State of Iowa Department of Corrections
Policy and Procedures

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Applicability: Institutions
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Chapter 6: Health Services
Sub Chapter: Pharmacy
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Subject: Drug Storage
ACA Standards: 5-ACI-6A-43(M)
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Authority:

1. PURPOSE

To establish procedures for storage of pharmaceuticals within the Iowa Department of Corrections (IDOC).

2. POLICY

It is the policy of the IDOC that storage of pharmaceuticals shall be under manufacturer recommended conditions for temperature, light, humidity, ventilation, segregation, sanitation, and security to safeguard their potency; promote effective administration; and to prevent illicit diversion.

3. PROCEDURES

A. Storage Conditions

All pharmaceuticals and supplies are stored under the supervision of the pharmacist according to the following specifications:

1. Disinfectants and drugs for external use shall be stored separately from internal and injectable drugs.

2. Drugs shall be stored according to the manufacturer's recommended storage conditions, as stated on the package. If no specific storage instructions are stated, it is understood that the storage conditions include protection from moisture, freezing and excessive heat

(temperatures above 40°C or 140°F). Controlled room temperature is a temperature maintained thermostatically between 15° and 30°C (59° and 77°F). Temperature in a refrigerator is maintained thermostatically between 2° and 8°C (36° and 46°F).

a. The temperature of the refrigerators containing all medications located in the pharmacy and all pill rooms will be monitored to meet requirements. The inspection is conducted twice a day and recorded on the Vaccine Temperature Log provided by the IDPH Immunization Program. If the temperature is out of range, proper adjustment will be made. Each incident is recored on the Vaccine Temperature Log.

b. In the event that the physical environment becomes unacceptable for drug storage, all medications will be moved to a suitable environment.

3. Proper consideration shall be given to the safe storage of poisons and flammable materials.

4. Each institution shall develop procedures to identify and process outdated, deteriorated, or otherwise unusable pharmaceuticals and supplies, including documented quarterly inspections of all drug storage areas.

5. Each institution's med room and medication storage areas shall be inspected at least quarterly by an IDOC pharmacist to assure that all policies, procedures and Iowa Code requirements are being met. The *Correctional Facility Inspection Report*, **HSF-406**, will be filled out, detailing any discrepancies found, and a copy sent to the Nursing Services Director of each institution, a copy forwarded to the Medical Services Director, and a copy kept by the Central Pharmacy serving that institution.

(5-ACI-6A-43(M))

B. Access

1. Bulk Stock

Bulk supplies of legend drugs are stored in locked cabinets or a locked room to which access is restricted in the absence of the pharmacist by policies and procedures established by the pharmacist in charge with the concurrence of the Department of Corrections. Such policies and procedures shall include a written procedure providing for nursing access to the correctional facility pharmacy in the absence of the pharmacist to meet emergent needs for legend drugs not available in either the provisional stock or the intake stock. The procedure must provide for a record of the date and time of entry; the signatures of the registered nurse and another staff member on a sign-in log; notification of the drug(s) taken; and, the name(s) and number(s) of the patient(s) for whom the drug was ordered.

2. Provisional Stock

Each facility shall have a "provisional stock" supply of medications, defined by the Pharmacy and Therapeutics/Health Services Committee as those items necessary to fill critical medical needs of the patients during the time when the pharmacy is not available. The provisional stock is stored in a locked box, cabinet or room. Access is restricted to designated Health Services staff. Provisional stock shall be inspected and rotated by the pharmacist or designee on a quarterly basis. When medications are removed from the provisional stock, a record, including the date, time, name of the medication, strength, dosage form; number of doses taken; name and ID of the patient for whom the med was ordered; and the name of the person removing the medication shall be provided, either by an entry into the ICON Medical record system or by a written record. Each institution's dispensing pharmacy will develop written procedures detailing the locations and restocking procedures for their provisional stock supplies.

3. Intake Stock

Facilities into which patients are directly admitted from outside law enforcement agencies (currently IMCC, ICIW, and NCF) will be allowed to keep a separate "intake stock". This additional supply of medications are essential items which may be needed, before medications can be obtained from the pharmacy, to initiate routine, necessary treatment of chronic health care conditions (Hypertension, Diabetes, HIV, etc.). Access and storage shall be the same as regular

provisional stock. Intake stock shall ONLY be used for patients who have just been admitted to the facility; it is NOT to be utilized for treatment of patients who are already at the facility, for new or existing orders.

4. Emergency Stock

Each institution shall develop written procedures detailing the contents and locations of, and, providing for periodic inspection, restocking; and sealing of emergency drug supplies such as First Responder Kits and First Aid Kits.

5. Controlled Substances

Supplies of controlled substances not dispensed for specific patients (stock supplies) and all provisional stock controlled substances shall be stored under double lock. Access is restricted, as for all other bulk and provisional stock. For additional information, see IDOC Policy **HSP-405** *Controlled Substances*.

6. Hazardous Medications

a. Receiving

1) All medications received by the pharmacy will be unpackaged in that pharmacy's designated receiving area. Medications identified as hazardous by the NIOSH List of Hazardous Drugs will be unpackaged separately from regular stock. In addition, any medication identified as hazardous will be marked as such. Any damaged product will be immediately quarantined from stock until arrangements can be made with the wholesaler for destruction. A chemotherapy/hazardous spill kit will be kept in the designated receiving area. Gloves will be required whenever handling of hazardous medications is required.

2) The Pharmacist in Charge or other Designated Individual will ensure these medications are received appropriately. Medications will be noted in ICON as hazardous.

b. Storage

1) A separate storage area will be used for all hazardous medications kept in stock. This area will be separate from the regular stock and will be marked as such. Separate storage of hazardous medication will be available in all areas, including but not limited to, bulk bottles, refrigerated items, controlled substances, injectables and topicals.

2) Hazardous waste disposal containers will be available in the pharmacy and on all units where medications are stored and dispensed. Full waste containers and any unused hazardous medications will be returned to the pharmacy for proper disposal with the pharmaceutical reverse distributor.

c. Identification of Suspect Product and Notification

1) In accordance with the Drug Supply Chain Security Act any suspect product received by the pharmacy that may be deemed suspicious, counterfeit, tampered with, or in any way unfit to dispense will be quarantined from regular stock. Examples of suspect product may include but are not limited to:

a) Missing information, such as the lot number or other identification, NDC, expiration date or the strength of the drug.

b) Any altered product information, such as smudged print or print that is very difficult to read.

c) Misspelled words.

d) Appearance of the package or container used for transport that seems suspicious.

e) Package that uses foreign terms, such as a different drug identification number.

f) Package that is missing anti-counterfeit technologies normally featured on the FDA-approved product that are easily visible to the eye,

such as holograms, color shifting inks, or watermarks.

g) Finished dosage form that seems suspicious (e.g. it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared unclear ink imprints).

h) A product name that differs from the name of the FDA-approved drug or that is the product name for a foreign version of that drug.

i) Lot numbers and expiration date of a drug product that do not match the lot number and expiration dates on the outer container.

2) If a suspect product is received from a trading partner both the trading partner and FDA will receive notification of the suspect product in question within 24 hours.

3) Transaction data for all products including transaction history, transaction information and a transactions statement will be maintained for a period of at least 6 years from the date of the transaction.