HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Correction
Division Of Prisons

SECTION: Care and Treatment of Patient - Medication Administration

POLICY # TX II-12

SUBJECT: Controlled Substances

EFFECTIVE DATE: April 2012
SUPERCEDES DATE: April 2009

References

Related ACA Standards — **4th Edition Standards for Adult Correctional Institutions 4-4378**

PURPOSE

To provide guidelines on the prescribing, storage, documentation, accountability, reporting of discrepancies, and ~~the~~ destruction of controlled substances.

POLICY

DOP staff shall strictly adhere to procedures set forth in this policy as mandated by the state and federal regulations governing controlled substances.

Definition

A controlled substance is any medication in Schedules CII through CV that is under the jurisdiction of the Federal Controlled Substances Act.

Regulatory Authorities

All correctional facilities shall register annually, prior to July 31st, with the North Carolina Department of Health and Human Services (DHHS), Drug Control Unit. The facility health care authority, in consultation with Apex Central Pharmacy, shall complete Form DHHS-226 and forward the form to DHHS. The facility Administrator, ~~or~~ Warden, or Chief Executive Officer shall be the authorizing signature on the DHHS registration application. DOP Administrative Services pays the annual registration fees.

Facilities that maintain controlled substances in stock inventories shall register with the Drug Enforcement Administration (DEA). The Chief of Health Services must approve any facility requests for DEA registration and must be the authorizing signature for fee exemption. The facility health care authority, in consultation with Apex Central Pharmacy, shall complete form DEA-224 and forward the form to the DEA. The, facility Administrator, Warden, or Chief Executive Officer shall be the authorizing signature on the DEA registration application.

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 Department of Correction, Pharmacy Director and Chief of Health Services.

PROCEDURE

I. PRESCRIBING OF CONTROLLED SUBSTANCES

A. 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:
   1. Authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice.
   2. Registered with the Drug Enforcement Administration and posses a valid DEA number.
   3. Registered under the Federal Controlled Substances Act.

B. Physician Assistants and Family Nurse Practitioners who have DEA registrations can prescribe controlled substances according to N.C. Board of Pharmacy, Drug Enforcement Administration, and Board of Medical Examiners guidelines.

C. DEA registration numbers shall be added to the appropriate pharmacy data base before a practitioner can prescribe any controlled substance.

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

E. It is the responsibility of the provider to sign and forward to pharmacy within 7 days all verbal orders for Schedule II controlled substances.

F. The date of reference for the start date of a controlled substances order is the date the order is written. The stop date for a controlled substance order is referenced to the start date.

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

1. Doses must be exact and not arbitrarily subjective.
2. Orders for one (1) or two (2) tablets every four (4) to six (6) hours are not valid. These orders will default to the lower dose and the greatest time interval.

H. As needed (PRN) orders for controlled substances with a duration specified that do not have a quantity specified will default to 30 dosage units unless the duration specified mandates less than 30 dosage units.

1. The maximum number of dosage units that can be prescribed on a PRN order in a 30 day period is #100.
2. The prescriber may authorize one refill of #100 which can be obtained after the first 30 days is completed.
3. A utilization review approval is needed for any PRN order which exceeds two (2) months.
4. PRN controlled substance orders with no duration, but with a quantity specified have a 30 day stop date.
5. Refer to Health Services Policy and Procedure Manual, Policy # TX II-9, Medication Duration for Outpatient Services for more information.

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

K. Orders for Schedule CIII through CV controlled substances can be written for a maximum of 5 refills and 180 days.

II. STORAGE OF CONTROLLED SUBSTANCES AND KEY CONTROL

A. Controlled substances must be stored in a double lock system.
1. The storage unit must be permanently fixed and locked within another locked room or cabinet.
2. Only controlled substances will be stored in the double locked storage unit.
3. One key to this double locked storage unit will be provided to the facility health care authority, and the second key must be maintained securely by the facility Administrator, Warden, and/or designee.

B. The key issued to the facility health authority will be secured on a ring and tagged according to facility S.O.P.
   1. This key shall be assigned to the medical area.
   2. The facility health authority, Nurse Supervisor, Lead or Charge Nurse shall assign the control medication keys to one nursing staff member each shift.
   3. The staff member assigned the control medication keys shall be the only person accessing the controlled substances on that shift.
   4. This assignment shall be documented on the shift assignment and report sheet.
   5. The control medication keys shall be exchanged between shifts, accounted for, and documented on The Controlled Medication Key Issue Log.
   6. 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 ~~will~~ shall also be documented on the Control Medication Key Issue Log.
   7. The Lead or Charge nurse shall make note of the re-assignment of key control on the shift assignment/ report form.

III. DOCUMENTATION AND ACCOUNTABILITY OF CONTROLLED SUBSTANCES

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

B. Documentation - The nursing staff shall document the administration of controlled substances on a Controlled Substances Medication Administration Record (MAR) (DC-175A).

   1. 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.
   2. The administration column on the DC-175A shall not be signed until the dose has been administered to the patient.
   3. Shift counts on 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~~s~~ 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.

C. Original container - Controlled substances shall be kept in the original container for tracking purposes and safety.
   1. If a medication is enveloped for future administration the following information must be contained on the envelope:
      a. inmate's name,
      b. OPUS number~~,~~
      c. medication name and strength~~,~~
      d. directions for administration~~,~~
      e. date and time of administration
      f. special administration instructions
   2. These enveloped medications must be transported to the medical units in a locked cart, box, or bag.
   3. Controlled substances do not need to be enveloped for administration during bus transfers of inmates.

D. Controlled substance transfer bags - Correctional facility personnel will transfer controlled substances in a tamper resistant security bag.
   1. Only one controlled substance order can be placed in a security bag.
   2. The facility nurse will complete the following information on the security bag:
      a. inmate's name
      b. OPUS number~~,~~
      c. sending location~~,~~
      d. name of sender~~,~~
      e. receiving location~~,~~
      f. sealed by and date
   3. The completed tear strip shall be removed and attached to the unit photocopy of the DC-175A.
   4. The controlled substance and original DC-175A shall be placed in the security bag and then be placed into a medication transport envelope.

E. Inmate transfer out - When an inmate transfers within the Department of Correction, all controlled substances with their corresponding Controlled Substance MAR (DC 175 A) shall be transferred with him or her in separate security bags.
   1. The sending facility shall record on the DC-175A:
      a. the intended facility destination
      b. quantity transferred
      c. date and time of packaging of the controlled substance
      d. transferring employee's legible signature
   2. A photocopy of the DC-175A with all transferring information shall be made and filed at the sending facility for 3 years.
   3. When an inmate transfers to a jail the same security bag and documentation procedure applies except a photocopy of the DC-175A accompanies the controlled substance instead of the original DC-175A. The original DC-175A must remain in the DOC health record.

F. Inmate transfers in – When an inmate transfers within the Department of Correction, all controlled substances with their corresponding Controlled Substance MAR (DC 175 A) shall be transferred with him or her in separate security bags.

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

      a. inmate's name
      b. OPUS number~~,~~
      c. name and strength of the controlled substance
      d. directions for administration,
      e. quantity received
   2. The receiving health care authority shall document on the original DC-175A the date and time of receipt and the receiving signature.
   3. For the receipt of controlled substances from another correctional facility, the receiving facility will continue documentation of administration on the transferring DC-175A. Do not initiate a new DC-175A.
   4. Once the receiving facility has verified all the information and the count to be correct the opened security bag may be discarded.

5. If there is any discrepancy upon receipt of the controlled substance, the security bag must be maintained for investigation purposes.

G. 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.

H. Release - Upon release, the facility health care authority may issue to the inmate the unused portion of a controlled substance.
1. The controlled substance must be issued in its original container.
2. The issuance must be documented on the DC-175A.
3. If the original container is not child proof, the facility employee shall follow the procedure in Health Services Policy and Procedure Manual, Policy # TX II-16, Inmate Release.
4. No more than #100 dosage units or a two week supply which ever is less may be issued on any controlled substance order for an inmate release.

IV. CONTROLLED SUBSTANCES DISCREPANCIES

A. A controlled substance discrepancy is any loss or gain of a dose or doses which the correctional facility cannot account for with a reasonable explanation.

B. Correctional facilities upon discovery of a suspected controlled substance discrepancy shall contact the Division of Prisons Pharmacy Director/designee within twenty four (24) hours.

1. If the Pharmacy Director believes there has been a reportable discrepancy, the facility shall initiate a custody investigation and be instructed to send the investigative report to the Apex Central Pharmacy designee for DEA reporting.
2. The Health Treatment Administrator, Regional Nurse Supervisor, ADON, and Facility Administrator shall be notified of the pending investigation.
3. The facility health authority shall compile the following information and forward to the pharmacy designee for DEA reporting either as a report or on the online form DEA-106 Report of Theft or Loss of Controlled Substances.
    a. Facility name, address, and phone number.
    b. Date of loss.
    c. Names of law enforcement agency handling the investigation. If this is an internal investigation, show individual handling the investigation. Attach copies of witness statements or supporting documentation to the report.
    d. Type of discrepancy (break-in, employee or inmate theft, improper record keeping, etc.)
    e. Name and strength of the controlled substance and quantity missing. (If the medication was in a prescription container, the report must state the patient's name, the pharmacy name, date of dispensing, and prescription number.)
    f. Description of any measures taken to prevent future thefts or losses.

4. A medication variance report (DC-929) shall be completed and forwarded to Risk Management per Health Services Policy and Procedure Manual, Policy # AD II-5, Medication Variances/Incidents Report.

C. The Apex Central Pharmacy designee shall review and complete the investigative report and forward the final document to the following:

1. Drug Enforcement Administration
2. Facility Administrator, ~~or~~ Warden, or Chief Executive Officer
3. Facility Nurse Manager
4. Division of Prisons Chief of Health Services
5. Division of Prisons Health Services Director of Operations
6. Division of Prisons Health Services Director of Nursing
7. Regional Assistant Director of Nursing
8. Division of Prisons Pharmacy Director
9. Health Treatment Administrator~~,~~
10. Standards Director

D. The facility health care authority shall maintain copies of the discrepancy reports along with other supporting documents at the correctional facility for three years.

E. Following review of investigative report, the Chief of Health services in consultation with the Deputy Director for Health Services and Director of Nursing, may recommend disciplinary action up to and including dismissal for those involved in loss of controlled substances.

V. DESTRUCTION OF CONTROLLED SUBSTANCES

A. Correctional facilities shall return discontinued, expired, or unused controlled substances to their Division of Prisons Pharmacy for destruction within seven (7) days of the discontinue date.

B. Destruction procedures for controlled substances being returned to the pharmacy are as follows:

1. Complete a Controlled Substances Destruction Record (DC-877) ensuring that the report includes the following:
    a. Facility name and complete address
    b. Facility number
    c. Name and title of person submitting report
    d. Date report submitted
    e. Patient's name
    f. Security bag number
    g. Pharmacy supplier
    h. Prescription number
    i. Name and strength of controlled substance (exactly as it appears on the prescription label)
    j. Quantity returned

2. Send security bag(s) of controlled substance(s) along with a photocopy of the DC-175A in each security bag and all four (4) copies of the completed Controlled Substances Destruction Record to your Division of Prisons Pharmacy by courier, courier mail, or officer transport. Keep a photocopy of the Controlled Substances 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.

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

a. 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.
b. 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.

4. 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.

C. Facility site destruction:

1. The facility health authority or their designee may destroy adulterated controlled substance doses according to the Rules and Regulations of the North Carolina Controlled Substances Act, Chapter 45, Subchapter G, Section 0408.
2. An adulterated controlled substance is any drug dose that cannot safely be administered to a patient. Multiple adulterated doses shall be returned to the DOP Pharmacy for destruction. Only one dose of a controlled substance shall be destroyed at the facility at one time. Adulterated controlled substances include these:
    a. dropped on floor
    b. crushed
    c. mishandled
3. A facility destruction of a controlled substance must be witnessed by two authorized health care authorities, one of which must be a nurse.
4. Whenever a partial tablet is given, the remaining portion should be wasted and documented on the DC-175A or the 24 hour Controlled Substance Disposition Record as an adulterated controlled substance.
5. The responsible health authorities shall document a record of the destruction on the Controlled Substance Medication Administration Record (DC-175A) showing the:
    a. date
    b. time~~,~~
    c. quantity~~,~~
    d. reason for destruction
    e. method of destruction~~,~~
    f. signatures of the two individuals destroying and witnessing the destruction

4/23/12

Paula Y. Smith, MD, Chief of Health Services Date

SOR: Director of Pharmacy