UNIVERSITY of VIRGINIA HEALTH SYSTEM

Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0299

A. SUBJECT: Controlled Drugs

B. EFFECTIVE DATE: October 1, 2012 (R)

C. POLICY:

The controlled drug (sedatives/hypnotics, narcotics, and medications classified by the Virginia Board of Pharmacy and/or the Drug Enforcement Agency (DEA) as scheduled II, III, IV, and V) distribution system at the University of Virginia Medical Center is tightly monitored. Inventories are maintained under oversight of the Pharmacy Department and tracked manually as well as by using computerized records via the Pyxis® CIISafe™ system and the Pyxis® automated dispensing cabinets (Pyxis®) throughout UVaHS. The system is designed to prevent diversion by tracking a number of processes, including: receiving, dispensing, administering and inventory of controlled drugs. All inpatient and outpatient pharmacies, all patient care units, and clinics sharing the same address as the Medical Center shall maintain a perpetual controlled drug inventory record of all controlled drugs in their respective areas.

All medications stored in CIISafe™ and Pyxis®, require biometric measurement for access. The vault and all other rooms in which controlled drugs are kept have limited access, have an electronic record of entry, and all keys used to access controlled drugs are tracked.

Manual records are kept in these areas: secured drawers in patient care areas, Student Health Pharmacy, the Operating Room Pharmacy Medication Storage, clinic boxes, the Pediatrics Sedation box, rescue squad cardiac boxes, and the Anesthesia Night, Labor & Delivery, Radiology and Lithotripter boxes. CIISafe™ electronically manages the records of controlled drugs in all other locations.

Chain of custody, appropriately documented in accordance with state/ federal law, shall be established and maintained for controlled drugs sent *via* the Medical Center's pneumatic tube system.

Only technicians who are trained as narcotic technicians are authorized to work directly with the inventorying, delivering, returning, and auditing of controlled substances. Narcotic technicians are involved with the secured delivery of controlled drugs to all Pyxis® locations, and the Operating Room Pharmacy Medication Storage. In regard to controlled drugs which are stored in locked locations, licensed nursing staff may transport these controlled drugs between the pharmacy and the locked location.

Only licensed pharmacists in the Commonwealth of Virginia may be involved in the dispensing of controlled substances. A Pharmacist who has a restriction on his/her license due to a felony conviction regarding controlled substances, a State Board of Pharmacy restriction, and/or who has an

EAP contract limiting his/her access to controlled substances, may not have access to controlled substances until such restriction is lifted and access is granted by the Director of Pharmacy.

Controlled drug records shall be utilized in those clinics that do not share the address of the Medical Center and where the physician obtains the medication through his/her DEA number and any Schedule II medications by his/her DEA 222 Form. Schedule II drug administration and receiving activity shall be recorded on the Schedule II record. Likewise, Schedule III, IV and V activity is to be recorded on the Schedule III, IV and V record. Pharmacy or the clinic shall file the completed forms in chronological order for at least two years to comply with State and Federal Regulations.

All unresolved discrepancies must be reported on the Controlled Drug Discrepancy Report and reported to the police and the State Board of Pharmacy if reason exists to suspect criminal activity or a significant amount is lost.

Keys to Patient Controlled Analgesia ("PCA") pumps shall be kept in Pyxis® in their assigned locations, to be removed for needed access, and returned to Pyxis®. Keys shall be counted as part of the shift controlled drug inventory count.

The Department of Pharmacy requires that all staff immediately report any suspected tampering of controlled drugs.

A monthly audit is required to be performed by the Director of Pharmacy or his/her designee, by a State Board of Pharmacy Regulation and as part of the Pharmacy CQI Plan. Additional reports may be used by the pharmacy and nursing departments to monitor for and prevent diversion.

Patients may not use their own supplies of controlled drugs. A controlled drug may be prepared for patient administration and, for various reasons, all or part of the dosage may not be needed for administration or the packaged dose may exceed the ordered dose. In addition to the administering nurse, a second employee-- either a nurse, pharmacist, or pharmacy technician-- shall witness and document the disposal of the controlled substance. Medical Center Management team members may request the testing of any wasted product volume or amount and may exercise the provisions for employee fitness for duty per Medical Center Human Resources Policy No.702 "Fitness for Duty".

D. DEFINITION

Discrepancy: An incorrect controlled drug count, whether over or short, constitutes a discrepancy. This can also include a missing controlled drug key to a secured drawer or a PCA pump.

E. PROCEDURES

I. INVENTORY OF CONTROLLED DRUGS

A. Inpatient Pharmacy:

1. After the controlled drug order is received by a pharmacist, a narcotic technician under the supervision of a pharmacist shall receive the inventory into the CIISafe™ System. The inventory is perpetual and records are maintained in the system for immediate retrieval. The CIISafe™ System also tracks the perpetual inventory of all Pyxis® locations throughout the Medical Center, and records are readily retrievable.
2. All paper receipts of controlled drugs are stored by the narcotic technician in the inpatient

pharmacy for two years in chronological order. The receipts and controlled drug records are filed in the controlled drug area in the designated storage facility. The facility personnel discard the records after two years.

B. Patient care areas:

1. Pyxis®:

a. Nursing shall not use the inventory function except when removing controlled drugs from Pyxis®.

b. Each time a controlled drug is removed from Pyxis®, and administered to the patient, the nurse shall use bar coded medication administration (BCMA) to chart the controlled drug in the patient's electronic medical record (See BCMA policy at: https://www.healthsystem.virginia.edu/documentation/get.cfm?manualdocument_id=5E47E841-110A-2E68-14AD76AE50CBB0D2)

2. If the pharmacy is unable to deliver additional non-stocked controlled substance inventory through scheduled delivery rounds, a designated Medical Center employee ("Designated Employee") from the respective patient care area, with a visible Medical Center ID, may go to the main pharmacy to retrieve the medication, in which event the following steps shall be followed by all staff involved:

a. The Designated Employee shall should bring to the pharmacy pick up window:

i. a copy of the printed EPIC order for the controlled substance and

ii. a completed controlled substance inventory record

b. A single dose of the needed controlled substance shall be dispensed;

c. The signatures of the Designated Employee and the dispensing pharmacist shall be required on the manual record to verify the correct drug, dose and quantity are dispensed;

d. The dispensing pharmacist shall attach the Pyxis® dispense receipt to the copy of the EPIC order and file the paperwork in the Pharmacy Controlled Substance vault;

e. The Designated Employee shall physically hand over the medication to the administering nurse or licensed independent practitioner (LIP)[1];

f. The nurse/LIP shall administer the dose of the medication and document the administration appropriately;

g. The controlled substance inventory record shall be completed and placed in either the pharmacy return bin or returned immediately to the pharmacy *via* the pneumatic tube system;

[1] For the purpose of this policy, licensed independent practitioner (LIP) includes physicians, nurse practitioners and physician's assistants

h. Pharmacy personnel shall retrieve any controlled substance records not returned to the pharmacy within 24 hours of dispensing the dose from the pharmacy window (*via* matching dispense documentation noted in CIISafe™ System) and reconcile the controlled substance documented administration with the EPIC MAR;

i. Pharmacy personnel shall be responsible for loading additional needed doses of the controlled substance into the Patient Care Unit's Pyxis® for future administrations up to, but not exceeding a week's supply;

j. Nursing staff shall maintain continuous balances as doses of the controlled drug are used on the manual form. The amount of the dosage form administered shall be subtracted from the previously recorded balance. This new balance shall be recorded on the same line with other administration data, in the appropriate column under the drug administered. If the number of spaces available for dosage administration is inadequate, a nurse may bring the balances forward to another controlled drug record. He/she shall staple the new record form to the previous form;

k. In the event that controlled drugs are no longer being used by patients, the patient care area's shift manager or pharmacy supervisor shall be paged immediately, so that the excess controlled drugs may be returned.

3. When time/ staffing are critical, pharmacy may, upon the request of the administering nurse, utilize the pneumatic tube system for controlled substance delivery provided the following steps are completed:

a. The controlled substance to be delivered by tube system must not appear on the organization's "do not tube" list;

b. The administering nurse shall place an EPIC Inbox message to the pharmacy to trigger the dose fill process, and follow the request with a phone call;

c. The pharmacist or pharmacy technician shall gather the necessary information from the nurse to document the chain of custody;

d. Pharmacy personnel shall assign a security number (generated by pharmacy and known only to the nurse) that will unlock the tube system at the delivery site;

e. The pharmacy shall place the medication in the tube along with a chain of custody form;

f. The nurse shall enter the security code to unlock the pneumatic tube system and immediately take receipt of the controlled substance;

g. The nurse shall fill out all necessary fields in the chain of custody form and shall return it to pharmacy immediately either by pneumatic tube system or *via* the pharmacy return bin.

h. Chain of custody forms shall be tracked and reconciled daily. Unaccounted forms shall be treated as lost controlled substances and full investigations shall be launched

regarding the potential diversion of that particular medication.

i. Only one dose shall be sent via tube system at any one time.

C. Clinics sharing the same address as the Medical Center:

1. Pyxis®:

a. Each time a controlled drug is loaded, refilled or unloaded from Pyxis® by pharmacy personnel, the area manager is required to count the quantity on hand in order to maintain a perpetual inventory.

b. Each time a controlled drug is removed from Pyxis®, and administered to the patient; the nurse will manually chart the controlled drug in Epic, the patient's electronic medical record.

D. Clinics not sharing the same address as the Medical Center:

1. These clinics are responsible for maintaining their own scheduled II controlled drug inventory.

2. After controlled drugs scheduled II-V are requisitioned from the inpatient pharmacy, the clinic is to maintain their own inventory records.

E. Operating Room (OR) Pharmacy:

1. Controlled drug records in the OR pharmacy are maintained manually. The OR Pharmacy technician shall submit a request for needed controlled drugs. The narcotic technician, under the supervision of a pharmacist, shall retrieve the necessary inventory from the CIISafe™ System. A pharmacist shall then check and sign off on the inventory request.

2. At the start of the first shift, the OR Pharmacy technician will take an inventory of all controlled drugs in the OR Pharmacy Medication Storage. This shall happen again at the shift change with the second shift OR Pharmacy technician. The final daily inventory shall be taken at the end of the second shift of the OR pharmacy technician.

3. During the normal business hours of the OR Pharmacy, controlled drugs may be distributed from the OR Pharmacy on a case by case basis.

a. The licensed professional or his/her designee shall sign out an order of controlled drugs prior to or during a related OR patient case.

b. Upon completion of the patient case the remaining controlled drugs shall be returned to the OR Pharmacy.

c. The OR Pharmacy technician shall reconcile returned controlled drugs with the electronic medication administration record to account for all distributed controlled drugs.

4. Pediatrics sedation boxes and the Anesthesia Night, Labor & Delivery, Radiology and Lithotripter boxes.

    a. These boxes are all used by Medical Center staff in the event of a medical emergency.

    b. Boxes are assembled by pharmacy staff in the OR Pharmacy.

    c. Boxes are issued in the morning with a log recording: who is receiving the box, and when they signed it out. They are then required to be returned by 9:00PM.

    d. If the box was used, then they are returned with a patient medication administration record.

    e. The OR Pharmacy technician shall reconcile returned controlled drugs with the medication administration record to account for all distributed controlled drugs.

    f. The exception to this is the Anesthesia Night Boxes.

        i. These boxes are prepared by the OR Pharmacy and stored in the OR Pyxis® stations for when the OR Pharmacy is not open for service.

        ii. In the event that these boxes are accessed by the night shift anesthesiologist, they are returned to their respective Pyxis® station with a log indicating who used it and the patient medication administration record. All access to these boxes is monitored electronically.

        iii. The OR Pharmacy technician shall reconcile returned controlled drugs with the medication administration record to account for all distributed controlled drugs.

F. Barringer Pharmacy:

1. Barringer Pharmacy utilizes Pyxis® for storing and securing all controlled substances.

2. The controlled drug inventory is received by the pharmacy supervisor directly from the wholesaler and then received into the Pyxis® inventory. Like all Pyxis® locations, the inventory of controlled drugs in the outpatient pharmacy is perpetual. This requires the specific drug to be counted every time the inventory is added or subtracted from.

3. The outpatient Pyxis® maintains electronic records of all additions and removals from the controlled drug inventory.

4. The outpatient pharmacy maintains records of all prescriptions written for scheduled II-V controlled drugs.

G. Student Health Pharmacy:

1. The controlled drug inventory is received by the pharmacist directly from the wholesaler and then manually received into the perpetual inventory.

2. Schedule II-V controlled drug inventories are maintained perpetually through a manual system.

3. Schedule II controlled drugs are stored in a locked cabinet and scheduled III-V controlled drugs are store scattered throughout the shelves.

4. The outpatient pharmacy maintains records of all prescriptions written for scheduled II-V controlled drugs.

H. Special Areas – Auxiliary/supplemental boxes:

1. Special areas for controlled drug storage include: pediatrics sedation boxes, rescue squad cardiac boxes, and the Anesthesia Night, Labor & Delivery, Radiology and Lithotripter boxes.

2. Rescue squad cardiac boxes (RSCBs)

a. The inpatient pharmacy supplies and replenishes local EMS, serving the Thomas Jefferson Health District, with their RSCBs.

b. Each time a used box is brought to the pharmacy by EMS, a signature log records who dropped off the box, which box it is, who from pharmacy received the box, and the box they are picking up.

i. A numbered plastic lock is placed on the box. This number is recorded to ensure that any leftover controlled drugs are not tampered with while the box is waiting to be refilled.

ii. The technician who fills the non-controlled drugs in the boxes works under the supervision of a pharmacist.

c. All replenishments of controlled substances are done so by pharmacists and records are kept both manually and in Pyxis®.

- Manual records are kept in the vault room.

II. CONTROLLED DRUG DISCREPANCY

A. Pyxis® Discrepancies:

1. If the count by the Health Care Professional ("HCP") is found to be in disagreement to what is expected by Pyxis®, when adding or removing controlled drugs, the HCP is then required to recount. If the recount confirms a discrepancy, the HCP is allowed to proceed with their actions and Pyxis® reports a discrepancy.

2. Two HCPs resolve the discrepancy in Pyxis® as soon as possible within the same shift and report any concerns to the nursing shift manager.

3. At the end of each shift the nursing shift manager, or his/her designee, runs a discrepancy

report for each Pyxis® for his/her respective patient care area.

a. If there are unresolved discrepancies at the end of the shift, a Controlled Drug Discrepancy Report must be completed.

b. Pharmacy personnel shall run a system wide discrepancy report every 24 hours and electronically mail this document to Nursing Administrators and managers.

B. Drug Discrepancy Report:

1. Formal Controlled Drug Discrepancy Reports are signed by the HCP who originated the discrepancy and the nursing shift manager. Any resolution concluded or investigative process should be clearly noted on the discrepancy report. Per Section II. A.3 of this policy, any encountered discrepancy should be resolved by the Shift/ Area Manager as soon as possible by the end of the shift.

a. The pink copy is immediately given to the nurse manager or placed in his/her office mailbox.

b. The nurse manager, or his/her designee, investigates and resolves the discrepancy within 24 hours of receiving the report.

c. The remaining two copies (white and yellow) of the report are sent to the inpatient pharmacy supervisor immediately. In the event that there is excess controlled drug found with the discrepancy, the report is delivered by a licensed HCP or anesthesia technician, with the excess controlled drugs, to the inpatient pharmacy or the OR pharmacy.

2. The discrepancy record is reviewed by the inpatient pharmacy supervisor immediately upon receipt.

The pharmacy supervisor may request any further information that is required. He/she shall not sign a discrepancy for an overage unless the medication is returned with the discrepancy report, or the Pyxis® ticket indicates that the medication was returned to inventory.

3. Discrepancy reports are filed in the pharmacy controlled drug records for two years.

4. If the reported discrepancy remains unresolved and diversion is suspected, the police shall be notified.

5. If the clinic or procedure area obtains their medications with a DEA 222 form or with a physician's DEA number, this area shall manage and maintain their discrepancy reports on-site for two years in case of DEA or State Board of Pharmacy inspection.

III. CONTROLLED DRUG TAMPERING

A. Before administering a controlled drug, the nurse carefully examines it as follows:

1. Injectable:

a. Is the tamper tab intact?
b. Is the indicated dosage contained in the injectable?

2. Oral:

a. Is the package of the individual dose intact?
b. Is the dose in correct order in the package?

3. Patch:

a. Is the patch covering intact?

B. If evidence of tampering is detected, the nurse does the following:

1. Contacts the inpatient pharmacy supervisor and nursing supervisor immediately.

2. Completes a Controlled Drug Discrepancy, obtains a co-signature of the nurse shift manager, and retains the pink copy of the form on the unit to be taken to the nurse manager's office.

3. Hand-delivers the suspect drug and the form to the inpatient pharmacy supervisor.

C. Pharmacy supervisory personnel determine the need to send the medication to the Toxicology Lab for testing or conduct a further investigation.

D. Nurse and Pharmacy managers may refer to Medical Center Human Resources Policy No. 702, "Fitness for Duty"

IV. PATIENT CONTROLLED ANALGESIA ("PCA") PUMP KEYS

A. PCA pump keys:

1. Keys for PCA pumps are stored in a specified location in Pyxis® and should only be removed for needed access to controlled drugs in a PCA pump.

2. The key is kept on a lanyard separate from any other unit keys.

3. The key should not be left unattended.

4. If a key is lost, it shall be treated as a lost Controlled Drug, and accountable personnel shall need to comply with investigative processes to resolve the discrepancy.

5. No keys shall be re-issued to the patient care unit until every reasonable effort has been made to resolve the discrepancy.

6. A new key shall be released by pharmacy upon presentation of the discrepancy report signed by the shift manager and nursing supervisor. The nursing director or administrator shall be notified when replacement keys are requested.

B. When the Anesthesia Provider assumes care of a patient with a PCA, it shall be the responsibility of the Anesthesia Provider assuming care to ensure that the PCA remains in the immediate vicinity of the patient, ideally remaining in-line, until hand-off of care is completed to another licensed provider.

1. The PCA shall be immediately returned to the OR pharmacy if the patient expires while under the care of the Anesthetist.

2. If the OR pharmacy is not open the PCA shall be returned to the unit from which the patient originated.

3. Any deviations from this policy may be addressed through the progressive corrective action policy or, in the case of a Graduate Medical Trainee, the Program Director and Chair shall be notified and formal documentation of the interaction shall be forwarded to the pharmacy.

V. AUDIT OF CONTROLLED DRUG RECORDS

Quality Assurance:

1. Pharmacy personnel audit controlled drug inventory records monthly.

2. The Pyxis® charge and credit record is checked one day per month for complete charting information.

   a. Charting in Epic is checked by comparing the Pyxis® charge and credit report with a controlled drug charting report called out of Epic for the appropriate 24 hr period or by looking at the on-line charting retrieval in Epic.

   b. The percentage of drugs charted is calculated.

   c. If the audit finds that a medication with an existing order is overridden and removed from Pyxis® without being charted, the respective nursing manager shall be notified in the report.

   d. If the audit finds that a medication is overridden and removed from Pyxis® without an existing order and without being charted, the respective nursing manager shall be notified in the report and a Quality Report shall be generated by pharmacy.

3. The pharmacy Supervisor of Supply Chain Services is in charge of Continuing Quality Improvement and checks all reports for correctness.

   This report shall include:

   a. A randomly selected one day summary of all Schedule II drugs removed from Pyxis® versus charted doses, a percentage of charted doses, and any noted suspicious behavior.

   b. A daily summary of all open/unresolved discrepancies.

c. A Pyxis® diversion report for the previous month.

d. An Rx Auditor diversion report for the previous month.

4. The results of the audit shall be sent by messenger mail to the nurse managers, directors, and administrators of their respective areas. However, in the event that activity suspicious for diversion is uncovered by the Supervisor of Supply Chain Services, a notifying email shall be sent to the respective nurse manager on the day it is discovered.

5. The Supervisor for Supply Chain Services should be the organization's primary contact for controlled substance diversion activities, and he/she shall convene an interdisciplinary investigational team to review all cases of suspected diversion.

   a. The team shall be comprised of members from a variety of disciplines and be relevant to the area of practice in which the diversion was suspected.

   b. This team should be convened and a preliminary finding shall be rendered within 48 hours of initial suspicion.

6. The pharmacy Supervisor of Supply Chain Services documents the monthly audit information on a Quality Improvement Spreadsheet and reports his/her findings to the appropriate interdisciplinary practice committee as assigned by the Director of Pharmacy.

VI. CONTROLLED DRUG WASTE

A. Partial Doses:

1. Orals:

   a. A Licensed Independent Practitioner (LIP) may order a controlled drug tablet or oral liquid dose that is not an available dosage. This results in the patient receiving a partial dose of the drug in its next largest available size.

   b. Upon removal of the oral medication from Pyxis®, the nurse shall administer the dose ordered via bar code medication administration (BCMA).

   c. The nurse shall waste the unnecessary medication with a witness and document as such in Pyxis®.

   d. All solid medication waste shall be disposed of per medical center guidelines.

2. Injectables:

   a. An LIP may order a controlled drug injectable (vial, bag or ampule) dose that is not an available dosage. This results in the patient receiving a partial dose of the drug in its next largest available size.

   b. Upon removal of the injectable (ampule or vial) medication from Pyxis®, the nurse shall administer the dose ordered via BCMA.

c. If the medication order calls for a fraction of the total dose, the nurse shall waste the unnecessary medication with a witness and document as such in Pyxis®.

d. IV bag volumes shall be measured prior to wasting.

e. All liquid waste shall be disposed of in accordance with Medical Center guidelines.

B. Controlled Drug Patches:

Upon removal of a fentanyl patch from the patient, the nurse shall fold the patch in half and dispose of it down the toilet (per manufacturer recommendations).

C. Wasted Doses:

1. If the patient refuses a dose or the dose is dropped/soiled, the prepared dose shall not be administered.

2. The nurse responsible for administration shall waste the controlled drug following the same procedure listed in section A.

D. Extended time for waste:

1. Situations in which an extension is allowed include:

i. Critical Care Units: Emergent situations.

ii. Emergency Department: Trauma alerts, active seizures, conscious sedations, and STEMI alerts, rapid sequence intubation.

iii. Extended time is defined as within 30 minutes of the end of the event or situation mentioned in either VI.D.1.i or VI.D.1.ii.

2. In the above mentioned select situations, an LIP may order a controlled drug injectable (vial or ampule) dose that is not an available dosage or shall be administered multiple times, in succession, from the same container. This may result in the patient receiving a partial dose of the drug in its next largest available size. Under these circumstances, the nurse may administer multiple portions of the full dose in the container.

3. In these situations, the witnessing and documenting of the wastage may be completed when the emergent situation has ended.

E. Unused/unopened controlled drugs for return:

1. Unused/unopened medications that are expired or appear unsuitable for use are witnessed and placed in the Pyxis® return bin.

2. If the medication does not fit in the return bin, the nurse is to page the pharmacy supervisor or shift manager for immediate return to pharmacy.

3. Pharmacy personnel on the units may return any whole, non-administered controlled

drugs to the pharmacy.

F. REFERENCES:

The Joint Commission Medication Management Standard, MM.02.01.01, MM.03.01.01, MM.05.01.19
State Board of Pharmacy Regulation 18 VAC 110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.
State Board of Pharmacy Regulation 18 VAC 110-20-210. Disposal of drugs by pharmacies.
State Board of Pharmacy Regulation 18 VAC 110-20-460. Floor Stock Drugs: Proof of Delivery; Distribution Records
State Board of Pharmacy Regulation 18 VAC 110-20-555. Use of automated dispensing devices.

SIGNATURE:

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9/26/12

DATE:

Medical Center Policy No. 0299 (R)
Approved October 2011
Revised September 2012
Approved by Quality Committee
Approved by Clinical Staff Executive Committee