



## Pharmacy Department Policy Controlled Substances

**A. EFFECTIVE DATE:**

August 17, 2021

**B. PURPOSE:**

To ensure compliance with state and federal handling requirements with the purchase, receipt, storage and distribution of controlled substances

**C. POLICY:**

The Pharmacy department will be responsible for the purchase, receipt, storage and distribution of all controlled substances used at John Dempsey Hospital locations.

**D. SCOPE:**

This policy applies to all John Dempsey Hospital (JDH) licensed locations where controlled substance medications are stored.

**E. DEFINITIONS:**

Controlled Substance Schedule: As defined by the Controlled Substances Act (CSA) places all substances which are in some manner regulated under existing federal law into one of five schedules. Placement is based on the substance's medical use, potential for abuse, and safety or dependence liability.

**F. MATERIAL(S) NEEDED:**

None

**G. PROCEDURE:**

A. Purchase, Receipt and Storage of Controlled Substances

1. Purchase

- a) Schedule I and II controlled substances will be purchased or ordered according to Federal Drug Enforcement Administration (DEA) requirements using DEA Form 222-(i.e. US official order forms for Schedule I and II) or electronic CSOS with a DEA issued CSOS certificate.
  - i) The DEA form 222 may be completed by the Purchasing and Inventory Specialist or designee and signed by an authorized registrant or power of attorney. The original and first copy of the form will be sent to the supplier. The second copy (blue) is retained in the Pharmacy.

- b) Schedule III, IV and V controlled substances will be purchased and ordered on a separate purchase order from Schedule I, II and non-controlled substances.

## 2. Receipt

- a) All controlled drugs will be given immediate priority in the receiving process, and all unopened totes or boxes should be secured in the Pharmacy Vault upon arrival to the Pharmacy. Every effort to document receipt and ensure proper security must be made.
- b) Schedule I and II drug orders require notation either on the CSOS form or DEA-222 form (blue copy) of date and quantity received. Completed DEA 222 forms are kept in the Purchasing and Inventory Specialist's files along with wholesaler purchase orders. Completed CSOS forms are stored electronically in the pharmacy shared drive. All forms must be indicated with the date and receivables noted.
- c) All controlled drugs are entered into the Pyxis CII Safe® System, which maintains a perpetual inventory.

## 3. Storage

- a) All controlled drugs will be stored in the Pharmacy Controlled Substance Vault. The Pharmacy utilizes a Pyxis CII Safe®, located within the Vault behind a locked day gate.
- b) Access to the Pyxis CII Safe® and Vault will be limited to pharmacy personnel required to perform the daily functions. All pharmacists with access to the Pyxis® Automated Dispensing Cabinet system are granted access to the Pyxis CII Safe®.

## B. Disbursement of Controlled Substances

### 1. Areas Utilizing Pyxis® Automated Dispensing Cabinets

- a) A daily refill list is compiled by using the CII Safe® Medication Auto Restock feature.
- b) Items below PAR are denoted in the Medication Auto Restock function which prompts the user to select medications below par from a list.
- c) The pulled medications are checked by a Pharmacist. The pharmacist will denote checking the pulled medication on the delivery sheet.
- d) Controlled drugs are delivered to nursing units by a pharmacist or technician. The controlled drugs are entered into the floor's Pyxis® unit, by scanning the bar code, and placing it in the proper drawer which is also scanned, and the count verified.
- e) Any discrepancies will be investigated immediately and reported to appropriate authorities.
- f) Any controlled drugs that must be returned from the nursing unit back to the Pharmacy will be removed from that Pyxis® unit and sent back to the Pharmacy. The returned drug will be added to the Pharmacy Vault by selecting the "Return" option in the Pyxis CII Safe®. If expired, this shall be documented in the Pyxis CII Safe®, and then the controlled substance destroyed; Documentation paperwork for the Pyxis CII Safe®/Vault shall be kept in the destruction log.

### 2. Non-Pyxis® Areas

- a) Controlled medications pulled from the Pyxis CII Safe® for patient-specific use must be hand-delivered by a pharmacist or pharmacy technician with a proof of use sheet that must be signed by receiving nurse and delivering personnel.
- b) Any controlled drugs to be returned to the Pharmacy must be recorded on the Controlled Drug Administration Record by a nurse and by the receiving technician/pharmacist. The returned drug will be added to the Pyxis CII Safe® or destroyed and documented (if applicable) in the Pyxis CII Safe® as well as the destruction log.

### 3. Removal of Controlled Substances for Use in IV Preparation or Oral Preparation

- a) Controlled substances may be removed for preparation of intravenous (IV) or oral compounds. The controlled substances will be signed out of the Pyxis CII Safe® using compound standard ratio, or non-standard ratio, with the unit quantity.
  - i) If the compound is non-standard, the patient's name should be included along with destination.
  - ii) A non-standard compound may be deemed to be a high alert product and may necessitate hand delivery (e.g. HYDROMORPHONE 1 mg/ml, 50 ml PCA syringes unless there is a designated Pyxis® compartment to place these). If controlled substance is hand-delivered, the necessary narcotic paperwork should accompany the compound and be signed by the licensed practitioner it is delivered to and returned to the Pharmacy.
- b) After preparation, other IV or oral preparations may be delivered to the patient floor using the same procedure as other controlled substances.

#### C. Destruction of Controlled Drugs

##### 1. Patient Care Areas

- a) If a dose of controlled drug is prepared and not given, or a partial dosage unit is used which cannot be saved, the dose can be destroyed or discarded on the nursing units. Such destruction must be recorded with witness co-signature in Pyxis®, or for those areas without Pyxis®, destruction must be recorded with witness co-signature on the Controlled Drug Waste Record (HCH-2568 form).
- b) This HCH-2568 Controlled Drug Waste Record form may also be used in instances of Pyxis® downtime

##### 2. Pharmacy

- a) Quantities of 100 dosage units or less may be destroyed in accordance with Connecticut statutes. The destruction must be recorded in a Record of Destruction Log and witnessed by another pharmacist. All controlled substances destroyed from supplies in the Pharmacy should be recorded on this document.

#### D. Controlled Drug Inventory

##### 1. Patient Care Areas

- a) In Pyxis® areas, a blind count is required at each removal therefore a perpetual inventory is consistently maintained.

##### 2. Pharmacy

- a) A biannual inventory of all controlled substances will be conducted as required by Connecticut statutes (i.e. within 5 days of May 1 in odd numbered years)
- b) A monthly count of non-accessed CII medications is carried out by pharmacy personnel.

#### E. Discrepancies

1. All discrepancies will be resolved within the day of discovery, unless the degree of investigation required precludes this. Discrepancies left unresolved at the end of the day shift will be reported to the Pharmacy Leadership. Pharmacy Leadership will be advised of any unresolved discrepancies.
2. The current procedure for notification of the DEA and State of Connecticut Drug Control authorities will be observed for any loss or theft of controlled drugs.

#### F. Records

1. On a weekly basis, an All Station Events and Discrepancy report will be generated for the Pyxis CII Safe®. In addition, this information will be archived to the pharmacy I drive Monday-Friday; the weekend reports are also run on Monday.
2. All records pertaining to controlled drugs must be kept on file for a period of not less than three years

**H. ATTACHMENTS:**

None

**I. REFERENCES:**

None

**J. SEARCH WORDS:**

**K. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS:**

On File

**M. COMMITTEE APPROVALS:**

None

**N. FINAL APPROVAL:**

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|--|-----------------------------------|
| <p>1. <u>Bruce T. Liang, MD (Signed)</u><br/>Bruce T. Liang, MD<br/><b>Interim Chief Executive Officer &amp; EVP for Health Affairs<br/>Dean, School of Medicine</b></p> | <p><u>11/07/2022</u><br/>Date</p> |
| <p>2. <u>Anne Horbatuck (Signed)</u><br/>Anne D. Horbatuck, RN, BSN, MBA<br/><b>Clinical Policy Committee Co-Chair</b></p>   | <p><u>11/02/2022</u><br/>Date</p> |
| <p>3. <u>Scott Allen, MD (Signed)</u><br/>Scott Allen, MD<br/><b>Clinical Policy Committee Co-Chair</b></p>  | <p><u>11/04/2022</u><br/>Date</p> |
| <p>4. <u>Caryl Ryan (Signed)</u><br/>Caryl Ryan, MS, BSN, RN<br/><b>Chief Operating Officer, JDH<br/>VP Quality and Patient Services &amp; Chief Nursing Officer</b></p> | <p><u>11/04/2022</u><br/>Date</p> |

**O. REVISION HISTORY:**

Date Issued: 11/12/12

Date Revised: 11/12/12, 7/28/15, 11/27/17, 5/19/21

Date Reviewed: 11/12/12, 7/28/15, 11/27/17, 8/17/21