POLICY OF STATE OF DELAWARE DEPARTMENT OF CORRECTION	POLICY NUMBER D-01	TOTAL PAGES 8
	RELATED NCCHC / ACA STANDARDS: NCCHC: P-D-01 (essential), J-D-01 (essential), MH-D-01 (essential), O-D-01 ACA: 5-ACI -6A-43 (Mandatory), 5-ACI-6A-44	
CHAPTER: 11 BUREAU OF HEALTHCARE, SUBSTANCE ABUSE, AND MENTAL HEALTH SERVICES	**SUBJECT: Pharmaceutical Operations**	
APPROVED BY THE BUREAU CHIEF:	**Bureau Chief, Michael Records (signature on file with BHSAMH)**	
APPROVED BY THE COMMISSIONER AND EFFECTIVE THIS DATE	**Commissioner Monroe B. Hudson Jr. March 21, 2023 (signature on file with BHSAMH)**	
APPROVED FOR PUBLIC RELEASE		

I. AUTHORITY: 11 *Del. C.* §6536 Medical Care

II. PURPOSE: To establish pharmaceutical operations that meet the needs of the facility and conform to legal requirements.

III. APPLICABILITY: All Delaware Department of Correction (DDOC) employees and Contract Provider staff, offenders, and any outside healthcare provider servicing DDOC offenders.

IV. DEFINITIONS: See Glossary

V. SUMMARY OF CHANGES: This policy was not updated significantly. Some grammar, punctuation, and the readability of the document were updated.

VI. POLICY:

A. It is the policy of the DDOC that pharmaceutical operations meet the needs of the facility and conform to legal requirements. This is accomplished in the following manner:

1. The facility complies with all applicable state and federal regulations regarding prescribing, dispensing, administering, procuring, storing, and disposing of pharmaceuticals.
    a. Each facility shall be registered to store and administer controlled substances pursuant to the Drug Enforcement Agency (DEA) and the Delaware Controlled Substance Registration (CSR) requirements. The contract providers shall collaborate to ensure that the facility's registration is current.
    b. A licensed DDOC credentialed pharmacist shall dispose of controlled substances, when necessary, in accordance with 21 CFR 1307.21. This shall be done in the presence of the site Health Services Administrator (HSA), or their designee.
    c. All disposals shall be documented in the Controlled Substance Book.

i. Controlled Substance Books are bound books, not spiral books, with consecutively numbered pages that are used to document controlled substance inventory, distribution, and destruction.
ii. Controlled Substance Books are obtained by the contracted medical provider.
iii. Controlled Substance Books shall be kept for at least five years.

d. A pharmacist, or designee, shall send a monthly Controlled Substance Destruction Report to the Bureau of Healthcare, Substance Abuse, and Mental Health Services (BHSAMH)
e. The facility warden is the registrant for each Facility's Clinic DEA License. The facility warden may execute a Power of Attorney agreement to grant one or more individuals the authority to issue purchase orders for Stock Schedule II narcotics.
f. The Bureau Chief of the BHSAMH (or designee) is the registrant for each facility's Opioid Treatment Program DEA license. The designated registrant may execute a Power of Attorney agreement to grant one or more individuals the authority to issue purchase orders for schedule II narcotics.

2. The contracted healthcare provider and contracted pharmaceutical provider shall collaboratively develop a diversion control plan that contains measures to reduce the possibility of diversion of controlled substances from legitimate treatment use.
    a. A diversion control plan must provide guidance on the prevention, detection, investigation, and reporting of mishandled or intentionally misdirected controlled medication that may lead to a diversion of the medication away from the patient(s) for whom it was intended. At a minimum, the plan should include:
        i. Chain-of-custody tracking for each stage of procurement, inventory, storage, administration, and disposal.
        ii. Monitoring patients during medication administration by both nursing and correctional officers
        iii. Safeguards and accountability procedures for the disposal and prevention of unintentional wastage of medication
        iv. Procedures for investigating and reporting of medication that cannot be accounted for
        v. Training of nursing and correctional officers on all aspects of the plan
        vi. Annual review and approval of the plan by the responsible physician and facility warden.
3. The DDOC, collaborating with the contracted pharmaceutical provider and contracted healthcare provider, shall develop and maintain a formulary.
4. The facility maintains procedures for the timely procurement, dispensing, distribution, accounting, storage, administration, and disposal of pharmaceuticals.
    a. Medications shall be kept under the control of appropriate staff members.

b. Offenders do not prepare, dispense, or administer medication except for Keep on person (KOP) programs approved by the facility and responsible physician.
    i. Offenders may be permitted to carry medications necessary for the emergency management of a condition when ordered by a clinician.
c. Documentation for any KOP protocol is approved by the responsible physician.
d. All patient specific medications shall be procured through the contracted pharmaceutical provider via medication orders placed in the Electronic Health Record (EHR).
e. Medications shall be packaged in offender specific prescription packaging except for items that are multi-dose packaging (e.g., insulin, glucometer strips, over the counter (OTC) medications, etc.), or intended for clinic/facility stock.
f. Post-release doses or prescriptions for opioid agonists for treatment of substance use disorder is limited to those enrolled in comprehensive maintenance treatment and usually is limited to no more than four days' supply.
    i. Patients on OTP buprenorphine (Subutex), a 4-day supply of buprenorphine and naloxone) (Suboxone) may be provided upon discharge through the backup pharmacy process.
    ii. Pregnant females on OTP buprenorphine (Subutex), a 4-day supply of buprenorphine (Subutex) may be provided upon discharge through the backup pharmacy process.
    iii. Patients on OTP methadone will not be discharged with methadone, but they will follow up in the community for continuity of care.
    iv. Take-home medication must be packaged according to federal regulations (child-resistant packaging).
    v. Any deviation to this policy must be discussed with the BHSAMH Medical Director prior to providing the medication.
g. Patients enrolled in short-term medically supervised withdrawal treatment or interim maintenance treatment may not be given opioid agonists for unsupervised take-home use.

5. The facility maintains records as necessary to ensure adequate control and accountability for all medication, except those that may be purchased over the counter. Each facility shall have inventory procedures for ensuring accurate counts of medications. At a minimum, each site will do the following:
    a. A perpetual inventory of all controlled substances, syringes, and needles is maintained at each site.
        i. At each shift change, the outgoing and incoming nurse shall together count the controlled substances at each facility. Both nurses will verify and record the count by legibly printing their full name with the date and time in the Controlled Substance Book.
        ii. A sharps inventory shall be completed at each shift change at each facility. Any discrepancies shall be documented in an

Incident Report in Delaware Automated Correction System (DACS) and security staff shall be notified immediately. Sharps, as used in this policy, refers to items that are subject to abuse (e.g., syringes, needles, lancets, scissors, nail clippers, and other sharp instruments).

iii. Sharps must be securely stored separately from controlled substances.

b. For non-controlled substances, a quarterly inventory shall be conducted to ensure what is being prescribed is available, and returnable or expired items are accounted for and returned in a timely manner.

c. Stock medications shall be inventoried at least monthly to ensure Pharmaceutical Automatic Refill (PAR) levels are appropriately maintained.

i. Inventory shall be maintained on all stock medications through an inventory control system that tracks medication on a daily and per-use basis.

a) The inventory control system shall include the date dispensed, quantity dispensed, name and SBI number of patients receiving medication, name and credentials of the staff member dispensing medication, and the staff member's signature.

6. If there is a discrepancy in medication inventory, the following shall occur:

i. The charge nurse will be notified.

ii. The charge nurse shall investigate, take appropriate action, and notify the Director of Nursing and Health Services Administrator (HSA) of the results within 4 hours of the notification.

iii. In the event the discrepancy involves a controlled substance, the HSA shall immediately notify security, the DEA registrant, and BHSAMH.

a) The DEA registrant in consultation with BHSAMH shall notify DEA Field Division Office in writing, of significant loss of controlled substances or theft within one business day of discovery of such loss or theft. In addition, a DEA Form 106 regarding the loss or theft shall be completed in accordance with DEA regulation (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)

iv. A medication error shall be reported pursuant to BHSAMH policy *D-02 Medication Services.*

b. Any discrepancies shall be documented in an Incident Report in the DACS.

7. The facility maintains maximum security storage of, and accountability for Drug Enforcement Agency (DEA) controlled substances.

a. All controlled substance dispensing shall be documented in the Controlled Substance Book with a legible printed name for the individual dispensing, date, and time.

b. All controlled substance disposals/destruction shall be documented in the Controlled Substance Book with a legible printed name for the individual performing the disposal/destruction, date, and time.

8. A staff or consulting pharmacist documents inspections and consultations of all sites, including satellites, at least quarterly.
9. An adequate and proper supply of antidotes and other emergency medications (e.g., naloxone, epinephrine) and corresponding equipment (for either injection or intranasal use) and related information are readily available to the staff.
10. The poison control telephone number is posted in the pharmacy and areas where overdoses or toxicologic emergencies are likely such as laundry rooms.

B. Medication Room Operations - each facility shall have designated medication room(s) to store medications.
   1. The medication room(s) shall be adequately staffed with properly trained staff based on the size and scope of needs of the facility.
      a. This training shall include specific training on DEA regulations on ordering, handling, inventory control, and/or access to controlled substances.
   2. A nurse and/or a pharmaceutical technician, shall be designated to oversee the medication room(s) daily.
      a. Responsibilities of the medication room nurse and/or pharmaceutical technician, shall include:
         i. Reconciling the daily deliveries from the Pharmacy Contract Provider
         ii. Stocking the medication carts
         iii. Receiving the Pharmacy Sick Call Requests for medication refills and ordering the refills through the EHR
         iv. Monitoring of the stock medicines for expiration dates and reordering stock as needed
         v. Documenting and sending the returns for credit to the Pharmacy Contract Provider
   3. Only the DEA registrant or persons with appropriate Power of Attorney shall execute DEA 222 forms for stock schedule II-controlled substances.
   4. Special care should be taken to ensure that medications are ordered utilizing the correct DEA license.
      a. In facilities that are licensed as OTP's, the following shall apply:
         i. All controlled substances (e.g., methadone, buprenorphine) that are prescribed for use as medication assisted treatment (MAT) or medication assisted withdrawal (MAW) must be ordered utilizing the Opioid Treatment Program DEA license and must be used solely for that purpose.
         ii. All controlled substances that are used for any purpose other than MAT or MAW shall be ordered under the facility DEA license (also called the hospital clinic DEA number).
         iii. Under no circumstances should controlled substances ordered for MAT or MAW (ordered under the OTP DEA license) be used for any purposes other than substance use disorder (SUD) treatment.
         iv. Under no circumstances should controlled substances ordered

under the facility DEA license be used for SUD treatment.

b. In facilities that are not licensed as OTP's, the following shall apply:
    i. When schedule II-controlled substances (methadone) are needed for continuation of substance use disorder treatment provided in the community, the medications shall be obtained from community-based OTP's while following all applicable procedures outlined by the DEA.
    ii. Non-schedule II-controlled substances (including buprenorphine) used for the treatment of SUD (MAT or MAW), shall be ordered using the facility (clinic) DEA license to treat SUD patients under the office-based opioid treatment (OBOT) program.
    iii. All other controlled substances shall be ordered under the facility (clinic) DEA license.

5. OTP controlled substances shall be stored under double lock separately away from the clinic's controlled substances.
6. All OTP controlled substance dispensing, and delivery records shall be stored separately from the clinic's records.
7. Medication storage and medication areas are devoid of outdated, discontinued, or recalled medications, except for those in a designated area for disposal.
8. All medications are stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
9. Antiseptics, other medications for external use, and disinfectants are stored separately from internal and injectable medications. Medications requiring special storage (e.g., refrigeration) for stability are so stored.
10. Key control and accountability
    a. Only assigned Medication Room staff and security shall have access to the keys for the Medication Room area.
    b. The HSA, or designee, shall be assigned as the key control for the Controlled Substance box and shall maintain possession of the keys to access controlled substance medications.
        i. The shift-to-shift controlled substance count verification and documentation in the Controlled Substance Book is required prior to the passing of the Controlled Substance box keys.
11. Equipment in the Medication Room shall include, at a minimum:
    a. Adequate storage space to accommodate the different types of medications that shall be kept separate, e.g., external use medications vs. internal use medications vs. ophthalmic vs. otic vs. inhalation medications. Injectable medications shall be stored separately from all other medications.
    b. A refrigerator dedicated to and appropriately labeled for storage of medications.
        i. Refrigerators and freezers used to store medications shall not be used for any other purposes.
        ii. Prescribed food supplements requiring refrigeration shall be stored in a separate refrigerator from the medication refrigerator.
        iii. Site-specific procedures shall be in place to make portable coolers or frozen cooler bags available when medications

requiring refrigeration are moved between locations.

c. A system to monitor temperature control that meets Food and Drug Administration (FDA) standards.
    i. Refrigerator and freezer temperatures will be documented by the continuous electronic temperature monitoring system.
        a) The HSA, or designee and BHSAMH will have online access to this continuous online temperature monitoring system.
        b) If at any point the continuous temperature monitoring system goes offline, monitoring of refrigerator and freezer temperatures will be documented manually until the system is back online.
        c) The HSA, or designee shall check the continuous online temperature monitoring system at least once per day to ensure the system is operating and that no temperatures are out of range.
        d) When a small refrigerator/freezer combination is used to store refrigerated medications, but not frozen medications, the temperatures of the freezers do not need to be taken and documented.
    ii. Medications requiring room temperature storage shall be stored and maintained between 59- and 86-degrees Fahrenheit.
        a) The room temperature is to be continuously monitored via an electronic temperature monitoring system.
            1) Staff shall check the electronic monitoring system at least once per day to ensure the system is operating and that no temperatures are out of range.
            2) If the temperature is found to be below 62 degrees, or above 80 degrees Fahrenheit at that time, maintenance is to be notified and the room temperature is to be rechecked every 4 hours until the temperature is in the correct range.
            3) Careful consideration shall be given to account for daily seasonal temperature variations (e.g., not reading temperatures early in the day if the high temperature is not until later in the day).
    iii. Medications requiring refrigeration shall be stored between 35- and 46-degrees Fahrenheit.
    iv. Medications requiring freezing temperatures shall be stored at or below 5 degrees Fahrenheit.
        a) It is preferable that these medications be stored in a central location where consistent freezer temperatures can be maintained and documented.
    v. Medications are considered compromised and shall be discarded if temperature controls are not maintained over a 48-hour period unless stability can be verified through the manufacturer or

published literature.

vi. Variations in temperatures shall be documented and addressed; the correction shall be documented on the temperature control log.

vii. The records of the temperature control documentation will be maintained by the HSA for a period of five years.

d. A double-locked storage box secured to either a wall or the floor, adequate in size to secure all controlled substances.

i. A double-locked refrigerator for temperature-sensitive controlled substances.

e. Current reference materials shall be available for Medication Room staff, such as a Physicians Desk Reference or one of various drug identification resources.

C. Orientation – all staff working in the medication room shall complete a Medication Room Orientation.

1. This orientation shall include, at a minimum, the following:
   a. All applicable DEA regulations on ordering, handling, inventory control, and/or access to controlled substances
   b. How to document medication dispensing in the EHR
   c. How to, and when to crush and/or float medications.
   d. How to complete a mouth check
   e. Knowledge of medication that require direct observation.
   f. Differences in medications used for external versus internal use.
   g. Obtaining refusals and documenting refusals
   h. Process for referring refusals to the prescriber for follow-up.
   i. The process for missed dose reconciliation.
   j. Proper Controlled Substance Book documentation
   k. Counting and verifying medication counts
   l. Ordering medication refills
   m. Key control policies
   n. Maintaining refrigerator temperature log.
   o. Storage system for the different type of medications
   p. Inventory processes
2. The site HSA, or designee shall maintain documentation for staff that complete this orientation.
3. This orientation shall be reviewed with each employee at least once annually.

D. Pharmacy and Therapeutics (P&T) Committee

1. The BHSAMH Bureau Chief, or designee, shall establish a P&T Committee that shall meet at least quarterly. At a minimum, membership shall include the following:
   a. Contract Pharmaceutical Provider Pharmacists working in DDOC facilities.
   b. BHSAMH Medical Director, or designee
   c. BHSAMH Behavioral Health Director, or designee
   d. Chief Medical Officer – contracted medical provider.
   e. Chief Nursing Officer – contracted medical provider.
   f. Other personnel as requested by the Bureau Chief of BHSAMH
2. The committee's primary purpose shall be to:

a. Determine what medications shall be available on the DDOC stock list to be available for emergency and night/weekend bridge-orders and determine what changes to the stock list should be made in response to nationwide shortages and Medication Utilization Reviews (DURs)
b. Discuss and recommend if any drugs require restrictions (Nurse Administered vs. Keep on Person (KOP) medications vs. Crush and Float Medications, etc.)
c. Discuss and evaluate errors in prescribing, dispensing, and administering medications in the facilities.
d. Discuss and evaluate Adverse Drug Reactions (ADRs) that occur in the facilities.
e. Discuss, approve, and review MURs used in the facilities; review DUR data and track for trending over time.
f. Discuss Quality Improvement measures, i.e., the Medication Room Inspections and Audits conducted by the pharmacists working in the DDOC facilities.

3.Minutes

a. Minutes shall be maintained by the BHSAMH staff and made available to all facility medical directors. P&T meeting minutes shall contain, at a minimum:
    i. Date of meeting
    ii. List of attendees
    iii. Reading and acceptance of previous minutes
    iv. BHSAMH Policy and site-specific procedures review and updates.
    v. Review of past unresolved issues
    vi. Inventory control activities, e.g., Returns for Credit and Narcotic Destruction
    vii. Medication recalls and/or shortages.
    viii. Medication errors; adverse drug reactions and monitoring
    ix. Quality improvement activities
    x. DUR reviews and new DUR proposals
    xi. Overall and specific pharmaceutical cost trends

E. The Contracted Healthcare Provider in collaboration with the Contracted Pharmaceutical Provider shall develop within 30 days of the effective date of this policy, a site-specific procedure for each Level 4 and Level 5 facility implementing this policy and coordinating the procedure with the BHSAMH.