I. PURPOSE

To outline staff practices on the prescribing, storage, documentation, accountability, reporting of discrepancies, and destruction of controlled substances.

II. DEFINITION

Controlled Substance

Any medication in Schedules CII through CV that is under the jurisdiction of the Federal Controlled Substances Act and the North Carolina Controlled Substance Act.

III. POLICY

North Carolina Department of Adult Correction (DAC) staff shall strictly adhere to procedures set forth in this policy as mandated by the state and federal regulations governing controlled substances.

REGULATORY AUTHORITIES

A. All correctional facilities shall register annually with the North Carolina Department of Health and Human Services (DHHS), Drug Control Unit. The facility healthcare authority shall receive email notification to renew their registration, shall complete Form DHHS-226, and shall forward the form to DHHS electronically. The Warden, Chief Executive Officer, or Human Services Facility Director shall be the authorizing signature on the DHHS registration application. Each facility is responsible for paying for their annual registration fee.

B. The North Carolina Controlled Substances Act authorizes the DHHS Regulatory Branch to inspect any correctional facility for compliance with controlled substance regulations and to file correctional facility compliance reports with the Division of Institutions (DOI) Warden or designee.

C. Facilities that maintain controlled substances in stock inventories shall register with the Drug Enforcement Administration (DEA). The Deputy Secretary of Comprehensive Health Services or designee must approve any facility requests for DEA registration and must be the authorizing signature for fee exemption. The facility health care authority shall complete form DEA-224 and forward the form to the DEA. The Warden, Chief Executive Officer, or Human Services Facility Director shall be the authorizing signature on the DEA registration application. The DEA license shall be renewed every 3 years.

IV. PROCEDURES

A. Prescribing of Controlled Substances

1. A physician, dentist, podiatrist, physician extender, (physician assistant, nurse practitioner), or other registered practitioner may authorize an order for a controlled substance provided they are:

   a) Authorized to prescribe controlled substances by the jurisdiction in which they are licensed to practice.

   b) Registered with the Drug Enforcement Administration and maintain a valid DEA number.

   c) Registered under the Federal Controlled Substances Act.

2. Physician Assistants and Nurse Practitioners who have DEA registrations can prescribe controlled substances according to North Carolina Board of Pharmacy, Drug Enforcement Administration, and Board of Medical Examiners guidelines.

3. DEA registration numbers shall be added to the Electronic Healthcare Record (EHR) before a provider can prescribe any controlled substance.

4. Controlled Substance orders that require DAC Pharmacy Services to dispense a supply to an individual offender cannot be entered into EHR and shall be written on a DC-834 and submitted to a DAC Pharmacy.

5. Controlled Substance orders where the drug will be obtained from a facility Automated Dispensing Cabinet (ADC) shall be entered into EHR and a DAC Pharmacy will profile the order without dispensing a supply to the individual offender.

6. Outpatient Schedule CII Controlled Substance orders where the drug will be obtained from a local pharmacy require two separate paper orders. One order for the local pharmacy to dispense and one order for the DAC Pharmacy to profile in EHR.

7. A licensed provider without a DEA number cannot independently prescribe controlled substances. This provider shall obtain a verbal order for the controlled substance from their sponsor provider. It is the responsibility of the sponsor provider to cosign and forward to pharmacy within seven days a copy of the cosigned order.

8. A telephone/verbal order for a Schedule II Controlled Substance shall be prescribed for an emergency period only not to exceed five days for acute pain and seven days for post-op pain. For DOI facilities, this emergency supply shall be the quantity needed to provide treatment until a provider is available to issue an additional written order, if deemed necessary, and nursing staff can procure the medication.

9. To qualify as an emergency order, the following parameters shall apply.

a) Immediate administration of the controlled substance is necessary for the proper treatment of the offender.

b) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Controlled Substance Act.

c) It is not reasonably possible for the prescribing provider to issue a written order or order in EHR.

10. The telephone/verbal order shall include the statement "Authorization for Emergency Dispensing" written by the nurse on the provider order.

11. It is the responsibility of the provider to sign and forward to pharmacy within seven days all verbal orders for Schedule II controlled substances.

12. The date of reference for the start date of a controlled substance order is the date and time the order is written unless a future start date and time are specified. The stop date for a controlled substance order is referenced to the start date unless a stop date is specified.

13. For taper (dose decreasing) or titrate (dose increasing) controlled substance orders that must be processed in the pharmacy software system by pharmacy services as separate orders, the start date and stop date shall be changed by pharmacy staff to accommodate all days of the taper/titrate. The first order is processed with the start date and time the order is written or with the future start date and time when requested, and subsequent entries have a start date being based on the stop date and time of the previous order.

14. When a provider writes multiple orders for a sequence of two or more different controlled substance medications, the start date and stop date shall change to accommodate all days of the therapy. The first order is processed with the start date and time the order is written or with the future start date and time when requested, and subsequent orders written on the same date and time have a start date, time, and stop date based on the stop date and time of the previous order.

15. The provider must specifically document dosage, dosage intervals, and quantities on each controlled substance medication order.

    a) Doses must be exact and not arbitrarily subjective.

    b) Orders for one or two tablets every four to six hours are not valid and a new provider order shall be obtained.

16. Limitations on Controlled Substances prescribing for all facilities and offenders.

    a) Initial orders of targeted controlled substances for acute pain including diagnoses caused by disease conditions, trauma, accident, surgery, or other causes may be written as scheduled or as needed (PRN) therapy.

i. The initial order shall not exceed five days for acute pain, except when immediately following a surgical procedure, where a seven-day order may be authorized. No refills may be authorized.

ii. Providers shall reassess the offender after the initial five- or seven-day treatment period if the same pain still persists and may issue an additional order not to exceed 30 days total treatment.

iii. PRN orders with a quantity specified, but without a duration, shall have a five-day stop date for acute pain and a seven-day stop date for post-op pain. The quantity dispensed shall not exceed the maximum number of doses that can be administered in the five- or seven-day duration.

b) Initial orders for non-targeted controlled substances for pain may be ordered for up to 14 days.

c) Chronic pain is defined as pain exceeding 30 days, and all controlled substance therapy extended beyond 30 days shall:

i. require utilization review (UR) approval for non-terminally ill offenders and offenders who are in maintenance/remission phases of cancer.

ii. require a 6-monthly review of a previously approved Controlled Substance UR for offenders with cancer, who are actively undergoing cancer treatment.

iii. not require UR approval to continue if the provider orders include either of the following confirmed indications:

a. Hospice care
b. Palliative care.

17. All Pharmacy dispensed controlled substance PRN orders for chronic pain shall comply with dispensing limits.

a) The maximum number of doses that can be prescribed on a PRN order in a 30-day period is 100 unless otherwise limited by UR approval.

b) PRN controlled substance orders with a duration specified that do not have a quantity specified shall default to no more than 30 doses or less if the duration mandates.

c) PRN orders with a quantity specified but without a duration shall have a 30-day stop date.

18. As needed PRN orders obtained from the ADC at Central Prison and NCCIW are exempt from the PRN quantity limit, and the quantity shall default to the maximum quantity allowable for the provider order without regard to the PRN.

19. Orders for Schedule CII controlled substances can be written for a maximum of 30 days.

20. Orders for Schedule CIII through CV controlled substances can be written for a maximum of five refills and 180 days.

B. Storage of Controlled Substances and Key Control

1. Controlled substances must be stored in a double lock system.

   a) DAC Prescription pads and Iron Key must be stored under double lock and may be stored with the controlled substances.

   b) One key to this double locked storage system shall be provided to the facility healthcare authority, and the second key must be maintained securely by the Warden or designee.

2. The key issued to the facility health care authority will be secured on a ring according to facility Standard Operating Procedure (SOP).

   a) This key shall be assigned to the medical area.

   b) The facility health authority, Nurse Supervisor, Lead, or Charge Nurse shall assign the control medication keys to one nursing staff member each shift.

   c) The staff member assigned the control medication keys shall be the only person accessing the controlled substances on that shift.

   d) This assignment shall be documented on the shift assignment and report sheet.

   e) The control medication keys shall be exchanged between shifts, accounted for, and documented on the Controlled Medication Key Issue Log.

   f) If there is a need to transfer key control during a shift, a documented count of all controlled substances shall be completed by the two staff involved in the key control transfer. This transfer shall also be documented on the Control Medication Key Issue Log.

C. Documentation and Accountability of Controlled Substances

1. Receipt – When a correctional facility receives a new or refilled pharmacy dispensed controlled substance medication order, a Controlled Substances Medication Administration Record (DC-175A) shall be completed.

2. Documentation – The nursing staff shall document the administration of controlled substances on the EHR eMAR (DC-175) and on a paper Controlled Substances Medication Administration Record (MAR) (DC-175A) for a pharmacy dispensed outpatient supply.

a) The preparation side of the DC-175A is used when medication is removed from the original container and set aside in a double locked storage unit for future administration by DAC custody.

b) The administration column on the DC-175A shall not be signed until the dose has been administered to the patient.

c) Shift counts on pharmacy dispensed controlled substances are documented on the back of the DC-175A. Counts must be completed at each shift change or change in key control by two authorized staff member authorities (nurse, med tech, officer). One of the authorized staff member authorities must be a health care staff member if health care staff are on duty. Otherwise, two trained correctional officers with the assigned controlled substance key responsibility may perform the shift count. If only one nurse is available, the count shall be done daily by that nurse. In a facility where two non-licensed health care staff are routinely assigned to administer medications, a nurse must count a minimum of weekly on each shift. The facility health care authority is responsible for reviewing the DC-175A regularly.

d) Paper DC-175A forms used in outpatient settings should be scanned into the Narcotic Record file in the Document Manager prior to offender transfer to another facility, when the controlled substance is returned to a DAC Pharmacy, or upon completion of the prescription.

e) If EHR is unavailable for administration documentation, the paper DC-175A shall be completed to document administration and scanned into The Narcotic Record file in the Document Manager.

3. Original container – Controlled substances shall be kept in the original container for tracking purposes and safety.

a) If a medication is enveloped for future administration, the following information must be contained on the envelope:

i. Offender's name

ii. OPUS number

iii. Medication name and strength

iv. Directions for administration

v. Date and time of administration

vi. Special administration instructions

b) These enveloped medications must be transported to the medical units in a locked cart, box, or bag.

c) Controlled substances shall NOT be enveloped for administration during bus transfers of offenders.

4. Controlled substance transfer bags – Controlled substances shall be transferred in a tamper resistant security bag.

   a) Only one controlled substance order can be placed in each security bag.

   b) The facility medical staff shall complete the following information on the security bag:

      i. Offender's name

      ii. OPUS number

      iii. Sending location

      iv. Name of sender

      v. Receiving location

      vi. Sealed by, and date

   c) The completed tear strip shall be removed and attached to the unit photocopy of the DC-175A.

   d) The security bag serial number and destination facility shall be written on the DC-175A prior to scanning into the Narcotic Record File in Document Manager.

   e) The controlled substance and original DC-175A shall be placed in the security bag and then be placed into a medication transport envelope.

5. Offender transfers between DOI facilities – When an offender transfers between DOI facilities, all controlled substances with their corresponding Controlled Substance MAR (DC-175A) shall be transferred with them in separate security bags by the sending facility.

   a) The sending facility shall record on the DC-175A:

      i. The intended facility destination

      ii. Security bag number

      iii. Quantity transferred

      iv. Date and time of packaging of the controlled substance

      v. Transferring employee's legible signature

b) A photocopy of the DC-175A with all transferring information shall be made, scanned into the Narcotic Record file in the Document Manager, and filed at the sending facility for three years.

c) The receiving facility shall open the security bag and verify the following information for the controlled substance order matches the information on the DC-175A.

i. Offender's name

ii. OPUS number

iii. Name and strength of the controlled substance

iv. Directions for administration

v. Quantity received

d) The receiving healthcare authority shall document on the original DC-175A the date and time of receipt and the receiving signature.

e) For the receipt of controlled substances from another facility, the receiving facility will continue documentation of administration on the transferring DC-175A. Do not initiate a new DC-175A.

f) Once the receiving facility has verified all the information and the count to be correct, the opened security bag may be discarded.

g) If there is any discrepancy upon receipt of the controlled substance, the security bag must be maintained for investigation purposes, and the process described in Procedure, Section (d) Controlled Substance Discrepancies of this policy shall be followed.

6. Retention of records – Copies of each completed or transferred Controlled Substance Medication Record (DC-175A) shall be kept at each facility site for three years.

7. Release – DAC Pharmacy Services dispensed controlled substance prescriptions shall not be sent with an offender upon release.

a) For chronic pain (UR approved) and chronic disease diagnosis, the facility staff shall provide a 14-day supply or 60 dosages whichever is less that is obtained only from a local pharmacy/hospital to send with the offender upon release.

b) For acute pain, the facility staff shall provide a five-day supply or less that is obtained only from a local pharmacy/hospital to send with the offender upon release.

c) Upon offender release, all DAC Pharmacy Services' dispensed, unused controlled substance prescriptions shall be returned to a DAC Pharmacy with a DC-877.

d) No DAC Pharmacy dispensed controlled substance may be sent with an offender upon release to home, court, or jail.

D. Controlled Substance Discrepancies

1. A controlled substance discrepancy/loss is any inventory not accounted for due to a reconciliation count shortage, theft, in-transit loss, or lack of final disposition documentation.

2. Upon discovery of any suspected controlled substance discrepancy, facilities shall contact the facility Warden, Chief Executive Officer, Human Services Facility Director, Nurse Supervisor III, Regional ADON, DAC DON, and the Deputy Secretary of Comprehensive Health Services within 24 hours.

   a) If there is a reportable discrepancy for any pharmacy dispensed prescription, the facility Warden, Chief Executive Officer, Human Services Facility Director, or designee shall notify the Region Director, the Deputy Secretary of Institutions, and the Deputy Secretary of Comprehensive Health Services within 24 hours; initiate an investigation; and determine if the discrepancy is reportable to local law enforcement as a controlled substance loss.

   b) If there is a reportable discrepancy for stock-controlled substances maintained in the automated dispensing cabinets or facility stock locations of a facility that has a DEA #, the facility Warden, Chief Executive Officer, Human Services Facility Director, or designee shall notify the Region Director, Deputy Secretary of Institutions, Deputy Secretary of Comprehensive Health Services, Director of DAC Pharmacy Services, DEA, and North Carolina Board of Pharmacy (NCBOP) within 24 hours and initiate an investigation.

   c) If there is a reportable discrepancy of controlled substances at the 3 DAC Pharmacies, the NCBOP permit holder shall notify the Director of DAC Pharmacy Services, the facility DEA license holder, the Facility Warden, the DEA, and the NCBOP within 24 hours. The Warden shall initiate an investigation and the Director of DAC Pharmacy Services shall notify the Deputy Secretary of Comprehensive Health Services.

   d) A Health Services Event Report shall be completed by Facility Nursing/Pharmacy and forwarded to Health and Wellness Quality Assurance/Risk Management Section.

3. The facility Warden, Chief Executive Officer, Human Services Facility Director, or designee, or NCBOP Permit Holder shall review the investigation report for their facility-controlled substance loss and forward the final document to the following if applicable:

   a) DEA

   b) NC Board of Pharmacy

c) Warden

d) Region Director

e) Deputy Secretary of Institutions

f) Facility Nurse Manager

g) Regional Nurse Supervisor III

h) Regional Assistant Director of Nursing

i) Facility Director of Nursing (CPHC and NCCIW)

j) Director of Nursing

k) Regional Primary Care Supervising Physician

l) Regional Medical Director

m) Chief Medical Officer

n) Chief Executive Officer (CPHC)

o) Human Services Facility Director (NCCIW)

p) NCBOP permit holder

q) Director of DAC Pharmacy Services

r) Director of Quality Assurance

s) Deputy Secretary of Comprehensive Health Services

4. For a facility that has a DEA number and a discrepancy of a stock-controlled substance, the facility Warden or designee shall file a final report with the DEA and the NCBOP.

5. The NCBOP permit holder shall file a final report with the DEA and the NCBOP after a pharmacy investigation concludes.

6. The facility healthcare authority or NCBOP permit holder shall maintain copies of the investigation report and the final DEA and NCBOP reports along with other supporting documents at the correctional facility or DAC Pharmacy for three years.

7. Following review of the investigation report, the Deputy Secretary of Institutions in consultation with the Deputy Secretary of Comprehensive Health Services may recommend

disciplinary action up to and including dismissal for those involved in a loss of controlled substances.

E. Destruction or Recovery of Controlled Substances

1. Correctional facilities shall return discontinued, expired, or unused controlled substances to their DAC Pharmacy within seven days of the discontinue date.

2. Destruction or recovery procedures for controlled substances being returned to the pharmacy are as follows:

a) The sending facility shall complete a Controlled Substances Destruction Record (DC-877) ensuring that the report includes the following:

i. Facility name and complete address

ii. Facility number

iii. Name and title of person submitting report

iv. Date report submitted

v. Patient's name

vi. Security bad number (one prescription per security bag)

vii. Pharmacy supplier

viii. Prescription number

ix. Name and strength of controlled substance (exactly as it appears on the prescription label)

x. Quantity returned

b) Send security bag(s) of controlled substance(s) along with a photocopy of the DC-175A in each security bag and all four copies of the completed Controlled Substance Destruction Record to a DAC Pharmacy by courier, courier mail, or officer transport. Keep a photocopy of the Controlled Substance Destruction Record in the facility file. Package controlled substance returns separately from other returns. Do not label the package in any manner that indicates controlled substances are contained in the package.

c) A pharmacy designee will verify the Controlled Substance Destruction Record (DC-877) and medication and return a receipt to the facility.

i. If all medications on the DC-877 can be recovered, the facility will receive the pink and yellow copy of the DC-877 to file for three years.

ii. If any of the medications on the DC-877 must be destroyed, the facility will receive a pink copy or photocopy to hold in a pending file until the medication is destroyed and the yellow copy is returned to the facility.

iii. The facility shall receive correspondence regarding the disposition of the DC-877 from a DAC Pharmacy within two weeks.

d) After the appropriate authority has destroyed the medication, the pharmacy will return a yellow copy of the Destruction Record (DC-877). The paper trail is not complete until the facility receives the yellow copy of the DC-877 to maintain in their records for three years.

3. Facility site destruction

a) The facility health authority or their designee may destroy adulterated controlled substance doses according to the laws set forth in Title 21 Code of Federal Regulations.

b) An adulterated controlled substance is any drug dose that cannot safely be administered to a patient. Multiple adulterated doses shall be returned to the DAC Pharmacy for destruction. Only one dose of a controlled substance shall be destroyed at the facility at one time. Adulterated controlled substances include these:

i. Dropped on floor

ii. Crushed

iii. Mmishandled

c) A facility destruction of a controlled substance must be witnessed by two authorized health care authorities, one of which must be a nurse.

d) Whenever a partial tablet is given, the remaining portion should be wasted and documented as an adulterated controlled substance on the DC-175A, in the automated dispensing cabinet for CPHC and NCCIW, or on the 24 hour Controlled Substance Disposition Record for the infirmaries.

e) The responsible health authorities shall document a record of the destruction on the Controlled Substance Medication Administration Record (DC-175A) showing the:

i. Date

ii. Time

iii. Quantity

iv. Reason for destruction

v. Method of destruction

vi. Signatures of the two individuals destroying and witnessing the destruction.

IV. REFERENCES

A. 5th Edition Standards for Adult Correctional Institutions

5-ACI-6A-43

B. NC Gen. Stat § 90 Article 5

C. Controlled Substance Act Title 21, Code of Federal Regulations (CFR)

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