Pharmacy Department Policy
Pharmacy Controlled Substance Compliance & Monitoring Program

A. EFFECTIVE DATE:
   August 17, 2021

B. PURPOSE:
The purpose of this policy is to provide a system of governance to oversee all controlled medications that are received, distributed, and stored throughout the organization. This policy assures the safe and responsible use of controlled medications while also mitigating incidence of diversion in compliance with DEA regulations.

C. POLICY:
The Pharmacy department will ensure storage, record keeping, accounting and traceability of all controlled substances distributed throughout JDH.

D. SCOPE:
This policy applies to all John Dempsey Hospital (JDH) clinical care areas where controlled substance medications are stored.

E. DEFINITIONS:
None

F. MATERIAL(S) NEEDED:
None

G. PROCEDURE:
   1. Compare Report - JDH
      a. This report is the accounting of controlled medications as they are removed from the safe perpetual inventory and/or removed from the ADM perpetual inventory. It ensures that the removal of controlled substances from one perpetual inventory is received into the other. It accounts for the correct intended destination and the correct quantity.
      b. **Description:** This report will identify any mismatched removals from the perpetual inventory of the safe and the perpetual inventory of the ADM cabinet. If a removal and receive into the respective perpetual inventories is completed accurately, then this transaction will NOT appear on the report. The report identifies any mismatched transactions, which will therefore warrant further examination and reconciliation. This report is examined for transactions occurring within JDH licensed space.
      c. **Frequency:** Performed daily (Monday-Friday). Weekend activity is reviewed on the Monday
2. **Discrepancy Report - JDH**
   a. This report is to identify any discrepancies that have been resolved or unresolved. All discrepancies regardless of resolution will be investigated to ensure no loss/diversion of controlled substances.
   b. **Description:** This report will identify all discrepancies that have occurred at a Pyxis Medstation over a certain period of time as they pertain to controlled medications. A discrepancy results, after the addition or removal of a medication when the users’ final count does not match the final count expected by the system. The report will serve as the start of the investigation to examine the resolution of the discrepancy to be valid. The activity surrounding the discrepancy will be examined to substantiate the discrepancy and either validate the resolution, assist with resolution, or warrant further investigation. If the investigation results in an unresolved loss, the loss will be reported to the DEA in accordance with DCP (Department of Consumer Protection) oversight.
   c. **Frequency:** Performed daily (Monday-Friday). Weekend activity is reviewed on the Monday

3. **Controlled Substances Received Report - JDH**
   a. This report is to identify all controlled substances coming into the organization and verify that all CII-V controlled substances were put into the controlled substance perpetual inventory record. Any deviation in this process may be diversion. The review of these transactions will ensure that all ordered controlled substances are accounted for from the time they arrive in the pharmacy to the time they are stored inside of the safe.
   b. **Description:** This is a report that summarizes what controlled medications have been stocked in the safe after they have been purchased from a vendor. This monthly report is then cross-referenced with the monthly invoice report from our contracted wholesalers to assure that all controlled medications that have been purchased are accounted for in the perpetual inventory.
   c. **Frequency:** Performed quarterly with a 90 day look-back.

4. **Controlled Substances Send Report**
   a. This report is to ensure accountability for any medications that are removed from the vault perpetual inventory and being delivered to a non-ADM location. A non-ADM location will not communicate back to the C2Safe for receipt and apply the necessary checks and balances. This report is to ensure any removals to a non-ADM location are not being diverted.
   b. **Description:** This is a report of all the controlled medications that are being removed from the vault perpetual inventory and being sent to a non-ADM location. All transactions should be either patient specific or clinic specific. All patient specific removals will require a cross-reference check to an order and documentation of administration, which will close the loop of removal reconciliation. All clinic specific removals are reconciled to active and processed proof-of-use sheets to close the loop of removal transaction.
   c. **Frequency:** Performed monthly with a previous month look-back

5. **Controlled Substances Off-Site Sent Report**
   a. This report is to account for any CII delivery transactions to hospital locations outside of 263 Farmington Ave. Any CII deliveries outside of the hospital DEA address will require a receiving DEA address 222 form to be completed and filed with the Hartford DEA office.
   b. **Description:** This is a report that shows controlled substances including CII that have been sent to a different location (a different facility) outside of the 263 Farmington Ave address. Any CII transactions sent to a location outside of the hospital address are followed up with a receiving DEA 222 form. The DEA 222 form is completed and copies sent to the Hartford DEA office.
   c. **Frequency:** Performed monthly with a previous month look back
6. **JDH Proactive Diversion Report**
   a. This report is to proactively identify individuals that have significantly higher usage of controlled drugs compared to their peers (2-3 standard deviations above the mean). This elevation in usage as compared to their peers may be indicative of possible diversion. This report is used as a tool to investigate controlled substance usage in more detail on a user by user level.
   b. **Description:** This report depicts the average and standard deviation above the mean control substance removals by drug on an individual user. Users are evaluated against their peers and any standard deviation above the mean >4 will require a complete investigation of the past 30 days usage of the drug identified in the report. Other individuals for further investigation may also be identified based on quantity of controlled substance removed per day, standard deviation above the mean comparison to nearest peer, and other factors suggestive of possible diversion. The investigation and results are shared with the manager for review with individual user. Any questionable investigation results are brought to the attention of the Pharmacy Director or designee for further review and determination of next steps.
   c. **Frequency:** Performed monthly as applicable with a previous month look back.

H. **ATTACHMENTS:**
   None

I. **REFERENCES:**
   None

J. **SEARCH WORDS:**
   Controlled substance, narcotic

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:

1. Andrew Agwunobi, MD (Signed) 09/23/2021
   Andrew Agwunobi, MD, MBA
   UConn Health Chief Executive Officer

2. Anne D. Horbatuck, (Signed) 09/23/2021
   Anne D. Horbatuck, RN, BSN, MBA
   Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 09/21/2021
   Scott Allen, MD
   Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 09/15/2021
   Caryl Ryan, MS, BSN, RN
   Interim Chief Operating Officer, JDH
   VP Quality and Patient Services & Chief Nursing Officer

O. REVISION HISTORY:
   Date Issued: 1/15/17
   Date Revised: 1/15/17, 8/17/21
   Date Reviewed: 1/15/17