Controlled Drug Procedures

I. General

The Drug Enforcement Administration (DEA) requires that drugs designated as controlled substances (Schedules I-V) have specific accountability and control procedures in place that insure proper ordering, dispensing, administration, and destruction - over and beyond that required for all other classes of drugs. These drugs are classified into five schedules, with Schedule I drugs being those drugs which are not recognized nor available for medical use in the United States (e.g., heroin), but can be used for scientific medical studies. The remaining four schedules (Schedules II-V) are available for medical use in this country, and are categorized in descending order of dependence liability with Schedule II drugs having the greatest dependence liability (e.g., cocaine) to Schedule V drugs (e.g., Lomotil®) which have the least dependence liability among controlled substances.
All ODOC processes and procedures regarding the control and accountability of controlled substances are in compliance with state and federal regulatory agencies including the federal Drug Enforcement Administration (DEA); the Oklahoma Bureau of Narcotics and Dangerous Drugs (Ok BNDD); Laws and Rules Pertaining to the Practice of Pharmacy (Oklahoma Statutes, Title 59, Chapter 8 and the Oklahoma Administrative Code Title 535 and Appendixes) enforced by the Oklahoma State Board of Pharmacy; and, policies and procedures promulgated by the Oklahoma Department of Corrections. Legal penalties for deliberate mismanagement of controlled substances are severe for health care professionals including potential loss of professional license, fines, and imprisonment.

These procedures for the control and accountability of controlled drugs are intended to supplement the policies and procedures for drugs as presented in OP 140130, entitled “Pharmacy Operations.” Detailed procedures and forms regarding the accountability and control of controlled drugs are found in the contract pharmacy provider “spiral bound controlled drug records.”

II. Characteristics of Effective System Controls

No system of control and accountability for controlled substances is infallible, but an effective system will have the following characteristics:

A. Well-defined, not necessarily simple
B. Comprehensive – ordering, purchase, receipt, administration, destruction, transfer, inventory, documentation, and recordkeeping
C. High Degree of Accountability and Control – balancing efficiency and effectiveness with distribution and reconciliation
D. Limited Access – only authorized qualified health care professionals have access
E. Red Flag Alerts – knowing when something is wrong

III. Ordering (4-4378)

Each facility will designate a medical provider of record to the contract pharmacy that takes the responsibility for the accountability and control of controlled drugs ordered at the facility.

Patient-specific controlled pharmaceuticals will be ordered on the “Controlled Drug Prescription Form” (DOC 140130F).

Stock controlled pharmaceuticals will be ordered on the “Controlled Drug Stock Order Form Schedules III-V Only” (DOC 140130G). Schedule II controlled pharmaceuticals for starter stock must be ordered via a “DEA 222” form specific for that DOC facility address (form available from DEA at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp).
The facility CHSA and the medical provider of record are responsible for the control and accountability of controlled stock drugs by determining and re-evaluating the stock level of each controlled stock drug maintained in medical services.

IV. Receipt and Storage

Controlled drugs are segregated, stored and secured *the same day as received* from the contract pharmacy provider by facility qualified health care professionals.

The facility health services administrator, or designee shall be responsible for verification that controlled drugs received from any source are properly recorded in the controlled drug perpetual inventory system.

Secured storage of controlled substances, syringes, and needles is in strict accordance with federal and Oklahoma state regulations, and operational policies approved by the Oklahoma Department of Corrections. The control and accountability of these items is maintained by daily perpetual inventory conducted by CHSA-designated/approved qualified health care professional. (4-4378M, b#5)

Community correctional facilities will use “Community Corrections Supervised Medication/Syringe Count Log” (DOC 140130J) for the control and accountability of controlled drugs issued by correctional officers for offender self-administration.

Unused or expired controlled substances must be segregated and stored in a secure area until either authorized for credit/return, or prepared for REVERSE DISTRIBUTORSHIP destruction as detailed in Section X of this MSRM.

V. Administration

All controlled substances are administered by or under the supervision of a qualified health care professional (e.g., nurse), or issued (as personal property) by a correctional officer for patient self-administration.

VI. Wastage

Any wasted dose, partial or full, must be recorded by a qualified health care professional on the spiral bound controlled drug records with a signature witness by a separate ODOC employee (e.g., ODOC Pharmacy Director, correctional officer). Wasted dose may be disposed by running water in sink or toilets; the placement in sharps containers is NOT permitted.
VII. Accountability and Control

Each Schedule II, III, IV, and V controlled patient-specific medication stored within the facility will be accounted for on a daily perpetual inventory system utilizing the spiral bound controlled drug records (4-4378, b#5)

Each Schedule II, III, IV, and V stock controlled medication stored within the facility will be accounted for on a daily perpetual inventory system utilizing the spiral bound controlled drug records

“Inventory counts of controlled substances (including expired or unused controlled drugs) will be conducted by two qualified health care professionals at the beginning and end of each shift using spiral bound book controlled drug Shift Count records. For instances when only one QHCP is onsite, one signature is acceptable for the shift count. This procedure only applies to Ok DOC HOST facilities, and does not include correctional officer witnessed offender self-administration of drugs; those procedures are detailed in MSRM 140143-02 entitled, “Correctional Officer Observation of Offender Self-Administered Medication and Issuance Procedure.”

All on duty staff who are authorized to access controlled substances (QHCPs and providers) are required to stay on duty until counts are accurate and correct, or cleared by security to leave the facility in the event that a discrepancy is unresolved.

Community correctional facilities will use “Community Corrections Supervised Medication/Syringe Count Log” (DOC 140130.J) for the control and accountability of controlled drugs.

Notations must be made to indicate days when the medical services unit is closed by noting “Closed” on the count sheet. (4-4378M)

The facility health services administrator, or designee shall be responsible for verification that controlled drugs received from any source are properly recorded in the controlled drug perpetual inventory system.

The facility health services administrator (CHSA) and medical provider are responsible for the control and accountability of controlled drugs by determining and re-evaluating the stock level of each controlled stock drug maintained in medical services.

VIII. Unresolved Discrepancies

Unresolved discrepancies must be verbally reported by the discovering party to the facility security shift supervisor and the CHSA within one hour of discovery. The time of discovery shall be defined as that time at which a suspected discrepancy is confirmed by search or documentation, and shall not exceed 2 hours from when initially suspected. The Oklahoma Department of Corrections Chief Medical Officer, or his designee will be notified by the CHSA of unresolved discrepancies within four (4) hours of discovery. An “Incident/Staff Report” (Attachment A, OP-050109) must be completed by the CHSA.
A “Serious Incident Report” (Attachment H, OP-050108) may be completed by the facility head, or designee, if warranted.

IX. Theft or Loss of Controlled Substances

Theft or loss of controlled substances is defined as an unresolved discrepancy after eight (8) hours of discovery, and must be reported to the deputy director of Treatment and Rehabilitation Services, or his designee. Internal Affairs will be contacted by the deputy director, or his designee to conduct an investigation of the alleged theft or loss of the controlled substance. The Oklahoma Department of Corrections Chief Medical Officer, or his designee following the investigation and written recommendation of Oklahoma Department of Corrections Internal Affairs may report the theft or loss to the Drug Enforcement Administration on DEA Form 106 (located at: https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp).

An “Incident/Staff Report” (Attachment A, OP-050109) as well as a “Serious Incident Report” (Attachment H, OP-050108) must be completed by the facility head, or designee.

X. Destruction of Expired or Unused Controlled Drugs

Other than the wastage of partial or full, refused, contaminated doses controlled drugs by running water (sink or toilet only - placement in sharps containers is NOT permitted), the destruction of controlled drugs on site at the facility is NOT permitted. ALL controlled drugs to be destroyed must be recorded on REVERSE DISTRIBUTORSHIP forms, and sent to the address specified on the form. The initial copy will be supplied to each medical unit by the contract pharmacy provider with subsequent copies obtained from REVERSE DISTRIBUTORSHIP and will be the responsibility of the CHSA to keep the forms available on the unit at all times.

All spiral bound controlled drug records must be complete and document doses that have been transferred to the REVERSE DISTRIBUTORSHIP forms for destruction.

Drugs to be surrendered to REVERSE DISTRIBUTORSHIP for destruction must be processed and sent via REVERSE DISTRIBUTORSHIP forms as soon as possible (no longer than 30 days). It is the CHSA’s responsibility to assure that controlled drugs intended for destruction are not stockpiled, but processed promptly.

All forms (DOC, DEA, REVERSE DISTRIBUTORSHIP) relating to the proper control and accountability of controlled substances must be kept on file for a minimum of FIVE (5) years. Destruction records of controlled drugs should be segregated from other controlled drug records.
XI. Credits

In general, credits for controlled substances are not permitted and are done only if authorized by the contract pharmacy provider.

XII. Transfer of Medications (4-4414)

Controlled drugs can be transferred per OP-140113 entitled “Health Assessment for Offender Transfers”, with proper notations in the spiral bound controlled drug records, as follows:

A. All offenders transported, regardless of destination, will be transported with their packaged, prescribed medications, including insulin.

1. Medications that are administered at pill line including controlled substances will be sealed in a manila envelope with the offenders’ name and DOC number and placed in the offender medical record or attached to the “Medical Transfer Summary” (DOC 140113A). The prepared medication package will be issued to transporting personnel prior to departure and will be stored appropriately where accessible to the transporting officers.

2. Offender access to and possession of prescription pharmaceuticals during transportation will be limited to keep-on-person (KOP) medications of respiratory inhalers, nitroglycerine sublingual tablets or any medications the healthcare provider/qualified health care professional determines to be medically necessary. All other KOP medications will be stored with the offender’s personal property.

B. Medications that are controlled substances that are specially dispensed for the offender and as defined by federal law will be transferred as described in Section III. C. item 2 of OP-140113 entitled “Health Assessment for Offender Transfers.”.

C. Offenders transferred for a Sheriff’s Office Writ will be sent with an adequate supply of medications to cover their estimated time to be spent at the county jail. The medications shall be clearly labeled with the offenders’ name, dose, route and frequency. Any medications and or medical care required after the initial supply sent by DOC is exhausted will be at the expense of the county.

D. When an offender comes from a county jail CTU will return medication supplies to DOC medical personnel at the receiving facility per OP-040401 entitled “Transportation of Offenders by Central Transport Unit (CTU)”.
XIII. Records

By Oklahoma law, all records for controlled substances (see listing below) must be kept for a period of five (5) years. These records should be filed and maintained by the facility CHSA in a secure location with limited access. Records to be filed include the following:

A. Completed spiral bound controlled drug records
B. Completed destruction logs (REVERSE DISTRIBUTORSHIP)
C. Completed shift count logs
D. DEA records (DEA 222, DEA 106)
E. Pharmacy licenses
F. Pharmacy invoices
G. Pedigrees
H. Inventory/audit records

XIV. References

OP-140113 entitled “Health Assessment for Offender Transfers”
OP-140130 entitled “Pharmacy Operations”
DEA Forms at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp

XV. Action

The chief medical officer, Medical Services will be responsible for compliance with this procedure.

The chief medical officer, Medical Services will be responsible for the annual review and revisions.

Any exceptions to this procedure will require prior written approval from the director.

This procedure will be effective as indicated.


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