



STATE OF WASHINGTON
DEPARTMENT OF CORRECTIONS

APPLICABILITY
PRISON

REVISION DATE
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NUMBER
DOC 650.020

POLICY

TITLE
PHARMACEUTICAL MANAGEMENT

REVIEW/REVISION HISTORY:

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SUMMARY OF REVISION/REVIEW:

Major changes to include updating titles and resources throughout. Read carefully

APPROVED:

Signature on file

SARA KARIKO, MD
Chief Medical Officer

8/17/21

Date Signed

Signature on file

DAN JOHNSON, MBA
Assistant Secretary for Health Services

8/19/21


Date Signed

Signature on file

CHERYL STRANGE, Secretary
Department of Corrections

8/19/21

Date Signed

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REFERENCES:


DOC 100.100 is hereby incorporated into this policy; [RCW 18.64](#); [RCW 70.14.050](#); [WAC 246.945](#); DOC 320.260 Secured Housing Units; DOC 420.375 Contraband and Evidence Handling (RESTRICTED); DOC 420.550 Key Control (RESTRICTED); DOC 640.020 Health Records Management; DOC 650.040 Over the Counter Commissary Items; DOC 890.030 Hazardous/Dangerous Waste Management; [21 CFR 1304](#); [Washington DOC Health Plan](#); Nursing Procedure N-306; [Pharmaceutical Management and Formulary Manual](#); [Records Retention Schedule](#)

POLICY:

- I. The Department will ensure management of pharmaceuticals is consistent with federal and state law.
- II. The Department has established procedures for prescription practice, medication procurement, receipt, distribution, storage, inventory, incident reporting, dispensing, administration, recordkeeping, and disposal.

DIRECTIVE:

- I. Responsibilities
 - A. The Director of Pharmacy will be responsible for oversight of medication management.
 1. Pharmaceutical services provided to incarcerated individuals will comply with the Pharmaceutical Management and Formulary Manual (i.e., The Formulary), Washington DOC Health Plan, facility specific Health Care Entity Pharmaceutical Management Procedure, and, if applicable, Care Review Committee decisions.
 - a. Facilities will update a Health Care Entity Pharmaceutical Management Procedure annually. The updated version will be forwarded to the Director of Pharmacy and maintained locally.
 - b. Any changes to local medication management processes or physical plant (e.g., medication storage) must be reported to the Director of Pharmacy prior to implementation.
 2. In facilities with a Health Care Entity License (HCEL), the Director of Pharmacy and Health Services Manager (HSM) will ensure that the area(s) where drugs are stored, compounded, delivered, or dispensed/administered are operated in compliance with Department policies and all applicable state and federal statutes and regulations.

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3. The Department will operate a central pharmacy (i.e., The Pharmacy) to provide pharmacy services to the facilities. The Pharmacy will be managed by an operational manager and assigned pharmacist supervisors.
 - a. The Director of Pharmacy will appoint a pharmacist in charge of The Pharmacy. The Pharmacist in charge will ensure compliance with federal and state rules and regulations, Department policies, and procedures.
4. The Director of Pharmacy will oversee the following list of delegated duties to ensure accuracy, accountability, and quality of supplied products while supporting safety and security.
 - a. Acquisition
 - b. Preparation
 - c. Distribution
 - d. Monitoring
 - e. Inventory management
 - f. Waste management
 - g. Recordkeeping/retention
 - h. Quality assurance

II. Pharmacy and Therapeutics (P&T) Committee

- A. The Chief Medical Officer (CMO)/designee and Director of Pharmacy will select P&T Committee members from various health care professions within the Department to establish, maintain, and recommend updates to The Formulary, based on the Washington DOC Health Plan.
 1. The committee will be chaired by the Director of Pharmacy and report to the CMO.
 2. The committee will meet quarterly in person and monthly by phone, as needed. Minutes will reflect a summary of topics discussed and any changes to The Formulary.
 3. The CMO will review suggestions from the committee and approve updates to The Formulary.

III. Pharmacy Quality and Medication Management Assurance Programs

- A. The Department will ensure the quality and accurate, appropriate management of pharmaceuticals through participation in:

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1. A Coordinated Quality Improvement Program (CQIP) to:
 - a. Monitor adverse events related to pharmaceutical therapies and medication incidents reported through the Medication Incident Reporting process on the CQIP SharePoint site, and
 - b. Develop quality improvement procedures, strategies, and tracking mechanisms at The Pharmacy and all Prison facilities.
2. Internal facility operational review inspections, and
3. Pharmaceutical Unit inspections.


IV. Medication Management

A. Acquisition (i.e., Ordering/Receiving)

1. The Pharmacy and facilities with an HCEL will purchase authorized medications from a contracted wholesaler.
 - a. Facility purchases are limited to controlled substance and intravenous fluid urgent stock, wound care products, dental anesthetics and limited treatment related supplies.
2. The Pharmacy and facilities with an HCEL will ensure the employee/contract staff placing an order with a wholesaler is not the same person receiving the shipment.
 - a. The employee/contract staff receiving the medication shipment must sign or initial any paper invoice, when applicable, and maintain a copy for 2 years or per the Records Retention Schedule, whichever is longer.
 - b. Non-controlled substance invoices from the wholesaler may be maintained electronically in the vendor's computer system or as a hard copy.

B. Prescribing

1. Medications will be prescribed as clinically indicated in accordance with the Washington DOC Health Plan and The Formulary.
2. Department prescribers will submit prescriptions to The Pharmacy using the current prescription software.

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- a. Handwritten prescriptions will be accepted for telephone orders and new and other authorized prescribers without access to the Computerized Prescriber Order Entry (CPOE) system.
- b. All prescriptions (i.e., written, generated by a database), must be hand-signed by the prescriber and placed in the patient's health record per DOC 640.020 Health Records Management by an employee/contract staff designated by the HSM.
 - 1) Controlled substance (i.e., Schedule II-V) prescriptions will be managed in accordance with the facility's Health Care Entity Pharmaceutical Management Procedure.
3. Prescriptions can only be legally filled when signed by the prescriber.

C. Dispensing

1. The Pharmacy will only dispense medication if the prescription order is fully compliant with the requirements specified in The Formulary.
 - a. Missing information that requires further clarification from the prescriber will be obtained per the facility specific Health Care Entity Pharmaceutical Management Procedure.
 - b. Except for Intensive Management Units (IMUs), Intensive Treatment Units (ITUs), Close Observation Areas (COAs), and Segregation, the prescription status will default to what is listed in The Formulary if the prescriber does not specify Keep on Person (KOP) or Pill Line on a prescription order.
2. Nursing employees/contract staff will consult with pharmacy employees/contract staff concerning any current and active controlled substance prescription orders that do not appear as active in the prescription management database within one business day of the written order date.

D. Pharmacist Consultation

1. Patient educational materials will be provided by pharmacy employees with each new prescription and each refill when required by the Federal Drug Administration.
 - a. Patient educational materials for urgent stock will be provided by The Pharmacy with each requisition.

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b. Nursing employees/contract staff will provide a copy of the appropriate patient educational materials each time a first urgent stock dose is administered to a patient.

2. Patients have the right to consult with a pharmacist and may submit medication questions via DOC 13-423 Health Services Kite to The Pharmacy through the local health services clinic.

E. Refilling

1. Nursing employees/contract staff will submit refill orders using the prescription management database.

a. Facilities will establish emergency processes for facility system failure.

2. Pharmacy employees/contract staff will only process a refill of routine medications greater than 7 days in advance when they are topical or as-needed PRN medications.

a. The Pill Line nurse may request an early refill by sending an explanation with the request specifying the following to docpharmacyservices@doc1.wa.gov:

- 1) Name and DOC number,
- 2) Name of medication,
- 3) Prescription number, and
- 4) Reason for early refill.

b. Pharmacist supervisors will review and authorize requests.


3. When The Pharmacy employees/contract staff cancel or deny a refill request they will notify facility Points of Contact (POC).

F. Administering


1. Medications will be administered or distributed, in a timely manner according to the prescriber's orders, by authorized persons per state regulation who have received training.

a. The Superintendent will ensure custody employees perform mouth checks for all outpatient Pill Line administration.

2. Administration will start once the medication is available from The Pharmacy unless the prescription order specifies:

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- a. Stat - Immediately
 - b. Now - Within 1-2 hours
 - c. Today - By the end of the day
3. Start and stop dates may be manually adjusted on Medication Administration Record (MAR) documentation based on the date the medication is received in order to accurately reflect prescriber duration intent and ensure a course of therapy is completed.
 - a. Stop dates are not equivalent to expiration dates.
 - b. For defined courses of therapy (i.e., antibiotic or antiviral therapy), the entire course must be completed unless discontinued by the prescriber.
 - c. Nursing employees should obtain clarification of any unclear prescription information from a prescriber.
 4. Nursing employees/contract staff will use a previously dispensed patient-specific medication to administer a newly ordered dose or continue an old dose until the existing medication supply is exhausted and a new supply arrives from The Pharmacy.
 5. Health services employees/contract staff will document administration or delivery in the patient's pre-printed MAR per Nursing Procedure N-306 located on the Nursing SharePoint site when medications are administered at Pill Line or issued as KOP.
 6. Medication not readily available from Pharmacy Services may be administered from Urgent Stock, Prescriber Office Stock, or a local retail or hospital pharmacy. Employees/contract staff will use appropriate Department contracts when purchasing from a local retail or hospital pharmacy.
 7. The Facility Medical Director (FMD) and Director of Pharmacy will approve a protocol for a blanket authorization for the crushing of selected medications (e.g., controlled substances) by the facilities at Pill Line if necessary for security.
 - a. A copy of the protocol must be posted at all medication administration locations.
 - b. A specific prescriber order is required to crush any other medications.

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8. Preprinted educational material provided by The Pharmacy will be given to the patient and documented in the MAR per Nursing Procedure N-306.
 - a. If the material poses a risk to patient safety and security, the material may be withheld if the prescriber has noted the risk in the patient record and offered necessary patient education.
9. Nursing and pharmacy employees/contract staff will notify the prescriber, or the FMD in the absence of the prescriber, of any non-compliance per Nursing Procedure N-306.

G. Delivering

1. KOP deliveries will be documented on the MAR per Nursing Procedure N-306 when:
 - a. A new supply of medication is issued to the patient.
 - b. Existing medications are returned to the patient by nursing employees/contract staff after the patient transfers to a new facility.
 - c. Preprinted educational material provided by The Pharmacy will be given to the patient.
2. Authorized, unlicensed employees/contract staff (e.g., correctional officers, office employees), may deliver medications to patients provided:
 - a. The employee/contract staff has been trained online or in person to manage medication delivery.
 - b. The entire Pill Line container is delivered to the patient for self-administration and returned.
 - 1) Employees/contract staff may not remove an individual dose from the container.
 - c. The KOP container is delivered to the patient upon receipt for self-management.
 - d. Documentation requirements for patients in secured housing follow DOC 320.260 Secured Housing Units.
 - e. Patients are referred to a health services clinical employee for medication questions.

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H. Expiration Dates


1. Multi-Dose Vial (MDV) expiration dates will default to a date no more than 28 days after the date the vial was punctured and/or removed from refrigeration or the manufacturer's recommended use by expiration date, whichever is earlier.
2. All KOP medications will be given a specific custody expiration date, beyond the prescription order expiration date, for use when determining the medication may be confiscated.

I. Confiscated Medication

1. Prescription medication discovered in the facility will be confiscated when:
 - a. It has been removed from an original container,
 - b. It does not have a prescription label,
 - c. It appears to be altered/manipulated,
 - d. The custody expiration date has passed, or
 - e. The patient has a quantity greater than a 37 day supply of an individual issued medication at any time.
2. Custody employees will forward confiscated medication to health services employees/contract staff for identification and/or disposal.
3. Custody employees will notify health services employees/contract staff when identifiable prescription medication has been confiscated and maintained as evidence/contraband.
4. Confiscated illegal substances will be managed per DOC 420.375 Contraband and Evidence Handling (RESTRICTED).
5. Prescription medication discovered during the intake process, including intake for violators, is not considered confiscated, but may not be used in the facility.
 - a. Items should be returned to designated external custodians or stored in the individual's property.

J. Medication and controlled substances will be disposed of per DOC 890.030 Hazardous/Dangerous Waste Management.

K. Pharmaceutical records will be maintained for 2 years or per the Records Retention Schedule, whichever is longer.

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1. Records of controlled substances must be maintained separately from other records.
2. Records of Schedule II controlled substances must be maintained separately from records of Schedule III-V controlled substances.
 - a. Order forms and invoices must be physically or electronically filed separately.
 - b. Controlled substance logbook entries for Schedule II controlled substances must be listed in separate sections on the same log page.

V. Controlling Medication Storage Area Access


- A. Access to The Pharmacy, medication management rooms, and other medication storage areas will be restricted except in an emergency per DOC 420.550 Key Control (RESTRICTED).
 1. Access to The Pharmacy is prohibited unless there is a licensed pharmacist onsite per WAC 246-945-410.
- B. A list of authorized employees/contract staff will be maintained locally and submitted to the Director of Pharmacy for review.
 1. The Director of Pharmacy will provide a sample list format upon request.
 2. Lists with specific names must be reviewed and updated on a quarterly basis.
- C. Employees/contract staff will log visitor access to medication storage areas in a logbook.

VI. Managing Controlled Substances


- A. General Requirements
 1. Controlled substances must be stored in a locked vault, safe, or cabinet in a secure storage room with security doors and locks.
 - a. Controlled substances that are designated for destruction will be maintained in a separate location from active controlled substances.

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2. Any physical transfer of controlled substances outside of the secured storage room is strictly prohibited unless conducted via a locked/secured container.
 - a. Transfer within an infirmary without a container for immediate administration is considered secure.
 3. Only authorized employees/contract staff will have access to controlled substances.
 - a. Designated Pharmacy and facility Health Services leadership will identify a limited number of employees/contract staff who may access controlled substances.
 - 1) A list of authorized employees/contract staff will be maintained locally and forwarded to the Director of Pharmacy for review.
 - 2) Lists must be reviewed and updated on a quarterly basis.
 4. The Pharmacy, facilities with an HCEL, and authorized storage locations will maintain a bound controlled substance logbook with consecutively numbered pages to record each controlled substance purchased, received, distributed, dispensed, or disposed.
 - a. Nursing Supervisors/designees will be responsible for ordering the controlled substance logbook for their facility from the Correctional Industries (CI) Print Shop. Logbooks may only be altered with Director of Pharmacy permission.
 - b. Entries of any controlled substances returned or added to the stock must be made in red ink and signed by 2 authorized employees/contract staff.
- B. Perpetual Inventory of Controlled Substances
1. The Pharmacy, facilities with an HCEL, and authorized storage locations must maintain a perpetual inventory record for each controlled substance, including those designated as waste.
 - a. The P&T Committee or Director of Pharmacy may require the statewide addition of a drug, other than a controlled substance, be added to the perpetual inventory.

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2. Two licensed health services employees/contract staff designated by the HSM or the Director of Pharmacy will perform a monthly count of all controlled substances, maintained separately from daily stock, including those that are expired and awaiting destruction.
 - a. The Pharmacy and facilities with an HCEL will maintain an additional destruction log separately from the working inventory.
 3. With each nurse shift change, the incoming and outgoing nurse will count the controlled substances stored at the authorized storage location(s). The outgoing nurse, using a dual witness process, will record the results in the controlled substance logbook.
 - a. If there is only one health services employee/contract staff, the Superintendent or HSM will designate an employee(s)/contract staff to serve as the witness.
 - b. The Nursing Supervisor or designated employee/contract staff will monitor usage and recordkeeping of controlled substances, at least weekly, by selecting a random sample of the records and reconciling the sample to the MAR, the prescriber's order, and the logbook.
- C. Transfer of Controlled Substances
1. Employees/contract staff will complete DOC 14-151 Transfer of Controlled Substance for all intrafacility and interfacility requests/transfers of a controlled substance.
 2. Transfers of controlled substances from The Pharmacy to a community pharmacy, clinic, or physician's office require written approval from the CMO/Director of Pharmacy.
- D. Loss or Discrepancy of Controlled Substances
1. Any unreconciled discrepancy must be reported in writing to the Shift Commander, Nursing Supervisor, Director of Pharmacy, HSM, and the appropriate Health Services Administrator (HSA) before the end of the shift. Reports will include:
 - a. Date and time the incident/loss was discovered,
 - b. Description/number of item(s) missing,
 - c. Names of persons involved,
 - d. Circumstances surrounding the incident/loss, and

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- e. Statements from all employees/contract staff with knowledge of or involvement in the incident/loss.
2. Loss of controlled substances must be recorded and monitored in the appropriate controlled substance logbook.
3. The HSM or designated employee/contract staff will conduct an investigation to determine the root cause and make recommendations to the HSA and Director of Pharmacy for an action plan to avoid future discrepancies.
4. For any significant loss of controlled substances (i.e., more than 5 tablets/patches or 10ml of injectable/oral solutions), the Director of Pharmacy will:
 - a. Notify the appropriate HSA, and
 - b. Complete [DEA-106 Report of Theft or Loss of Controlled Substances](#) and submit to the Drug Enforcement Administration (DEA). A copy of the printed form will be emailed to the Washington State Quality Assurance Commission and maintained for 2 years.
5. The Appointing Authority will determine the level of investigation required.

VII. Managing Urgent Medications and Prescriber Office Stock

- A. Facilities with an HCEL may maintain both urgent medications and prescriber office stock.
- B. Facilities without an HCEL may only maintain prescriber office stock.
- C. A standard list of prescriber office stock will be developed by the Department FMD group, CMO, and the Director of Pharmacy from the statewide authorized list of urgent stock medication. The prescriber office stock:
 1. Must be secured and only accessible by the assigned prescriber(s),
 2. Will be documented when dispensed,
 3. Will not contain controlled substances, and
 4. Is subject to removal by the Director of Pharmacy and the FMD if the prescriber does not follow proper procedures for storing, accessing, and logging the medications.
- D. Controlled substances that are not patient-specific may be urgent stock if the facility is registered with the DEA.

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E. Nursing employees/contract staff/designees must submit DOC 14-162 Urgent Stock Administration and Inventory Log to The Pharmacy within 24 hours for any medication administered or issued using the facility's urgent stock.

1. Nursing employees/contract staff with a valid prescription order obtained from a Department prescriber may access urgent medication and administer one dose at a time for up to 72 hours until the remainder is received from The Pharmacy.

a. An additional 72 hours may be authorized by a prescriber.

2. Pharmacy employees/contract staff will verify that there is a valid prescription order when medication is administered from urgent stock for uses other than immediate single dose administration.

a. If a valid order is not listed, the facility POC will be contacted to provide an order. The new order will be added to the individual's medication profile in the prescription management database.

F. Prescriber office stock may be used to dispense medication directly to an incarcerated individual as KOP or dispensed to nursing employees/contract staff for administration at Pill Line.

1. Prescribers must write their own name, the patient's name and DOC number, and the date dispensed on the label provided by The Pharmacy.

a. Use of any other label must meet the requirements in WAC 246-945-015.

2. The prescriber's order will be documented in the CPOE system by the prescriber when dispensing office stock.


VIII. Managing Medications in IMU/ITU/COA/Segregation

A. When an individual is placed in IMU/ITU/COA/Segregation, custody employees will immediately retrieve all medications, including Over the Counter (OTC) items, from the individual's assigned cell and provide them to health services employees/contract staff at the nursing station.

B. A nurse or practitioner will evaluate the individual's health status and immediately return any critical medications to the patient as KOP.

1. Critical medications allowed in IMU/ITU/COA/Segregation include:

a. Anti-virals,

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- b. Rescue inhalers (i.e., albuterol, levalbuterol, metaproterenol/ Alupent®),
- c. Sublingual nitroglycerin tablets,
- d. Eye drops, and
- e. Glucose tablets.

2. The FMD/designee may order critical medications to be administered at Pill Line, in extraordinary cases, when it is determined the risk of KOP use exceeds the benefits.

- a. In these circumstances, the medication will be kept in a bag attached to the cell door and documented in the patient's health record. Custody employees will make the medications available as soon as possible to the patient upon request.

C. Non-critical medications will be administered at Pill Line.

1. The FMD may authorize medications to be KOP if the dosing schedule exceeds the number of established Pill Line times. The exception will be documented in the health record.


D. OTC medications will only be available to incarcerated individuals in an IMU/ITU/COA/Segregation by prescription order and dispensed by The Pharmacy per DOC 650.040 Over the Counter Commissary Items.

E. Medication will return to the original status indicated on The Pharmacy label when the individual returns to general population, unless there is a new order specifying the change.


IX. Monitoring and Auditing Medications Stored Outside The Pharmacy

A. The Director of Pharmacy will establish a procedure to conduct audits for quality assurance and management of:

- 1. Urgent stock medications,
- 2. Secure storage of supplies,
- 3. Utilization of controlled substances,
- 4. Prescription orders,
- 5. Medication administration/delivery,
- 6. Temperature logging,
- 7. Medication expiration dates, including dates for MDVs, and
- 8. Disposal of medications.

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- B. At least one Pharmacist will use DOC 14-134 Pharmaceutical Unit Inspection to monitor proper storage, administration, inventory, and recordkeeping of medications stored outside The Pharmacy.
 - 1. Facilities with HCEs will be inspected monthly and facilities without HCEs will be inspected quarterly.
 - 2. The HSM/designee will establish a corrective action plan within 7 days of receiving the report if issues were found in the inspection.
 - a. The HSM/designee will implement the plan within 14 days and may delegate an employee/contract staff responsible for resolving the issues.
 - 3. The Director of Pharmacy and appropriate HSA will be notified of inspections with repeated unresolved issues for further corrective action.
- C. Pharmacy employees/contract staff will review the controlled substance logbook used by nursing employees/contract staff at least once a month by selecting a random sample of the records to determine proper usage and recordkeeping.
- X. Annual Pharmacy Inventory
 - A. Each June, the Director of Pharmacy will ensure the annual inventory of all medications is conducted at The Pharmacy.
 - B. All medications, including controlled substances, stored in The Pharmacy as waste for destruction will not be included in the annual inventory.
 - C. The inventory will be conducted by teams of 2, including one pharmacy employee/contract staff designated by the Director of Pharmacy and one employee/contract staff designated by the Comptroller/designee.
 - 1. If a paper system is used, both employees/contract staff will sign each page of the inventory. Otherwise, the Director of Pharmacy/designee will document the names of the employees/contract staff and their work areas.
- XI. Biennial Controlled Substances Inventory
 - A. A separate controlled substance inventory will be conducted at all locations that maintain controlled substances biennially by the Director of Pharmacy/designee and the HSM/designee.
 - B. Controlled substances stored as waste for destruction will be included in the biennial inventory.

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- C. The inventory record will be maintained separately from other pharmacy records and will include, at a minimum:
1. Name, address, and DEA number of the facility, as applicable,
 2. Time the inventory was conducted (i.e., open or close of business day),
 3. Signature of the Director of Pharmacy, and
 4. An exact count of all medications.
 - a. Schedule II controlled substance inventory records will be maintained separately from other inventory records per 21 CFR 1304.

DEFINITIONS:

Words/terms appearing in this policy may be defined in the glossary section of the Policy Manual.

ATTACHMENTS:

None

DOC FORMS:

- DOC 13-423 Health Services Kite
- DOC 14-134 Pharmaceutical Unit Inspection
- DOC 14-151 Transfer of Controlled Substance
- DOC 14-162 Urgent Stock Administration and Inventory Log