the inmate patient's property, thrown in "hot trash,"or distributed or administered to an inmate patient by anyone other than a health care provider.

j. Psychiatric Medication

Refer to the Program Statement **Psychiatric Services** for procedures on obtaining informed consent, non-compliance, and patient counseling. Ordinarily, informed consent will be obtained and documented before dispensing or administering psychiatric medication. The prescribing provider will be responsible for obtaining the informed consent. This task may be delegated to another qualified healthcare provider when the prescribing provider is not present.

Psychiatric medication for a current DSM Axis V 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 inmate patients 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.

- Maintaining documented informed consent in the health record.
- Upon intake, consent for psychiatric medications should be obtained as soon as possible but medications should not be held pending consent.

(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.

k. OTC Medications

See the Program Statement **Over-the-Counter Medications**.

12. MEDICATION ERRORS

a. Definitions

- A **medication error** is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is the control of the healthcare professional, patient, or consumer," according to the National Coordinating Council for Medication Error Reporting and Prevention.
  - Except for errors of omission, the patient must receive the drug for the incident to be classified as a medication error.
- A **near miss** 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 patient, 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

Medication errors are categorized as:

- Prescribing error.
- Pharmacy processing error.
- Dispensing error.
- Administration error.
- Monitoring error.

These types of medication errors are subcategorized to include:

- Deteriorated/Expired medication.
- Incorrect method of administration.
- Wrong dose.
- Wrong dosage form/preparation.
- Wrong route.
- Wrong medication
- Missed dose.
- Unauthorized drug.

- Wrong time.
- Wrong quantity.
- Monitoring error.
- Medication not ordered.
- Medication ordered but not available.
- MAR documentation – administration confirmed, not signed off.
- MAR documentation – not administered but signed off.
- MAR documentation – dose administered is not dose signed off
- AMDC – wrong medication in pocket.
- AMDC – wrong medication removed from drawer.

c. Applicability and Procedures

Listed below are the required elements of the institution's Medication Error 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.
- Pharmacists and others responsible for processing medication orders will have routine access to appropriate clinical information and patient information (including medication, allergy and hypersensitivity profiles, diagnoses, pregnancy status, and laboratory values) to help them evaluate the appropriateness of medication orders. The EHR will contain adequate information to allow monitoring of the following:
  - Medication histories.
  - Allergies.
  - Potential drug interactions and adverse drug reactions.
  - Duplicate drug therapies.
  - Pertinent laboratory data.
  - Other information.
- The Pharmacy Department must be solely responsible for procuring, distributing, and controlling all drugs used within the organization. Except in emergencies, all sterile and non-sterile drug products will be dispensed from the pharmacy.
- Comprehensive local policies and procedures that provide for efficient and safe distribution of all medications and related supplies to patients will be established.
- Only abbreviations approved in the Program Statement **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 inmate 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, MUE 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 must be complete and will include:
  - Drug name.
  - Route and site of administration.
  - Dosage form.
  - Dose.
  - Strength.
  - Frequency of administration.
  - Duration of therapy.
  - Prescriber's name.
  - In some cases, a dilution, rate, and time of administration should also be specified.
- Prescribers will enter medication orders into the EHR. When appropriate, 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 record the order in the EHR.
  - The prescriber will confirm the order by signing the chart entry within 24 hours or the next working day.
- "Hold medication" orders are not allowed. All medication orders must be discontinued and rewritten to initiate therapy as appropriate.
- "Range orders" and "as needed" (PRN) orders without specific, objective measures to determine the correct dose/frequency are not permitted. The objective criteria and dose associated with the objective criteria must be clearly specified within the medication order. "Per protocol" or "per sliding scale" are not to be utilized because these can differ between institutions, clinics, and providers.

(3) Pharmacist Responsibilities.

Pharmacists will participate in drug therapy monitoring and MUE 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.
- MUE programs.
- Allowable delegation of authority procedures.
- Procedures to alert health care providers and others to new drug orders.
- Standard administration times.

- Before dispensing medications in non-emergency situations, the pharmacist will review the medication order.
- 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 ensure timely delivery of medications to the patient care area after receipt of the orders.
    - If medication 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 reason for the delay if the delay could cause patient harm.
- 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).

d. Monitoring and Managing Medication Errors

The staff member identifying the error will report near-miss and actual medication errors through the electronic reporting system. The Institution Chief Pharmacist or pharmacist designee will review the submitted error and notify the physician when clinically indicated.

Medication Error Severity Ratings

Severity Category	Description	Did error Reach Patient	Example
A	No error, capacity to cause error (near miss)	NA	NA
B	Error occurred that did not reach the patient	No	NA
C	Error that reached the patient but unlikely to cause harm	Yes – Note errors of omission are considered	Multivitamin was not ordered on admission
D	Error that reached the patient and could have necessitated monitoring and/or intervention to preclude harm		Regular release metoprolol was selected on processing rather than extended release that was ordered

E	Error that could have caused temporary harm	to have reached the patient.	Blood pressure medication was inadvertently omitted from the orders
F	Error that could have caused temporary harm requiring initial or prolonged hospitalization		Anticoagulant was processed for daily rather than every other day as ordered
G	Error that could have resulted in permanent harm		Immunosuppressant dose was ordered for one-fourth of the correct dose
H	Error that could have necessitated intervention to sustain life		60 units of Short acting insulin given rather than long-acting insulin
I	Error that could have resulted in death		Antiplatelet agent was not ordered post-stenting
Definitions **Harm -** Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from. **Monitoring-** To observe or record relevant physiological or psychological signs. **Intervention -** May include change in therapy or active medical/surgical treatment. **Intervention Necessary to Sustain Life -** Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)			

The QIP coordinator and the Institution Chief Pharmacist will meet at least quarterly to review the data collected, analyze, and classify the errors to report at the P&T Committee.

- This summary will not identify those making the error by name.
- After reviewing the available information, the HSA, Clinical Director, and Institution 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.

- The P&T Committee will suggest process improvements that results from the review. Suggestions may include:
    - Conducting organizational staff education.
    - Making recommendations for staffing levels.
    - Revising policies and procedures.
    - Changing facilities, equipment, or supplies.

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

- Error discussion.
- Staff training.
- Local review (Refer to Program Statement **Health Care Provider Credential Verification, Privileges 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 will evaluate errors resulting in permanent patient harm or death (e.g., sentinel events) per the Program Statement **Health Services Quality Improvement Program**.

13. ADVERSE DRUG REACTION REPORTING

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 electronic Adverse Drug Reaction reporting system.
- Drug product defects will be reported in accordance with the FDA drug product problem reporting program.

14. RELEASE/TRANSFER MEDICATION

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

For RRCs, community-based programs, and release from custody, new medication orders are only needed for controlled substances. The number of days supplied for controlled substances may be less than 90 days and will be determined on a case-by-case basis, dependent upon clinical justification, release planning for the inmate patient, and DEA regulations.

a. Transfer to Residential Reentry Centers (RRC) or Community-Based Programs
When an inmate patient is transferred to one of the above, a 90-day supply of current chronic medications will be provided.

b. Release from Custody
An inmate patient releasing from custody will be provided a 30 to 90-day supply of chronic medication(s). The medication, with directions, will be given to the releasing officer as indicated by local procedure.

c. Transfers between institutions and other agencies
All intra-system transfers and transfers to other agencies 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-A0659) or exit summary in the EHR.

- 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.
- A copy of the Medical Summary of Federal Prisoner/Alien in Transit (BP-A0659) form may be used to transcribe current medications.

15. 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, e.g., purchase from FSS, mandatory source, or open market.

The Institution 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 Bureau Chief Pharmacist.

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

All medications purchased from a vendor other than the Prime Vendor must utilize the current project code as directed by the Administration Division and Health Services Division.

16. NEEDLES AND SYRINGES

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

a. Storage

Local procedures will identify the party responsible for storing needles and syringes.

- Needles and syringes must be segregated from controlled substances.
- All unused sub-stock needles and syringes will be stored in a separate locked cabinet or AMDC, 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. Physical count of mainstock items will be verified with documented perpetual inventory when removing items for sub-stock.
- Each facility will have suitable storage space.

b. Usage

The HSA will ensure a Certificate of Disposition for Control of Needles and Syringes is provided for all areas accountable for these items. For institutions using an AMDC, the Activities Report will take the place of the Certificate of Disposition.

- Needles and syringes obtained from main stock will be added to the sub-stock inventory and the new totals brought forward.
- The Certificate for Disposition for Control of Needles and Syringes will be retained for two years.

The individual 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 or in the AMDC the inmate patient’s name or reason that the item(s) was used, and sign for the item(s),

indicating date and time.

- Staff may check out needles/syringes in small quantitiesfor specific activities (e.g., lab, insulin line). At all times all needles and syringes will be maintained in a secure manner. All unused needles/syringes will be returned to stock or sub-stock promptly upon completion of the activity.

c. Sub-stock Inventories

For institutions using AMDCs, a complete sub-stock needles and syringes inventory must be completed at least once every seven days. For institutions with higher usage rates, more frequent inventories are recommended.

- Each institution will develop local procedures for conducting the sub-stock inventory.

For institutions not using AMDCs, all unused needles and syringes in sub-stocks will be inventoried on each medically staffed shift.

- Each area of use will have an individualized inventory.
- The HSA or designee will review and maintain each form for spot-check inventories of used needles and syringes.
- Local procedures will specify responsibility for conducting the inventory.
- The time the inventory is conducted will be documented.

The only exceptions to the needle and syringe inventory requirements are properly sealed emergency carts or kits.

Employees will not handle disposed/contaminated syringes, needles, scalpels, and other accountable items to conduct a physical count.

d. Discrepancies

Discrepancies may occur for a variety of reasons, and it is important to distinguish between human error and potential misconduct. If the cause of the discrepancy is easily determined, staff will attempt to resolve the discrepancy immediately.

- The staff member discovering the discrepancy will notify the Institution Chief Pharmacist and Health Services Administrator per local procedures.
- For institutions using an AMDC, an institution pharmacist will generate and review sub-stock discrepancy reports daily. At institutions without a pharmacist, the HSA will perform this task.
- Local pharmacy procedures will include processes for addressing unresolved discrepancies.

17. OPIOID USE DISORDER

Inmate patients will be considered for the treatment of opioid use disorder (OUD) on an individual basis in accordance with clinical guidance issued by the Medical Director. Inmate patients who are treated for OUD with medications will have the indications for use documented in the medical record as referenced within the clinical guidance issued by the Medical Director.

a. Regulations
The DEA and the Substance Abuse Mental Health Services Administration (SAMHSA) have regulatory authority over some of the medications and methods utilized to treat OUD. Health Services Division will provide instruction and should be consulted to ensure compliance with applicable Federal regulations. For those institutions that do not yet meet Federal requirements, a contingency plan must be in place with a local outpatient clinic to provide medications for the treatment of opioid use disorder consistent with the institution OUD procedures to ensure treatment is not interrupted or delayed.

To prescribe buprenorphine a prescriber must have the required DEA waiver or be prescribing within a certified Opioid Treatment Program (OTP).

The Federal regulations on purchasing, prescribing, and storing of methadone vary depending on the clinical reason for its use. There are several options available to institutions regarding the use of methadone.

- Per 42 CFR Part 8, an institution may treat OUD with methadone if it is certified as an OTP by SAMHSA and registered with the DEA as an NTP. This registration allows the maintenance and detoxification of patients with opioid addiction by institution providers.
    - Methadone ordered for use in a certified OTP may be used for maintenance and medically supervised withdrawal (referred to as detoxification in Federal regulations) purposes as specified on the NTP registration. 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.
    - For storage of methadone refer to Section 10.i. of this Program Statement.
    - If the institution chooses to register as an OTP, an application to SAMHSA must be submitted.
    - If the institution chooses to maintain a methadone license the Institution Chief Pharmacist will be responsible for the accreditation process. The institution will be responsible for the corresponding fee.
- For institutions without a methadone license, the DEA allows physicians to administer methadone for up to 72 hours, in an emergency, to a narcotic dependent person.
    - The medication order may not be extended or renewed for that individual under any circumstances.
    - Per 21 CFR §1306.07(b), this 72-hour window allows for the relief of acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment when an inmate patient enters the institution.
    - 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.
- A contract with a local OTP may be pursued to supply methadone for maintenance or medically supervised withdrawal. All institutions which do not have a certified OTP will have a contingency plan, in place consistent with the institution OUD procedures.
    - Any pregnant female arriving at the institution on methadone or alternative medication for OUD needs to be maintained on it, unless medically

contraindicated, until the baby is delivered.

- Post-partum females should be evaluated for maintenance with medication for OUD, or medically supervised withdrawal after delivery, in accordance with guidance issued by the Bureau Medical Director and in consultation with the Regional Medical Director or Chief of Health Programs, as needed.

b. Informed Consent

Informed consent will be obtained and documented before dispensing or administering medication for the treatment of OUD. Providers should use the following forms as appropriate based on the medication to be utilized:

- BP-A1147 Informed Consent to Treatment with Buprenorphine Products for Opioid Use Disorder (including buprenorphine/naloxone or buprenorphine only)
- BP-A1148 Informed Consent to Treatment with Methadone for Opioid Use Disorder
- BP-A1149 Informed Consent to Treatment with Naltrexone for Opioid Use Disorder or Alcohol Use Disorder

In addition, an agreement for treatment of OUD will be obtained upon the initiation of therapy. The following form should be utilized:

- BP-A1146 Medication Assisted Treatment (MAT) Agreement

The prescribing provider will be responsible for obtaining the informed consent. This task may be delegated to another qualified healthcare provider when the prescribing provider is not present.

18. TREATMENT OF PAIN WITH METHADONE

Bureau physicians may prescribe methadone for inmate patients with severe pain for an extended period. The procedures for prescribing methadone for pain are the same as those described in 11.c of this Program Statement.

- When prescribed for severe pain, methadone may be purchased without a DEA NTP registration.
- 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 license. These inventories must be kept separate.

19. URGENT CARE CARTS

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

- Needles and syringes and approved DEA controlled substances may be maintained on

urgent care carts and will be inventoried 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 Bureau Chief Pharmacist.