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## DEFINITIONS

DEA – Drug Enforcement Association

Discrepancy – A situation resulting the ‘expected count’ and ‘actual count’ of a controlled substance not being identical. A discrepancy can be identified by physical count when tracking is done manually or can be automatically identified via Pyxis®.

NTP – Narcotic Treatment Program; specifically, this refers to the Methadone Clinic owned and maintained by the Kansas University Physicians, Inc. (KUPI) on the KU Med campus, which obtains methadone for treatment of addiction through The University of Kansas Pharmacy department.

Unresolved Discrepancy – A situation where a discrepancy has been investigated through review of data and interview of employees that had access to the controlled substances in question and no explanation for the discrepancy is identified.

## POLICY

All DEA controlled substances that enter, are consumed by patients or dispensed from the Hospital will be handled in accordance with all local, state and federal laws and regulations.

## PROCEDURES

- I. DEA Registration
  - A. The Director of Pharmacy will maintain current registration of The University of Kansas Hospital with the DEA for all necessary activities (Standard DEA and NTP registrations) and will be responsible for all documentation.
  - B. Individual physicians and other licensed practitioners must register with the DEA in order to write outpatient prescriptions for DEA controlled substances.
  - C. Use of a DEA Form 222 (obtained from the DEA after registration) is required to obtain DEA schedule II substances from the Department of Pharmacy for use and storage of these medications in a non-Hospital area (e.g., KUPI clinic, research lab).
  - D. DEA registration is not required to write inpatient drug orders for DEA controlled substances.
- II. Control and Regulation
  - A. The Director of Pharmacy has been authorized to perform responsibilities necessary to maintain appropriate DEA registration and to maintain operations that effectively procure and distribute controlled substances as defined by the DEA. The Director of Pharmacy may delegate authority, to ensure continuity of service, by maintaining a power of attorney document authorizing pharmacy managers to procure and handle controlled substances.
  - B. Controlled substances will be obtained and secured in a manner compliant with DEA regulations.
    - a) Schedule I controlled substances – substances having no accepted medical use (e.g., marijuana, heroin, etc.). The DEA registration of the hospital does not allow procurement of these substances. Individual

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investigators may apply for special DEA registration allowing the procurement of schedule I controlled substances.

- b) Schedule II controlled substances – substances having high abuse and addiction potential. All schedule II drugs must be obtained through the Pharmacy and controlled in accordance with local, state and federal regulations. Schedule II drugs must be ordered using an official DEA schedule II order form (DEA form 222). Dispensation of schedule II drugs from the Pharmacy may occur by two mechanisms: 1.) Transfer to another entity registered with the DEA via a DEA form 222. 2.) Filling a legal prescription for a specific patient.
  - c) Schedule III, IV & V controlled substances – substances having abuse and addiction potential less than schedule II. All schedule III, IV & V drugs must be obtained through the Pharmacy and controlled in accordance with local, state and federal regulations. Dispensation of schedule III, IV & V drugs from the Pharmacy may occur by two mechanisms: 1.) Transfer to another entity registered with the DEA. 2.) Filling a legal prescription for a specific patient.
  - d) Methadone for NTP – Methadone is a schedule II controlled substance that can be used in the treatment of addiction. A unique DEA registration number is assigned to the NTP that allows procurement only of methadone and no other controlled substances. Methadone for the NTP must be ordered using a DEA form 222, specifically assigned to the DEA registration number for the NTP. Methadone for the NTP is stored separately from all other controlled substance inventory and is never transferred to regular inventory or another entity. See the Pharmacy policy on the NTP for complete information regarding the procurement and control of methadone for the NTP.
- C. To decrease the potential for forgery and or alteration of prescriptions for controlled substances, distribution of controlled substance prescription pads ('green scripts') is restricted. In Hospital areas, controlled substance prescription pads are only available in outpatient treatment areas (e.g., GI endoscopy, Emergency department, Outpatient Dialysis, etc.). In addition, controlled substance prescription pads are secured and access is limited (Pyxis®). In all areas where access to controlled substance prescription pads is not required, the Discharge Prescription form (printed on security paper) is used for controlled substance prescriptions.
- III. **Distribution and Handling**  
Only licensed healthcare providers (nurses, pharmacists, physicians and respiratory therapists) and pharmacy personnel are authorized to distribute and handle controlled substances. Whenever possible, electronic records, via Pyxis® are used to record the distribution and transfer of medications. When manual transfer is necessary, the signature of the receiver and issuer of the controlled substance documents transfer of accountability.
- IV. **Inventories**  
Physical inventory of all controlled substances stored in the Pharmacy will be conducted periodically in addition to the biennial inventory required by federal regulations. Patient care areas with Pyxis® will verify controlled substance counts at each access. Patient care areas without Pyxis® will conduct a physical inventory of

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controlled substances no less than weekly. A written report of discrepancies found in non-Pyxis<sup>®</sup> using areas will be reviewed by pharmacy management regularly.

V. Discrepancies

- A. All unresolved discrepancies involving controlled substances must be reported to pharmacy management as soon as they are suspected or identified.
- B. If initial investigation indicates that the discrepancy is not due to record keeping error, appropriate managers of the department involved and the Risk Manager will be notified.
- C. If there is reasonable suspicion of diversion or illegal activity, the Director of Pharmacy or designee will contact Nursing Administration. The Director of Pharmacy, Risk Manager, and/or Nursing Administration will coordinate to inform and involve the appropriate authorities and take steps needed as indicated by the situation.

**RESPONSIBLE FOR REVIEW:** Director of Pharmacy



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Director of Pharmacy