# U.S. DEPARTMENT OF JUSTICE
# Federal Bureau of Prisons

## PROGRAM STATEMENT
## Pharmacy Services

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| Approved by | William K. Marshall III<br>Director, Federal Bureau of Prisons |
| DPI | HSD |
| Number | 6360.03 |
| Date | May 7, 2026 |

### Summary of Changes

*Program Statement Rescinded:*

- 6360.02 Pharmacy Services (10/24/2022)

*Changes:*

- Updates have been made throughout regarding the treatment of Opioid Use Disorder (OUD) to align with changes to the Code of Federal Regulations (CFR) and Bureau of Prisons clinical management of OUD.
- Extensive changes to include reorganization and renaming of sections have been made throughout this program statement to improve clarity and flow.
- Requirement for Institution Supplement has replaced prior requirement for local procedures.

## 1. PURPOSE AND SCOPE

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

### a. Program Objectives.

- Access to safe, quality, necessary, and cost-effective pharmaceutical care will be provided to all inmates.

b. **Institution Supplement.** The following provisions of this program statement require an Institution Supplement. Further information regarding institution supplement requirements can be found in each respective section.

- Section 5. Standards of Operation, Subsection b. Equipment

- Section 7. Pharmacy Operations
- Section 9. Controlled Substances, Subsection g. Discrepancies
- Section 15. Patient Safety, Subsection a. Medication Non-adherence
- Section 16. Medication Errors, Subsection b. Applicability and Procedures
- Section 17. Medication Inventory Management, Subsections b. Necessity of Timely and Consistent Medication Procurement and c. Pharmaceutical Prime Vendor Contract (PPV)
- Section 18. Needles and Syringes, Subsections a. Storage and d. Discrepancies

## 2. ACRONYMS AND DEFINITIONS

### a. Acronyms.

- ADHD Attention Deficit/Hyperactivity Disorder
- AMDC Automated Medication Dispensing Cabinet
- APP Advanced Practice Provider
- BPA Blanket Purchase Agreement
- CD Clinical Director
- CFR Code of Federal Regulations
- CPS Central Pharmacy Services
- DAW Dispense as Written
- DEA Drug Enforcement Administration
- DOT Directly Observed Therapy
- EHR Electronic Health Record
- EMT Emergency Medical Technician
- FDA U.S. Food and Drug Administration
- FDC Federal Detention Center
- FSS Federal Supply Schedules
- HSA Health Services Administrator
- 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
- 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

b. **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 and verifying the medication order described in Section 11 of this program statement.
  - Only pharmacists may routinely dispense medications.
- **Distribution** is defined as physically handing a filled medication order or over-the-counter (OTC) product to an inmate.
- **Filling** is the act of placing a medication in a bottle or unit of use system and labeling it with patient specific information.
  - Filling may be done by an appropriately trained staff member.

3. **STAFFING**

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

At a minimum, institutions utilizing Central Fill and Distribution (CFAD) must be staffed by trained medication technician(s). Additional pharmacy staff, to include pharmacists, may also be required dependent on institution volume, care level, and as determined by the Health Services Division (HSD).

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 (CO) approval.
- Planned closures of pharmacy due to scheduled leave (e.g., annual training, scheduled medical procedures, etc.) must have concurrence by the Regional Medical Director and Regional Chief Pharmacist.

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, special projects, etc.) one of the following options will be used:

- **TDY Within the Bureau.** Arrange for TDY assistance from another Bureau pharmacist. TDY assistance should not leave another institution without pharmacist coverage (e.g., TDY from an institution with only one pharmacist).
- **Contracting (Amend Existing Contract).** Include 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).
- **Obtain the Services of a Second Pharmacist.** A second pharmacist provides the added benefit of coverage of vacations, training, and sick leave, as well as increased clinical services.

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 inmates 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 require a waiver to policy to utilize physician verification for the period covered by the physician.

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

## 4. TRAINING AND EDUCATION

Pharmacy personnel will participate in relevant education programs, including orientation of new staff, in-service, and outside continuing education.

a. **Orientation.** Institution HSAs and Chief Pharmacists will ensure pharmacists and all other staff working within the pharmacy (e.g., pharmacy and medication technicians) complete Pharmacy Services Orientation prior to assuming pharmacy responsibilities. Documentation of orientation will be maintained per the Program Statement **Health Care Provider Credential Verification, Privileges, and Practice Agreement Program**.

Any Bureau staff or contractor who has completed the required training and competencies, as established by the HSD, may distribute or administer medications.

b. **Pharmacist Peer Reviews.** A pharmacist peer review will be completed for each Bureau pharmacist as specified in the Program Statement **Health Care Provider Credential Verification, Privileges, and Practice Agreement Program**. The Bureau Chief Pharmacist or designee will identify the peer reviewers responsible for conducting the review.

Corrective action reviews are used when circumstances indicate a need for an onsite review of the institution pharmacist (clinical or administrative) or pharmacy programs, as determined by the Regional Chief Pharmacist, Chief of Clinical Pharmacy Programs, or Bureau Chief Pharmacist. Refer to the Program Statement **Health Care Provider Credential Verification,**

**Privileges, and Practice Agreement Program** for policies related to corrective action reviews.

## 5. STANDARDS OF OPERATION

Each institution will provide space, equipment, and supplies for the professional and administrative functions of the pharmacy to promote inmate safety through the proper storage, preparation, dispensing, and administration of drugs.

a. **Reference materials.** The Institution Chief Pharmacist will have consistent access to up-to-date on-line reference materials **(**e.g., UpToDate, Dynamed, Facts and Comparisons, etc.), that includes drug information, drug interaction checkers, pharmacology and pharmacotherapeutics, and patient information.

b. **Equipment.** Equipment in the pharmacy will include at least the following:

- Adequate computer equipment including a computer workstation for each pharmacist position plus at least one extra station for pharmacy technicians and/or medication technicians with intra-agency email, electronic health record (EHR), and internet access.
- Adequate power supply and server access ports to operate computers and automation.
- A dedicated and appropriately labeled medical grade refrigerator, regardless of location.
- Adequate lighting and ventilation.
- A sink with hot and cold running water.
- A system to monitor temperature control that meets compendia/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 institution supplement 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. Refer to Section 7(d) for disposal of non-viable medications.
- Medical Care Level 4 institutions – hoods, dedicated spaces, and other equipment meeting current compendia standards to compound intravenous medications. Medical Care Level 3 institutions may also have this equipment, if approved by HSD.

c. **Key Control.** Only pharmacy staff, contractors, or designee(s) will have keys to the pharmacy. Only the Institution Chief Pharmacist and/or 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 main stock medications.

## 6. MEDICATION FORMULARY

a. **National Drug Formulary.** Each institution will use the Bureau's National Drug Formulary. The Bureau formulary is a list of medications approved by HSD to ensure high-quality, cost-effective drug therapy for the population served. The P&T Committee is responsible for the development and maintenance of the National Drug Formulary, with final approval by the Bureau Medical Director. National P&T voting members will include, at a minimum, Regional Medical Directors and Regional Chief Pharmacists. Additional members are assigned as determined by the Bureau Medical Director or designee.

All Bureau institutions, including medical centers, are expected to abide by the formulary. Requests for changes to the National Formulary (i.e., additions, deletions, changes in restrictions) are sent through the process determined by the Bureau Chief Pharmacist. All requests will be reviewed at the National P&T Meeting.

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

b. **Local Drug Formulary.** A local formulary may be more restrictive than the National Formulary. Medications may not be added or national formulary use criteria removed. Any changes to local formulary are made through the local P&T Committee. Changes to local formulary outside of local P&T meetings may be necessary at times and require approval of the Institution Chief Pharmacist, CD, and HSA at a minimum; and must be reviewed and documented in the next local P&T minutes. Local formularies will be made available to all the institution's health services staff and consultants.

c. **Utilization of Non-formulary Medications.** Authorization for use of items not on the National Formulary or beyond the listed restrictions must be requested using the Non-Formulary Request process. The process is completed through the EHR.

- A new non-formulary request is not required for intra-system transfers who previously had a non-formulary medication approved.
- All comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
- Non-urgent non-formulary medications will not be initiated until after authorization is received, even if the medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.

- Consultant providers are expected to utilize and stay within the Bureau National Formulary when making recommendations and to provide specific and adequate justification for the use of non-formulary medications.
- Court orders recommending or ordering specific treatments will be referred to the appropriate Bureau attorney(s). All such orders/recommendations are still subject to the non-formulary review process.

d. **Non-formulary Medication Continuity of Care.** There are times when inmates are processed into an institution after normal working hours, weekends, and holidays. In these cases, continuation of non-formulary medications prior to approval may be medically necessary because of the following reasons:

- There is no formulary substitute or changing to a formulary substitute will not allow for appropriate follow up monitoring until the next workday.
- Not providing the medication would pose a significant risk to the inmate.

When continuation of a non-formulary medication prior to approval is medically necessary, an allowance is given to dispense/administer the medication for four days while awaiting approval. This four-day allowance is only to be utilized for urgent continuity of care purposes and not for the purpose of initiating routine/non-emergency non-formulary medications without appropriate approval. It is the prescriber's responsibility to ensure follow-up and submission of a non-formulary request prior to expiration of a currently approved non-formulary request.

Medication orders that do not meet the above criteria for continuity of care should not be written, entered into the pharmacy software system, administered, or dispensed prior to appropriate non-formulary request approval.

## 7. PHARMACY OPERATIONS

The Institution Chief Pharmacist will develop and maintain an institution supplement pertaining to pharmaceutical services, in concert with medical staff and, as appropriate, with representatives of other disciplines. This supplement will include the control, accountability, and distribution of drugs. The supplement will be reviewed/revised annually, as necessary.

a. **Institution Pharmacy and Therapeutics (P&T) Committee.** The CD will establish an institutional P&T Committee that meets biannually in April and October and will review the previous six 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.

- **Meetings.** The required minimum agenda for this committee meeting includes review of the following:

- Changes in the National Formulary
- Review of local formulary restrictions
- Requests for addition to National Formulary and changes to local formulary
- Floor stock medications
- Errors and near misses in prescribing, dispensing, and administering medication in the institution
- Adverse drug reactions that occur in the institution
- A review of current Look Alike/Sound Alike and High-Risk medications in the institution
- Medication Use Evaluations (MUEs) used in the institution with accompanying data and trending
- Clinical pharmacy outcomes as well as interventions
- Current DEA registration(s), expiration dates, and power(s) of attorney
- Overall and specific pharmaceutical cost trends
- Medication shortages and recalls affecting the institution
- Policy and procedure issues

- **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 Regional Chief Pharmacist within 30 days after the meeting. The Bureau Chief Pharmacist will provide a meeting template on the Chief Pharmacist's page under the Health Services Division on the Bureau's intranet site. Institution P&T Committee meeting minutes will contain:
  - Date of the meeting
  - List of attendees
  - All agenda items listed above
  - Signatures of the CD, HSA, and Institution Chief Pharmacist

b. **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 located on the Chief Pharmacist's page under the Health Services Division on the Bureau's intranet site that will be used for this purpose. A copy of the documentation will be electronically sent to the Regional Chief Pharmacist for review within 30 days of the end of each quarter.

c. **Drug Recall.** A drug recall procedure, including provisions for documenting results, will be established at each institution.

d. **Outdated and Non-Viable Medications.** The Institution Chief Pharmacist will maintain adequate records and procedures to ensure outdated and non-viable medications are not used.

- Expired and non-viable 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 and non-viable medications. Refer to Program Statement **National Environmental Protection** for additional information on environmental regulations for disposal.
- 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 Pharmacopeial Convention, General Chapter <797> or by the manufacturer's specifications, whichever is sooner.
- The institution Hazardous Waste Storage Site Coordinator must be contacted when disposing of any pharmaceuticals classified as hazardous waste.

e. **Patient Counseling.** The Institution Chief Pharmacist will ensure patient counseling is provided by a pharmacist when indicated and/or requested. Patient counseling will comply with federal regulations.

- Patient counseling 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 by a pharmacist will be facilitated upon inmate request when a new medication is started. It is not necessary to furnish patient counseling for each medication refill.
- If a 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 patient counseling and consultation at each location.
- Oral counseling may be done at the pharmacy window, a designated counseling area, the inmate's cell, or virtually, always being mindful of confidentiality.
- The patient counseling will also consider literacy and primary language.

## 8. CLINICAL PHARMACY SERVICES

Each Institution Chief Pharmacist will develop clinical pharmacy services programs to enhance patient care and support the Program Statement **Patient Care**. The scope of clinical services will vary based on institutional mission and pharmacy staffing. Guidance for clinical pharmacy services is provided by the Chief, Clinical Pharmacy Program with oversight by the Bureau Chief Pharmacist, including Collaborative Practice Agreement management, peer review, and reporting clinical outcomes annually.

## 9. CONTROLLED SUBSTANCES

a. **Applicability of Federal Law.** 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 section 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 21 CFR Chapter II.

b. **DEA Registration.** The institution is the DEA registrant. The Institution Chief Pharmacist who manages the registration on behalf of the institution is the Officer of the Registrant. At institutions without a Bureau pharmacist, the following staff are responsible for fulfilling the role of the Officer of the Registrant in this order of precedence: acting Chief Pharmacist (if applicable), HSA, Assistant Health Services Administrator (AHSA), CD, Associate Warden (AW), and the Warden. If the Institution Chief Pharmacist is vacant, the alternative Officer of the Registrant will fulfill the functions listed throughout the remainder of this section.

The Officer of the Registrant may provide Power of Attorney (POA) for persons other than the person who signed the current DEA registration to be able to manage the DEA registration and/or order Schedule II controlled substances (i.e., obtaining and signing the DEA Form 222, U.S. Official Order Forms – Schedules I & II). POA forms are kept with other controlled substance records. POAs are void upon departure of the Officer of the Registrant. Refer to 21 CFR 1305.5 for further details and POA example.

The contact information for DEA registration and renewal is available at the DEA Diversion Control Division portal. 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. These applications are completed on-line.

- To obtain an initial DEA registration number under the Controlled Substances Act, the Institution Chief Pharmacist completes a DEA Form 224, Application for Registration Under the Controlled Substances Act. 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 DEA Form 224a, Renewal Application for Registration Under the Controlled Substances Act or DEA Form 363a, Renewal Application for Registration Under the Narcotic Addict Treatment Act of 1974.

The institution DEA registration number is used only for official business and providers may not use the institution DEA registration, provided under federal fee-exemption, outside of the Bureau. Fee exemption is not authorized for personally held DEA numbers regardless of whether they are being newly acquired or renewed.

Each institution will only have one registration number for controlled substances. One additional DEA registration for Narcotic Treatment Program (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.

- **Change of Officer of the Registrant.** When an Officer of the Registrant (i.e., Institution Chief Pharmacist) permanently departs from an institution, they should ensure the Officer of the Registrant is updated to a new Officer of the Registrant, or that a POA for Officer of the Registrant is on file with the DEA. Prior to departure, the off-going registrant and new registrant or the newly designated POA will complete an inventory of:
  - Main stock, sub-stock, and destruction controlled substances
  - Controlled substance records

  When a permanently assigned Officer of the Registrant arrives at an institution, the Officer of the Registrant will be updated with the DEA, and a similar inventory will be completed as soon as practical.

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

- The Institution Chief Pharmacist is the responsible authority for all controlled substances.
- The main stock of controlled substances is kept locked and stored in a vault or safe that meets all DEA requirements. Only the Institution Chief Pharmacist and/or 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 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 main stock vaults or safes storing 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.
- Controlled substances that are damaged, expired, or retrieved from inmates through R&D will be segregated in the safe from other controlled substances and maintained on a separate destruction inventory.
- Institutions with OTP certification providing methadone for opioid use disorder (OUD) treatment may store bulk methadone in either a separate safe, distinct from that used to store other controlled substances, or stored in the same vault, provided it is clearly segregated from other controlled substances.
- 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 restricted to only controlled substances or in a locked drawer within the refrigerator if shared with non-controlled substances.

d. **Purchasing and Receiving.** Purchase orders for controlled substances will be prepared by a designated staff member. The Institution Chief Pharmacist will establish a proper system of security for their receipt. Controlled substances will be purchased in single-dose packaging when available.

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. 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."

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 controlled substances or their records.

- **Main stock Records.** The pharmacist will maintain adequate main stock inventory 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 or dispensing
  - Balance on hand
- **Sub-stock Records.** Controlled substances in sub-stock locations are to be used for administration only (e.g., on medical/nursing units or DOT).

  Sub-stock will have records maintained for proof of use for each controlled substance 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.

  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
- Signature of person administering
- Balance on hand

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 quarter. For institutions with higher usage rates, more frequent inventories are recommended.
- **For institutions not using AMDCs,** at the beginning of each shift, a staff member will conduct a complete sub-stock inventory. 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 substances 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 resolve the discrepancy immediately.

- The staff member discovering the discrepancy will notify the Institution Chief Pharmacist and HSA per procedures outlined in the institution supplement.
- For institutions using an AMDC, an institution pharmacist will review discrepancy reports daily. At institutions without a pharmacist, the HSA will perform this task.
- The institution supplement will include processes for monitoring and addressing unresolved discrepancies.

h. **Biennial Inventory.** The Controlled Substances Act requires each registrant to make a

complete and accurate record of all controlled substance stock on hand in all main stock and sub-stock locations every two years. The Institution Chief Pharmacist will complete the biennial inventory on the date mandated by federal law. The Institution Chief Pharmacist 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

i. **Additional Auditing Requirements.**

- **Controlled Substances Inventory Team.** The Controlled Substances Inventory Team will consist of the HSA or designee, 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 including controlled substances marked for destruction.
  - Each team member will then sign the BP-A0825, Quarterly Narcotics Audit Team Certificate form to be filed with the controlled substance records.
  - A copy of this form should be sent to the Bureau Regional Chief Pharmacist.
  - This count may be done at any time within the time frame of the quarter.

- **Quarterly Report by Date Range.** At the end of each quarter, the Institution Chief Pharmacist will complete an Inventory Report by Date Range as produced by the pharmacy software for controlled substances to include both main stock and destruction. An electronic copy will be submitted to the Bureau Regional 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.

j. **Theft or Loss.** Any incident of theft or loss must be documented by the individual discovering it. The Institution Chief Pharmacist will in turn send a memorandum to the HSA, with a copy to the Warden. The Institution Chief Pharmacist, upon consultation with the Warden will notify the DEA of significant loss, as defined by the DEA, of controlled substances via DEA

Form 106, Report of Theft or Loss of Controlled Substances. The Institution Chief Pharmacist will maintain a copy of this submission with the controlled substance records.

k. **Disposal.** The Institution Chief Pharmacist 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.

10. **PRESCRIBING**

a. **Essential Elements of a Medication Order.** A medication order is any medication a health care practitioner orders for an inmate. Prescribers will evaluate the inmate'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).

When available, the EHR will be used to prescribe and process all medication orders. When the EHR is unavailable, prescribers will write legible medication orders. An illegible handwritten order will be returned to the prescriber and regarded as a potential error.

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

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

- 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).

"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.

When an inmate is hospitalized, undergoes surgery, or is transferred from outpatient to inpatient status, or inpatient to outpatient status, a full medication reconciliation is completed upon return to the institution.

b. **Medication Order Duration.** All medication orders for chronic care medications, 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 program statement. 30-day fills are recommended for DOT medications.

c. **Telephone/Verbal Orders (TO/VO).** The use of TO/VOs is limited to prevent medication errors from occurring. TO/VO may be used as outlined in Program Statement **Patient Care**.

d. **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 physician before the medication order may be processed and dispensed.

e. **Prescribing Controlled Substances.** When a controlled substance is classified as "physician use only" in the Bureau National Formulary, the physician or dentist will initiate the order or give a TO/VO and countersign the medication order in the health record by the close of the next business day.

Corrected or amended medication orders for controlled substances will be completed per Program Statement **Health Information Management** and a new medication order will be written.

- **Schedule II Controlled Substance Order Duration.** Schedule II controlled substance orders will be valid for 96 hours only. All orders for Schedule II 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, ADHD, and other disease states defined by the Bureau National Formulary will be valid for up to 30 days, unless otherwise defined by the Bureau National Formulary and within federal regulations. All such orders must be supported by on-going documentation in the EHR.
- **Schedule III, IV, and V Controlled Substance Order Duration.** Schedule III, IV, and V orders may be written for up to 180 days unless otherwise restricted by the Bureau National Formulary.

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

Psychiatric medications prescribed for non-psychiatric diagnoses do not require an informed consent (e.g., amitriptyline for trigeminal neuralgia or headache disorder), but do require routine patient counseling.

- **Continuity of Care.** Upon intake, consent for psychiatric medications should be obtained as soon as possible but medications should not be held pending consent.

g. **OTC Medications.** For guidance regarding OTC medications, refer to the Program Statement **Over-the-Counter Medications**.

11. **DISPENSING**

The pharmacy staff must be solely responsible for procuring and dispensing all prescribed drugs used within the organization. Except in emergencies, all sterile and non-sterile drug products will be dispensed from the pharmacy. Non-pharmacist staff and contractors will not have access to bulk stock packages that would permit them to dispense a medication order or administer doses.

Before dispensing medications in non-emergency situations, the pharmacist will review the medication order. Pharmacists and others responsible for processing and dispensing 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. 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

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).

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.

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 inmate harm.

a. **Technician Check Technician (i.e., 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 performed by another technician or robotics (e.g., PACMED).
- Checking medications that have been legally repackaged into unit dose form by another technician.
- Checking stock prepared by another technician for addition to inventory for AMDCs.
- Performing the visual check verification of the medication to be dispensed manually filled by another technician.
- Performing verification for an automated dispensing robot (e.g., ScriptPro®).

At no time will tech check tech functions be permitted without a pharmacist on-site providing oversight. 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 processes requested. The period of approval is limited to one year, after which a renewal must be submitted.

b. **Night stock.** Night stock are limited quantity fills of medication for urgent/emergent or continuity of care situations, such as after-hours acute care or medical trip returns. A pharmacist must check each medication order before it is placed in a drug administration cabinet and distributed or administered to the inmate. To satisfy these requirements during evenings and weekends, each institution will utilize the following night stock procedures.

- The National Formulary provides an approved national list of night stock medications and approved days' supply that institutions may choose to utilize locally.
- Night stock containers will be pre-labeled with the name, strength, formulation, and standard directions for use.
- Night stock must be secured in an AMDC or locked, metal cabinet in the designated medication administration area or urgent care room.

When the after-hours health care provider needs to utilize night stock, the following procedures will be used:

- The inmate may be placed on DOT to be administered single doses of the prescribed medication until a medication order can be dispensed or the health care provider may access the off-shift night stock, remove a night stock container, and write the inmate's name and number, date, provider's name, and the expiration date on the package and distribute it to the inmate.
- 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

12. **ADMINISTRATION AND DISTRIBUTION**

a. **Administration.** The following procedures will be followed for directly observed therapy (DOT):

- Medications will be provided by pharmacy and stored in appropriate packaging and clearly labeled until administration.
- DOT stock will not be in bulk containers. DOT storage systems 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 provided by the pharmacy
  - Automated medication administration cabinets
- Pharmacists will work with the Institution CD and HSA to ensure DOT administration times align with recommended medication dosing schedules. While operational and custody considerations must be considered, clinical appropriateness and the safe and effective timing of medication administration will remain the primary priority.

b. **Drug Samples.** The use of drug samples within the institution is prohibited.

c. **Distribution.**

- All self-carry medications provided to inmates must be documented as distributed to the inmate 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 ensure medications not picked up after no more than 14 days are returned to stock in the EHR. Medications not picked up at CPS serviced institutions are returned to the filling pharmacy using the return module of the EHR.
- Medication dispensing will be in light-resistant moisture-resistant vials and not plastic bags.

d. **Medications for Inmates in Special Housing Units (SHU).** Each institution will develop a procedure to ensure all inmates placed in SHU during the previous 24 hours have their current medications available. Per Program Statement **Special Housing Units**, prescribed medications will be collected and provided to the inmate as soon as possible.

- Local procedures will be developed 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.
- Under no circumstances will medication be locked up with the inmate's property or thrown in "hot trash."

13. **INTAKE MEDICATIONS**

All medication arriving with inmates through R&D will be reviewed by institution intake staff for disposition as below:

- During the intake screening process, health care staff will determine the need for any medication orders.
- An inmate may retain medications prescribed by another Bureau institution if they are not otherwise restricted by policy (e.g., controlled substance, DOT-required, etc.).
- When an inmate enters an institution with medications from the community, the pharmacy will ensure 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).
- The Institution Chief Pharmacist will dispose of all controlled substances in a manner prescribed by the DEA and as described in Section 7(d) of this program statement.
- Pharmacy staff will dispose of all other medications as described in Section 7(d) of this program statement.

## 14. **RELEASE/TRANSFER MEDICATION**

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

a**. Transfer to Residential Reentry Centers (RRC) or Community-Based Programs.** When an inmate is transferred to one of the above, a 90-day supply of current chronic medications will be provided, unless otherwise restricted by an FDA Risk Evaluation and Mitigation Strategy (REMS) or other regulations. 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, and DEA regulations.

b. **Release from Custody.** An inmate releasing from custody will be provided a minimum of 30-day supply of chronic medication(s). Up to a 90-day supply of chronic medication(s) may be dispensed on a case-by-case basis..

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 BP-A0659, Medical Summary of Federal Prisoner/Alien in Transit form or exit summary in the EHR.

- On a case-by-case basis, less or 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 controlled substances and other items subject to abuse will be restricted to minimum quantities.
- A copy of the BP-A0659, Medical Summary of Federal Prisoner/Alien in Transit form may be used to transcribe current medications.

## 15. **PATIENT SAFETY**

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. Through local P&T, institutions will identify

medications used locally that are potentially high risk and implement mitigation strategies to reduce risk of error.

Look Alike/Sound Alike medications and High-Risk medications will be updated at each local P&T meeting for staff to reference in their daily operations.

The HSD participates in adverse reaction reporting programs sponsored by the FDA of the Department of Health and Human Services (DHHS).

- Adverse drug reactions will be reported using the system defined by the Bureau Chief Pharmacist.
- Institutions may also choose to report adverse drug reactions through MedWatch: The FDA Safety Information and Adverse Event Reporting Program on the FDA's website.
- Drug product defects will be reported in accordance with the FDA drug product problem reporting program.

**Medication Non-Adherence.** Institution supplements will include procedures for timely notification of non-adherence. Such notification will be made to the CD and other relevant staff.

## 16. **MEDICATION ERRORS**

Reporting and evaluating medication errors and near misses are an essential function of a successful healthcare system.

a. **Definitions.**

- **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.
- **Near miss** is an error in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention, by another health care provider or the 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. **Applicability and Procedures.** 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. The responsibility to detect and prevent

medication errors lies across the entirety of the health services operations and includes the following:

- 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.
- The institution supplement provides for efficient and safe distribution of all medications and related supplies to inmates.
- 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, Quality Improvement Program (QIP), and the medical staff, will conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence.

c. **Monitoring and Managing Medication Errors.** The staff member identifying the error will report near miss and actual medication errors using the system defined by Bureau Chief Pharmacist. The Institution Chief Pharmacist or pharmacist designee will review the submitted error and notify the physician when clinically indicated.

The Institution Chief Pharmacist will collaborate with the QIP coordinator and other stakeholders to review, analyze, and classify the errors and near misses and develop process improvements. This review will not identify those making the error by name. Reviews should focus on the improvement of performance by recognizing errors and developing a plan to minimize future errors.

Errors resulting in permanent harm or death (e.g., sentinel events) should be reported according to the requirements in the Program Statement **Health Services Quality Improvement**.

## 17. MEDICATION INVENTORY MANAGEMENT

a. **Electronic Inventory Management.** All institutions will utilize the designated electronic inventory management system as directed by the Bureau Chief Pharmacist for all medication inventory and procurement activities. In order to maintain optimal inventory levels that minimize waste, periodic automatic replacement (PAR) levels will be utilized.

b. **Necessity of Timely and Consistent Medication Procurement.** The provision of medically-necessary treatment may not be prevented or delayed due to administrative reasons.

The Cost-Center Manager over medication procurement and Chief Pharmacist will collaborate with the institution's Business Office to develop and implement an institution supplement that supports seamless inventory management and medication procurement.

c. **Pharmaceutical Prime Vendor Contract (PPV).** The national contracts for medications and pharmaceutical products are mandatory. All institutions will order from these contracts, which are applicable for 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. An institution supplement 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 HSD.

d. **Annual Inventory.** Unless otherwise authorized by the Bureau Chief Pharmacist, all pharmacies will complete a full inventory of all main stock medications in August of each year.

- Pharmacies will be given adequate time, staff, and equipment to complete this inventory. Inventory will generally require at least one eight-hour day during the regular work hours without interruption.
- Additional hours or days may be required to complete the inventory, however, overtime or off-shift work should not be utilized.
- During inventory, pharmacies must pause all other pharmacy operations. Urgent or medically necessary medications may be accessed via night stock or AMDC.
- For sites without a pharmacist due to vacancy, the authority responsible for pharmacy operations (generally the HSA), is responsible for ensuring the inventory is completed.
- Certification of inventory completion will be sent to the Regional Chief Pharmacist.

## 18. **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.

Unless otherwise specified by HSD, the following items are identified as accountable sharps, needles, and syringes:

- Any hollow core needles to include pen needles
- Scalpels
- Syringes with a barrel and plunger

For purposes of inventory management and accountability, the following are examples of items not identified as accountable sharps, needles, or syringes:

- Punch biopsies
- Stapler and staple removal kits
- Non-hollow core needles such as lancets or sutures
- Urine transfer straws
- Multi-use medication pens stored separately from pen needles

a. **Storage.** The institution supplement will identify the party responsible for storing needles and syringes.

- All main stock inventories of sterile needles and syringes will be stored in a secure area and have a perpetual inventory. Physical count of main stock items will be verified with documented perpetual inventory when removing items for sub-stock
- 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.
- Each institution 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 staff member using the needle or syringe will designate on the form or in the AMDC the inmate's name or reason the item(s) was used, and sign for the item(s), indicating date and time.

- Staff may check out needles/syringes in small quantities for 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 quarter. For institutions with higher usage rates, more frequent inventories are recommended.
- **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.
  - The time the inventory is conducted will be documented.

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

Staff 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 HSA per local procedures.
- The institution supplement will include processes for addressing unresolved discrepancies.

## 19. OPIOID USE DISORDER (OUD)

Inmates will be considered for the treatment of OUD on an individual basis in accordance with clinical guidance issued by the Medical Director. Inmates 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 SAMHSA have regulatory authority over some of the medications and methods utilized to treat OUD. HSD will provide instruction and should be consulted to ensure compliance with applicable federal regulations. Refer to 42 CFR 8.11(h)(3) for additional guidance related to treatment of OUD in a correctional institution. If an institution

receives a patient on methadone for OUD, the institution will consult with the Regional Chief Pharmacist for guidance to ensure federal regulations are followed.

b. **Informed Consent.** Informed consent will be obtained and documented before dispensing or administering medication for the treatment of OUD.

An agreement for treatment of OUD will be obtained upon the initiation of therapy utilizing the BP-A1146, Treatment for Opioid Use Disorder (OUD) Agreement form.

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. Upon intake, consent for OUD treatment should be obtained as soon as able but medications must not be held pending consent.

## 20. URGENT CARE EMERGENCY CARTS & KITS

The Institution Chief Pharmacist is responsible for all medications located in the urgent care carts, kits and bags.

- Needles, syringes and controlled substances may be maintained in urgent care carts and will be inventoried at least quarterly and whenever the urgent care cart seal is broken.
- Medications approved for the urgent care carts, based on institution care level are determined by the National Formulary.

## REFERENCES

*Program Statements*
Health Care Provider Credential Verification, Privileges, and Practice Agreement Program
Health Information Management
Health Services Quality Improvement
National Environmental Protection
Over-the-Counter Medications
Patient Care
Psychiatric Services
Special Housing Units

*Bureau Forms*

| | |
|---|---|
| BP-A0659 | Medical Summary of Federal Prisoner/Alien in Transit |
| BP-A0825 | Quarterly Narcotics Audit Team Certificate |
| BP-A1146 | Treatment for Opioid Use Disorder (OUD) Agreement |

*Federal Regulations*
21 CFR Chapter II, Part 1300 Controlled Substances Act
42 CFR § 8.11 Opioid Treatment Program certification

*Other Forms*

| | |
|---|---|
| DEA Form 106 | Report of Theft or Loss of Controlled Substances |
| DEA Form 222 | U.S. Official Order Forms – Schedules I & II |
| DEA Form 224 | Application for Registration Under the Controlled Substances Act). |
| DEA Form 224a | Renewal Application for Registration Under the Controlled Substances Act) |
| DEA Form 363a | Renewal Application for Registration Under the Narcotic Addict Treatment Act of 1974 |

*Other References*
United States Pharmacopeial Convention. (2023). *General chapter <797> Pharmaceutical Compounding – Sterile Preparations.*
National Coordinating Council for Medication Error Reporting and Prevention. (2026). *About Medication Errors.*

*ACA Standards*
Performance-Based Standards and Expected Practices for Adult Correctional Institutions (5th Edition)**:** 5-ACI-4A-15, 5-ACI-4B-14, 5-ACI-6A-42, 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), 5-ACI-6D-02 (M)

Performance-Based Standards and Expected Practices for Adult Local Detention Facilities (5th Edition): 5-ALDF-2E-14, 5-ALDF-2F-11, 5-ALDF-4C-36, 5-ALDF-4C-37(M), 5-ALDF-4C-38, 5-ALDF-4D-15 (M), 5-ALDF-4D-17 (M), 5-ALDF-4D-18 (M), 5-ALDF-4D-31 (M)

Standards for the Administration of Correctional Agencies, 2nd Edition**:** 2-CO-1F-14

*Records Retention Requirements*
Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on the Bureau's intranet site.