

SECTION VI
CONTROLLED SUBSTANCES
WHITING FORENSIC HOSPITAL
PHARMACY POLICY AND PROCEDURE MANUAL

SECTION VI: CONTROLLED SUBSTANCE

CHAPTER 6.1: CONTROLLED SUBSTANCES (EXPLANATION OF)

POLICY: Controlled Substances at WFH are classified according to Federal and State regulations.

PROCEDURE: In compliance with the Controlled Substances Act and its amendments, the Federal Drug Enforcement Agency (DEA), formerly known as the Bureau of Narcotics and Dangerous Drugs (BNDD) has classified all controlled substances into five (5) schedules.

SCHEDULE I: Highest potential for abuse; no accepted medical use in the United States; used primarily in research.

SCHEDULE II: High potential for abuse with severe psychic and physical dependence liability.

SCHEDULE III: Drugs with lesser abuse potential than those listed in Schedules I and II.

SCHEDULE IV: Drugs with a lesser potential for abuse than those listed in the above Schedules, but greater than those in Schedule V.

SCHEDULE V: Drugs which have the least potential for abuse of those classified by the DEA.

All physicians, dentists and other authorized practitioners must have a DEA registration number to be eligible to prescribe Controlled Substances. A registration number is assigned upon application to the DEA. Psychiatric residents and dental interns are covered by a coded internal registration number issued by the hospital. All controlled substances may be administered by a registered nurse, licensed practical nurse, or an authorized licensed practitioner.

All records, orders, counts, and storage of controlled substances must comply with Federal and State Laws.

REFERENCE: GENERAL STATUTES OF CONNECTICUT, VOLUME IV: Chapter 359 page 704(2) et seq. TITLE 19

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WHITING FORENSIC HOSPITAL PHARMACY POLICY AND PROCEDURE MANUAL

SECTION:VI CONTROLLED SUBSTANCES CHAPTER: 6.1.1 USE OF AUTOMATED MEDICATION CARTS

PURPOSE: To define the policy and procedure for the storage, record keeping and distribution of controlled substance (as well as non-controlled) medication using an automated medication dispensing system. Any changes or updates to this policy must be approved by the State of Connecticut Drug Control Division.

DESCRIPTION

At Whiting Forensic Hospital, Pharmacy and Nursing Services use the Pyxis Automated Medication 400 Supply and Distribution system for the storage, record keeping and distribution of medication.

The Pyxis Medstation 4000, is a microprocessor controlled secure storage and record keeping system. The pharmacy also utilizes the Pyxis CII safe which is located inside the pharmacy vault.

The station is durably built to provide secure and reliable storage for medication including Controlled Substances. The hospital utilizes the medstation with the following specifications; Electronic access doors, removable rear panel for emergency access which require two non-identical keys to open, and eyebolt for a security cable.

Controlled Substances are stored in a carousel drawer within the nursing Pyxis Medstations on each unit. One or more auxiliary storage unit as well as towers and refrigerators are added to the basic configuration as appropriate. The Medstation Rx User's Manual contains detailed information on the operation of the Pyxis system. A manual or manual section appropriate to the policy may be found in each patient care location at which Pyxis is operational. An on-line tutorial is also available.

Pyxis Medstations are used at Whiting Forensic Hospital with an Rx Interface - where the medstation is interfaced to all medication orders for patients residing on the patient care units.

The automated medication carts are on wheels and have the ability to be mobile. The carts will be stored in the locked medication room in each patient care unit and rendered immobile. At no time will be moved out of this locked room.

Pyxis automated medication carts will be securely located in the following areas and will communicate and transmit data through the hospital's local area network system:

Patient care units Whiting Building: WU1, WU2, WU3, WU4, WU6.

Patient care units Dutcher Building: DN1, DS1, DN2, DS2, DN3, DS3

POLICY

At Whiting Forensic Hospital, Pharmacy and Nursing Services will use the Pyxis Pharmacy Medstation 4000 automated medication cart supported by integrated pharmacy medication use software (Performance) and nursing medication administration records for the storage, record keeping, and patient specific distribution (for medication administration) of controlled substances.

The Pyxis Medstation will be used for inventory, information and quality assurance systems for the control and distribution of medication for the following types of medication: 1) Controlled Substances, 2) Stat and/or first doses (while the pharmacy is closed), 3) Stock medications, 4) PRN medications, and 5) Scheduled medications

The types and quantities of controlled substances stored in each medication cart will be those necessary for a reasonable period of time and will be determined by current and historical use of medications by each clinical division. The facility will maintain a list of controlled substances stored in each cart. Requests for changes to established inventory items or par levels should be directed, in writing, to the Pharmacy Services Unit via the pharmacist covering that patient care unit.

In accordance with established policies and procedures for controlled substances, all record keeping requirements, dispensing, and administration practices conform to the regulations implemented by the Federal Controlled Substances Act of 1970 and/or the Connecticut Comprehensive Laws Concerning Drugs, whichever is the stricter for each situation. The established hospital policy and procedures for reporting of any loss, unresolved discrepancy, or inventory problem involving controlled substances will be followed. The hospital reports abuses and losses of controlled substances in accordance with laws and regulations, to the pharmacy supervisor who may further report such abuse or loss to the chief executive officer when deemed necessary. The pharmacy supervisor will fill out all necessary organization paperwork (Critical Incident Report) to initiate the necessary investigation.

The employee's authorized user Bio-ID or password sign-on identification will serve as the employee's electronic signature in the integrated Pyxis system.

Performance Pharmacy Software uses an authorized user ID and password for employees to process medication orders, and all other activities relating to providing information to nursing staff necessary when accessing medications via the automated medication carts.

The sign-on identification code will be the WFH employee ID number. In cases where an individual is not an employee of WFH or the State of Connecticut (contracted, temps, etc), this number will be a pre-determined number assigned by the pharmacy supervisor.

The password is chosen by the user, must be between 4 and 8 characters in length and may be any combination of numbers and letters. The password is secret and does not appear on any screen or field in the computer nor does it appear on any standard or custom reports.

Willful abuse or inappropriate use of the employee's electronic signature is expressly prohibited and will result in disciplinary action equivalent to the disciplinary actions that would be initiated for willfully falsifying records. Each sign-on ID code will be maintained and archived by the Hospital and will be available for inspection by the Drug Enforcement Agency (DEA) and the State Division of Drug Control.

The Pyxis system manager(s) will be responsible for entering users into the system. Access privileges in Pyxis are based on approved templates determined by the Pyxis System Manager. Template privileges are defined by the user's job responsibility.

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SECTION: VI CONTROLLED SUBSTANCES
CHAPTER: 6.1.2 ACCESS & SECURITY PRIVILEGES

PROCEDURES

I. Authorized Access - Access is strictly maintained to insure adequate security for medications including controlled substances, provide for proper documentation of medication use, and to insure confidentiality of patient data. Once signed on the system will automatically log-off the user should there be no activity for 30 consecutive seconds.

A. PASSWORD - The Pyxis System manager (Pharmacy Supervisor or Nursing System Administrator or Designee) assigns permanent ID and temporary passcodes to all new users. Each user has an ID assigned according to a uniformed format and password of their own. The first time a new user signs on to the system he/she must change the temporary password (which is new) to a unique & permanent one.

1. The Pyxis Password must consist of a three-eight digit combination of numbers or letters
2. Passwords are to be used only if Bio-ID is not working
3. Users who have forgotten their passwords must contact The Pyxis System manager to have their password reset. The Pyxis System manager will require positive identification of the user before resetting the password. Users should contact the Pharmacy or Nursing or Operations Manager for clearance to assign a new password.
4. Users may change their password any time at the Pyxis station. All passwords information is encrypted in the database and is not displayed on the screen. When a password is changed at one Pyxis medstation, the information will be transmitted to all of the Pyxis Medstations that the user is authorized to use automatically.

B. BIO-ID - The Bio-ID is initiated the first time a user accesses the Pyxis System in all departments.

1. Procedure for setting up Bio-ID
 - a. Begin log-in with permanent ID and password.
 - b. Answer yes to registering your Bio-ID.
 - c. Apply right second finger or middle finger to scanner for a total of 4 times. This will take approximately one minute to complete.

d. The next time at user login, the user will be instructed to enter user ID (not password), then place user finger on the scanner to enter main menu.

2. Procedure if user is unable to validate using Bio-ID. After three failed login attempts, the user will be prompted to log in with password for that particular attempt but will require a witness to verify identity. Users with high login failures should be evaluated and retrained re-scanned if necessary or possibly exempt from Bio-ID login.

C. USER TYPES:

1. Permanent Users: Users who will use the Pyxis system on a regular basis.
2. Individuals will have different access privileges assigned to them. These will be determined by the Pharmacy/Nurse managers on the basis of an individual's job responsibilities.

D. ACCESS PRIVILEGES:

Determined by assigning each operator a security level. The different security levels are defined by the System Administrator.

1. An operator title is used to designate each security level. Operator titles at WFH are:

- a. System Administrator/Pharmacy Supervisor
- b. Nursing Supervisor
- c. Pharmacist
- d. Pharmacy Technician
- e. RN
- f. RN (cubie recoverer)
- g. Super user

2. Permanent access codes are approved by the Head Nurse of each patient care unit. These codes will be entered and maintained by the System Manager(s). Only an authorized person with appropriate levels (i.e. the System Manager, Pharmacy Supervisor) can create access privileges for a new operator (user). Each user will sign a statement indicating that he/she understands his/her responsibilities for maintaining security of the system.

3. Any additions, deletions, or changes to the permanent access codes must be sent by the Head Nurse/Nurse Educator to the system manager as confidential information in an e-mail to the Pharmacy supervisor. The change will be made and the user notified when the change has occurred.

II. Entering Patient Information

A. Patient information is located in the gray boxes that take up most of the Idle Screen. The gray boxes contain the following information: Last Name, First Name, location, date/time of next scheduled medication dose, Icon denoting various other information such as dose past due or dose due now or charting required. This information is entered by nursing and/or pharmacy as part of the admission process and the processing of medication orders.

III. Entering Medication Orders

A. Medication orders entered by a pharmacist must be verified by a nurse prior to administration to a patient. Medication orders entered by a nurse when the pharmacy is closed must be verified by a second nurse prior to administration to a patient. Only verified orders appear on the Pyxis Medstation screen allowing access to the medications in the automated cart.

B. Orders verified by two nurses when the pharmacy is closed are verified by a pharmacist on the next day that the pharmacy is open. Orders verified by those other than a pharmacist must do the proper Lexi comp checks and documentation before the nurse can administer the medication to the patient.

C. In instances when the patient name is unknown (i.e. stat dose for emergency situation, etc.), the pharmacist, pharmacy technician, nurse, or other authorized personnel will admit the patient using the Temp Name field. Once the patient's real name is known the alias is replaced by the person's real name. All medication administration history will be preserved under the patient's real name.

D. In instances when the MPI number (patient ID number) is not known the pharmacist, pharmacy technician, nurse, or other authorized personnel will admit the patient using a temporary MPI number. This number is usually an X with the patient's date of birth. Once the MPI number is ascertained, this temporary MPI number is replaced with the correct MPI number. All medication administration history will be preserved under the admission with the correct MPI number.

IV. Administering Scheduled Controlled Substances: Pyxis Medstation will automatically pre-select and display on the touch screen patient medications as they come due, based on the dosing times entered on the medication order

- A. Sign on to the system
- B. Touch or click on the patient chosen
- C. Review the medications selected for administration for accuracy
- D. Touch the accept button
- E. The dosing information screen now appears for each medication
- F. To administer each medication touch enter on the dosing information screen for that medication (or press enter on the keyboard) and remove the medication from the medication cart drawer that has opened.

- G. Verify the controlled substance count as prompted then close the drawer
- H. Touch the "next med" button if prompted (returns process to #5 until all medications have been accessed)

V. Administering PRN Controlled Substances

- A. Sign on to the system
- B. Touch the screen ICON of the patient
- C. The medication screen appears; touch the PRN medication order(s) for administration
- D. The order(s) now show as "selected"
- E. Review the selected PRN medication order(s) and touch accept
- F. The dosing information screen now appears
- G. Proceed as outlined in a. 6-9 above.

VI. Return of Controlled Substances

- A. The "Return Med" function is used to return controlled substances to the cart.
- B. This feature should only be used when the nurse is physically returning an unused, intact medication to the cart.
 - 1. Press the Return Med button
 - 2. Select the medication to return
 - 3. Select "return item"
 - 4. The appropriate drawer on the cart opens
 - 5. Return the medication
 - 6. Verify count as prompted

VIII. Wasting Complete Doses of Controlled Substances

- A. The "Waste Item" feature under the waste function is used to waste unused full doses of medication.
- B. This feature should only be used when the nurse is wasting a full dose (vs. a partial dose) of medication. The documentation must occur at the time the medication is wasted.
 - 1. Select the "waste" button
 - 2. Select the patient
 - 3. Select the medication being wasted
 - 4. Have wastage verified by a second nurse or authorized witness
 - 5. Waste the medication
 - 6. Document the method of wastage/disposal
 - 7. Choose a different medication if needed.

IX. Wasting Partial Doses of Controlled Substances

- A. The "Waste Item" feature under the "Adjust Dose" function is used to waste unused partial doses of medication.

- B. This feature should only be used when the nurse is wasting a partial dose (vs. a full dose) of medication. The documentation must occur at the time the medication is wasted.
1. Select the patient, and then press the Adjust Dose button.
 2. Select the medication originally dispensed.
 3. Select "adjust".*
 4. Enter the witness I.D. and password (i.e. a second nurse)
 5. Double touch the medication order.
 6. Enter the actual dose (amount) administered to the patient.
 7. Choose a different medication if needed.
 8. Review the displayed information; if correct touch the "adjust dose" button.
 9. On the dose notes screen enter the reason the dose is being adjusted. Press save.
 10. Waste the remainder of the dose.
 11. In the use wastage/disposal method box document the method of wastage and disposal of the partial dose.

X. Reports

- A. An Auto-Restock Report for Controlled Substances- This report is printed daily which determines the quantity of controlled medications needed for refill on each unit.
- B. Meds Ordered and Not Loaded Report- This report prints once a day or as required. A pharmacist reviews this report to determine which medication to load into the medstation.
- C. All Station Events Report and the CII Safe Events Report - this report prints daily. This includes loading/unloading, returns, wastes, inventories done, discrepancies and open discrepancies on all the units.
- D. The Pyxis vs. CII Safe Compare Report - this report is printed daily. All activities done the prior day to determine if what controlled substances pulled were actually delivered to the patient care units.
- E. Diversion Report-Users with CS Doses Dispensed > 2 SD (Station) by Generic Name and All Stations Report- This report will be run monthly and also as needed to identify high users to evaluate possible diversion. This report will be shared with the Nursing Directors as needed.

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SECTION: VI CONTROLLED SUBSTANCES
CHAPTER: 6.1.3 SYSTEM MAINTENANCE, STATION INVENTORY, REFILLS
LOAD/UNLOAD AND OUTDATES

Procedure:

I. Inventory Counts

- A. The Medstation tracks adjustments to inventory.
- B. A physical count is done weekly by nursing staff on the units and monthly by a pharmacist and pharmacy technician in the pharmacy.

II. Refilling

- A. The Pharmacy controlled drug technician views all medications at or below minimum in the CII Safe, and adjusts all counts to the nearest 10. See Section XIX, Chapter 19.9 c.
- B. Pharmacy technicians and pharmacists will be responsible for all refills.
- C. Registered Nurses will not have refill privileges.
- D. Stock Outs/ Stock Low bulletins will automatically show up on the Pharmacy workstation as the predetermined levels are reached.

III. Load/Unload Medications

- A. The Loading/Unloading report lists per user all loads and unloads of medication including controlled substance medication.
- B. The Pharmacist will authorize changes to the Medstation inventory.
- C. Pharmacists and pharmacy technicians will have privileges to Load and Unload medication.
- D. All first doses will be delivered from the Pharmacy subsequent to order entry if not loaded into the Medstation during regular pharmacy hours.
- E. Ordered medication not loaded bulletins will be filled as soon as possible by the pharmacy technicians.
- F. Controlled Substances not loaded at the Medstation will be handled as any other medication
- G. The Pharmacy technician will review the Meds Ordered and Not Loaded Report to determine which medication needs to be loaded to the medstation. For new control medication loads, a proof-of-use sheet will accompany the medication.

IV. Outdated Medication

- A. Outdated tracking function will be instituted for all medication.

- B. When loading medication into the Medstation, the earliest date of expiration will be entered.
- C. A Pyxis report will be generated weekly to identify all outdated medication.
- D. Each medstation will be checked for outdates during the routine monthly environmental conducted by the pharmacy technicians.

V. Archiving: Archiving will be performed at a frequency established by the Systems Administrators.

VI. Inventory Maintenance:

The Pharmacy Services Unit will be responsible for the refill and loading of all medications in the Pyxis automated medication carts. Each instance in which Pyxis is refilled requires the technician to validate the quantity remaining in the drawer/cubie, document the quantity, and add the refill quantity and expiration date of medication. Pyxis will update the stock level and identify a discrepancy as appropriate. Pyxis bulletins at the workstation will list "Critical Lows" and "Outs" of all medication including Controlled Substances. Attention is paid to these items to see that medication is properly stocked on the Medstations. If a nurse notices that a medication is running low and the Pharmacy has already made a delivery or is about to make it's last delivery, he/she should notify the Pharmacy. In the event a delivery cannot be made, arrangement is made with the pharmacy to obtain the medication by visiting the patient to another unit that has the medication stocked until delivery of the medication by the pharmacy can be made.

Controlled Substances – Procedures:

A. Inventory

1. The CII Safe will monitor control medication inventories and as they go below minimum, they will appear on the Restock List for refill by the pharmacy technician at the unit level.
2. The drug control technician signs out all controlled medications from the controlled drug inventory in the CII Safe in the pharmacy vault sets them up for delivery for each unit.
3. The medications are matched to the Auto-Restock Report per unit; the medications are bagged with the corresponding bar-code label. A Review Send Report is printed at this time and signed off by the drug control technician verifying accuracy.
4. A pharmacist, along with the assigned delivery technician, reviews and signs off the controlled medications required to refill the corresponding unit. This process is repeated for each unit on campus.
5. A copy of the initialed lists are retained in the pharmacy for later reconciliation.
6. A CII Safe Compare report is printed the next day to verify what was pulled from the safe for delivery to the unit was in fact loaded/refilled to that unit.

B. Discrepancies-

A discrepancy occurs when the physical count does not match the blind count from the Pyxis Medstation System. Discrepancies may be identified during the change of shift, discrepancy report, inventory, refilling, or at any time when a nurse removes medication for the patient. An icon will appear at the Pyxis medstation once a discrepancy is created and remain visible until resolved.

1. At the conclusion of each shift the charge nurse is responsible for resolving all Open Discrepancies from the Pyxis medstation. At the end of the shift, the charge nurse must view the bottom of the sign on screen for a picture of a capsule with a slash through it, indicating there are discrepancies. If a capsule is present a Discrepancy Report must be generated.
2. Documenting discrepancies- The RN should look at each discrepancy and try to find the reason why the count is off between the two transactions on the slip. If the past 24 hours activity information is not sufficient to cover prior transaction related issues, the pharmacy may provide more information. The reason must be documented in Pyxis.
3. To Resolve Discrepancies:
 - a. Select "Procedures"
 - b. Select "Resolve Discrepancies"
4. The reasons for discrepancy resolution can be selected from an electronic list. An unusual reason may be entered as free text if the reason does not fit any available list entries. Select "Other" and enter the appropriate discrepancy code.
5. A discrepancy should be resolved at the time the discrepancy is discovered or at the change of shift. A discrepancy is resolved by asking the nurse with prior access what the circumstances were surrounding administration of the medication. Various reports can be generated at the medstation to aid in resolution of the discrepancy.
6. Contact the pharmacy supervisor or Director of General Medical Services to add reasons to the electronic discrepancy resolutions list.
7. Report any unresolved controlled substance discrepancies to the Pharmacy Supervisor or to the Pharmacy Drug Control Technician.
8. Medication discrepancies are documented and printed on the Pyxis Medstation and the Pyxis workstation located in the Pharmacy. The pharmacy monitors all open discrepancies. The Pharmacy Supervisor, Drug Control Technician or Nurse Administrator for Pyxis may generate additional reports off the workstation to resolve discrepancies.

C. Discrepancies –Report and Resolution

1. Each time the system detects a discrepancy resulting from a controlled drug verification count, a report of that specific discrepancy prints in the pharmacy. Every effort should be made to resolve the discrepancy at the time of discovery. A copy of all unresolved controlled drug discrepancies that prints in the pharmacy will be forwarded to the pharmacy supervisor or designee along with the narcotic access report.

2. The pharmacy supervisor or designee ensures the reported discrepancy has been resolved no later than the next business day.
3. The resolution of the discrepancy is documented on the narcotic access report and the report filed in the pharmacy for at least three years.
4. Copies of discrepancy reports not resolved by the pharmacy supervisor or designee within 24 hours of receipt are forwarded to the division Chief of Patient Care Services for further investigation and resolution.
5. Any discrepancies that remain unresolved after 72 hours are reported to the State of Connecticut Drug Control Division.
6. The Pharmacy will generate a "narcotic access report" each day the pharmacy is open to serve as a permanent record of controlled substance transactions and to replace the controlled substance administration record (proof of use record). This report reflects information available on-line and provides a hard copy of all controlled drug related activities including restock, wastage, discrepancies, administration, return, etc. This report is kept on file in the pharmacy for at least three years.

Emergency Controlled Substance Backup Procedure:

- A. In the event of a system power failure, it may become necessary to manually open the cart for medication access. The nurse who signed as the oncoming nurse at the last change of shift count will be notified and has the key to open the back of the cart to allow removal of controlled substances.
- B. For extended down time all controlled substances are transferred to the double lock narcotic box located in the medication room on each nursing unit. Both narcotic box keys (key 1 for the outside door and key 2 for the inside door) are locked in a cubie in the Pyxis medstation on that unit.
- C. At the time of the transfer of a controlled drug to the narcotic cabinet, a manual proof of use sheet will be completed by the nurse who signed as the oncoming nurse at the last change of shift count noting the number of doses for each controlled substance transferred.
- D. Any controlled substances administered during "down time" will be documented on the manual proof of use sheet. These manual proof of use sheets are stored in the med room in the appropriate three-ring notebook binder.
- E. After the automated medication cart is back on line, the back of the cart is locked and a change of shift count is done to verify the contents of the cart.
- F. All manual proof of use sheets will be sent to pharmacy immediately after the system is back on-line and the cart contents are verified by comparing the discrepancies on the narcotic access report to the doses administered on the manual proof of use sheet.
- G. The amount of the discrepancy for each controlled drug should equal the number of doses administered on each manual proof of use sheet.
- H. Discrepancies are investigated immediately as described within page 16, Discrepancies-Report and Resolution.

Override Functions Procedures:

- A. A limited number of “emergency or stat” medications, including controlled substances, have been approved by pharmacy and nursing for which the override function is available regardless of the patient’s medication profile in the pharmacy system. (Override medications are unit and/or user specific).
- B. If the medication is needed and is available as an override medication, the nurse should:
 - 1. Verify selection of the correct patient.
 - 2. Check for the drug under the generic or brand name.
 - 3. Re-check the drug order using the practitioner’s order on the MAR.
 - 4. Verify that the drug order has not expired, (i.e. Schedule II Controlled Substance orders expire after 72 hours and must be reordered if the patient continues to need the medication).
 - 5. If the above information has been verified and the override-approved medication is needed, select “Override Meds” from the “Remove Meds” function.
- C. Miscellaneous items stored in the Pyxis medstation system may be accessed from the “Override” function and selecting “the name of the item”.

If the override function is not available for the needed medication, nurse should expedite the normal order entry procedure to facilitate the availability of the drug. This includes faxing or bringing all NOW/STAT’s to the pharmacy for rapid order entry. If the pharmacy is closed or the medication is otherwise unavailable, the nursing supervisor or medication nurse will obtain the medication from another medstation containing the medication by visiting the patient to that medstation. (See Section III, Chapter 3.16a)
- D. An Override Report can be generated daily by the operations manager to monitor unusual removal of medication.

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.2: KEYS - MEDICATIONS SECURITY**

POLICY: The key to the back of the Pyxis 4000 medication carts are locked in the building Nursing Supervisors office and the key to the back-up controlled drug double-lock narcotic cabinet are located in a cubie in the Pyxis 4000 medstation in the medication room. To access the keys to the narcotic cabinet on the wall, all authorized personnel must remove the keys through the Pyxis medstation.

PROCEDURE: The medication room key is to be in the possession of a staff member qualified to give medications at all times. At the end of the shift, the key is passed on to the person responsible for medications on the next shift. If there is no qualified person on the next shift, the key is given to the person designated by the supervisor or to the supervisor.

 The key to the back of the medication cart shall be kept in the Nursing Supervisors office at all times. This key shall be kept on a separate and distinct key ring, not attached to any other key ring.

 Controlled substances are to be counted and the count documented by incoming and outgoing licensed staff at each change of shift only if the controlled substance is in the locked narcotic cabinet. The narcotic cabinet keys must stay in the possession of the oncoming nurse. After this count is done, the narcotic keys are passed to the new oncoming nurse who is responsible for them until the next change of shift count is completed. Controlled substances located in the Pyxis Medstations are counted once weekly, Wednesdays, between the outgoing 2nd shift nurse and incoming 3rd shift nurse.

 The unit medication cart drawers are kept closed at all times except when medications are being administered and the back of the cart is kept locked at all times except in emergency situations when access to medications is needed and the medstation is inoperable.

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SECTION VI: CONTROLLED SUBSTANCES CHAPTER 6.3 STORAGE AND HANDLING

PURPOSE: To define the policy and procedure for the storage, record keeping and distribution of controlled substance medication using the Pyxis CII Safe located in the pharmacy department.

DESCRIPTION:

At Whiting Forensic Hospital, the Pharmacy Department uses the Pyxis CII Safe for the storage, record keeping and distribution of controlled substance medications that will facilitate the management of controls within the pharmacy services department from the wholesaler to the point of administration at the patient care units. Access to the CII Safe will be by Bio-ID only.

POLICY

1. Pyxis CII Safe improves controlled substance inventory management, while creating detailed tracking and reporting for each transaction.
2. Processes are set up in the CII Safe to facilitate the withdrawal of, return of, expiring of, inventory of, and filling of all controlled substance medication and prescriptions for TL or discharge.
3. CII Safe assists the pharmacy in complying with state and federal regulations
4. CII Safe reporting provides real-time audit capabilities for all controlled substance transactions
5. CII Safe assists with the detection of controlled substance diversion at pharmacy department and nursing levels.
6. All procedures for the Pyxis CII Safe are detailed in Section 19, Chapter 19.9.

PROCEDURE

1. Each time a transaction is performed in the CII Safe, it will be done by the pharmacy supervisor, pharmacist, or pharmacy technician. On a daily basis, the removal of controlled substances for replenishment at the level of the patient care units shall be done by the drug control technician or designee. Prior to delivery, a pharmacist will verify the accuracy of the medication removed and sign off that it is correct.
2. When controlled substances are needed on off hours (evenings after 5:00pm or on holidays/weekends) then the pharmacist or pharmacy technician on duty will

remove what is needed for the unit. The pharmacist will sign off on the accuracy of what was removed.

3. Once a stock bottle has been opened, the remaining tablets/capsules, etc will be repackaged in unit dose packaging, whether it be reverse-numbered narcotic trays, pre-packed by the pharmacy automated Prepacker, or manually prepacked using the Healthcare Logistic trays, labels, and roller. An expiration date of 1 year (unless the manufacturers date precedes that date) will be placed on the prepacked medications, along with the lot number, and initials of both the pharmacist and pharmacy technician. Whenever possible, the bottle will be saved and placed with the prepacked meds for future verification. UNOPENED bottles can be stored in the Safe as such since the bottle is sealed. However, once the bottle is opened, the remaining stock will be re-packaged as unit dose. When time and staffing levels permit, the stock bottles will be re-packaged in unit dose ahead of time. This will occur with the pharmacy technician removing the stock bottle(s), prepacking the medication and the pharmacist verifying the count.
4. While processing a transaction in the CII Safe and the safe times itself out, the person in the safe must log back into the safe and complete the transaction that was started. The timing out process can be delayed by simply touching the screen.
5. All pharmacists and pharmacy technicians must always log out of the CII Safe when completing a transaction and shut the vault door.
6. The system will automatically log-out a user if there is no activity for 30 consecutive seconds (required by State of CT Drug Control).

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.4: RECEIVING CONTROL DRUGS FROM VENDOR**

POLICY: Controlled substances are received into pharmacy inventory from vendors following all required state and federal regulations. A clear paper trail of the receipt of controlled substances is maintained.

PROCEDURE:

1. When receiving controlled medications from vendors, all counts will be verified by a pharmacist. Those bottles and unit dose boxes that are sealed do not need to be counted during receiving. Those units dose boxes that do not have a safety seal on them, will be counted by the pharmacist prior to being stored in the CII Safe.
2. The pharmacist will verify amount received against invoice and documents on the DEA 222 form (if Schedule II controlled substances were received), how many packages were received and the date received.
3. Once the controlled medications have been received by the pharmacist, they will immediately transfer them to be processed in the CII Safe. The controls will be received by the control drug technician, who will process them into the CII Safe. Theses medications will be added to the existing inventory in the safe.
4. On the original and copy of the invoice note: date received, and initials.
5. Add invoice to the file in the controlled drug file cabinet labeled Cardinal Health Invoices. S-II and Methadone invoices shall be filed separately from C-III-V invoices.
6. Forward original of the invoice to the person in fiscal services assigned to process the primary vendor order.
- 7.

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.5: ORDERING OF SCHEDULE III-V CONTROLLED
 SUBSTANCES**

POLICY: Schedule III-V controlled substances are ordered and received into pharmacy inventory from vendors following all required state and federal regulations. A clear paper trail of the ordering and receipt of schedule III-V controlled substances is maintained.

PROCEDURE:

1. Based on current use, the controlled drug technician or pharmacist places an order directly to the prime vendor.
2. The technician assigned to place the drug order with the prime vendor processes schedule III-V controlled drugs as other drugs except these controlled substances are ordered on a separate purchase order. The purchase order is a blanket po used for every order involving medications.
3. Upon receipt from the prime vendor the controlled substances are processed described in chapter 6.4.

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.5.1: ORDERING AND RECEIVING OF SCHEDULE II
 CONTROLLED SUBSTANCES OTHER THAN
 METHADONE**

POLICY: Schedule II controlled substances are ordered and received into pharmacy inventory from vendors following all required state and federal regulations. A clear paper trail of the ordering and receipt of schedule II controlled substances is maintained.

PROCEDURE

1. Based on current use, the drug control technician or a pharmacist fills out the DEA 222 form and has the pharmacy supervisor or authorized designee sign it, checking for accuracy.
3. Upon receipt from the prime vendor the schedule II controlled substances are signed in along with other controlled substances.
4. The original invoice and invoice copy are forwarded to the control drug technician.
5. The control drug technician checks in the CII drugs as with other controlled drugs.
6. The controlled drug technician/pharmacist completes the DEA 222 form by filling in the quantity received, the date received, and the NDC of the medication received and files the carbon copy of the DEA 222 form in the controlled drug file cabinet.
7. The drugs are placed in the CII safe by the pharmacist or the drug control technician, assuring proper rotation of the old and new stock.

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**SECTION VI CONTROLLED SUBSTANCES
CHAPTER 6.5.3 METHADONE FOR PAIN/MAINTENANCE
 ORDERING, RECEIVING, STORAGE, DISTRIBUTION AND
 ADMINISTRATION**

POLICY: Methadone for Pain or maintenance is ordered from a vendor using the Hospital DEA Form 222 following all state and federal regulations. A clear paper trail of ordering and receipt is maintained.

PROCEDURE: The procedure outlined above is followed with the exceptions below:

1. In line 2 in the above procedure, Methadone for pain is ordered using a Hospital DEA form 222.
2. Methadone is distributed to patient care units pursuant to an order written by a physician and reviewed and processed by a pharmacist. Pharmacy Technicians will then stock the Pyxis medstation on the unit.
4. Methadone is administered to patients by nurses following Nursing Policy and Procedure for medication administration via the Pyxis MedStation 4000 and using the Nursing Kardex.

Reviewed 03 April 2018

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SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.6: INPATIENT DISPENSING (Back-up Procedure)

POLICY: There is a back-up procedure for inpatient dispensing of controlled substances should the Pyxis Medstation 4000 automated medication carts go off-line. Dispensing of controlled substances for the inpatient care units at WFH follows all required state and federal regulations. A clear paper trail of dispensing activities is maintained.

PROCEDURE:

1. Nurses will either fill out a form with the name and quantity of the controlled substance that is needed on the unit. A nurse may also call in, from each unit, needed controlled drugs on days the pharmacy is open and the drug control technician or pharmacist will receive the order via the telephone. All orders received in the pharmacy will be processed for delivery on the same day. The pharmacy asks that all orders be processed as soon as possible to ensure delivery in a timely manner.
2. The drug control technician processes the order for each unit:
 - a. Access the CII Safe with the order to be processed
 - b. pick medications from CII Safe
 - c. compare picked medications to items ordered (double check)
 - d. for each medication on the order for the unit
 - find corresponding inventory sheet in the inventory notebook
 - retrieve a blank proof of use sheet (POUS)
 - fill out line on inventory sheet for drug being dispensed with date, POUS number, unit, amount dispensed, inventory total and initials
 - fill out POUS, write date on stub and POUS, sign name under date on POUS and stub
 - write drug name, dosage form, strength, amount dispensed, and ward for POUS and stub
 - e. Write the POUS# on the controlled substance order form in the column marked POUS # adjacent to the corresponding drug. The POUS# is noted just above the dotted line.
 - f. For all unit dose medications place in a baggie
 - place POUS number on white sticker and place on baggie
 - wrap the baggie with the POUS with the writing facing out
 - place elastic band around POUS and baggie
 - g. For all non-unit dose medications/liquids, write POUS number on package (or on a sticker and place the sticker on the package) and wrap in sheet as in e. (above)
 - h. Place the medications in a plastic bag and write the unit on the outside of the bag.
 - i. Place the plastic bag in the delivery box adjacent to the control drug desk in the vault
 - j. Initial the order slip with the date filled.
 - k. Staple the order slip to the corresponding sheets in the unit order sheet notebook.
 - l. A pharmacist checks the POUS#'s against the POUS actually being delivered

Reviewed 03 April 2018

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PHARMACY POLICY AND PROCEDURE MANUAL**

SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.7: INPATIENT DELIVERY OF CONTROLLED DRUGS TO
PATIENT CARE AREAS.

POLICY: Distribution (delivery) of controlled substances to the inpatient care areas at WFH follows all required state and federal regulations. A clear paper trail of delivery activities is maintained. Controlled substances are delivered to the patient care unit on an as needed basis (usually three times a week) when the pharmacy is open.

PROCEDURE:

2. Pharmacy technicians will be assigned to deliver drugs to the patient care units on an assigned day the pharmacy is open. Part of this assignment includes the delivery of controlled drugs to the various patient care areas.
3. The assigned technician delivers the controlled drugs to the medstation using the unit scanner.
4. The carousel drawer opens to the pocket the controlled substance is to be placed.
5. The technician verifies the count and adds the medication to the existing inventory.

Reviewed 03 April 2018

**WHITING FORENSIC HOSPITAL
PHARMACY POLICY AND PROCEDURE MANUAL**

SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.7B: INPATIENT DELIVERY OF CONTROLLED DRUGS TO
WARDS (Back-up Procedure)

POLICY: There is a back-up procedure for distribution (delivery) of controlled substances to the inpatient care areas at WFH should the Pyxis Medstation 4000 automated medication carts go off-line. The procedure follows all required state and federal regulations. A clear paper trail of delivery activities is maintained. Controlled substances are delivered to the patient care area on an as needed basis (usually three times a week) when the pharmacy is open.

PROCEDURE:

1. A pharmacy technician or pharmacist will be assigned to deliver controlled drugs to the various patient care areas.
2. Go to each patient care area and find a nurse. A nurse is needed to verify and sign the POUS.
3. Give the bag of controlled drugs to the nurse.
4. The nurse reviews the medications delivered and compares them to the proof of use sheets (POUS) and stubs. The nurse signs the POUS and stub.
5. Pharmacy staff takes signed stub from nurse.
6. Nurse gives a completed POUS for each controlled drug delivered.
 - a. The POUS notebook is checked by the person assigned to controlled drugs for completed sheets and all completed sheets are collected for return to the pharmacy.
7. Return to pharmacy and give the completed POUS and stubs to the drug control technician for filing.
8. The drug control technician places stubs corresponding to the unit.
9. Completed POUS are matched to stubs and stapled together. These are set aside on the controlled drug desk for filing at the end of the day or sooner if time allows
10. Sheets with matching stubs are filed in the controlled drug filing cabinet according to drug and strength.

Reviewed 03 April 2018

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.9: TEMPORARY VISIT, DISCHARGE
 PRESCRIPTIONS**

POLICY: Temporary visit and discharge orders or prescriptions for controlled substances are filled by the WFH pharmacy following all required state and federal regulations. A clear paper trail is maintained.

PROCEDURE:

1. Retrieve the yellow prescription and label for the controlled drug from the pharmacist
2. Retrieve the correct controlled drug medication from the CII Safe.
3. Retrieve the prescription pick-up receipt from the Pyxis printer; this will have the patients name, the prescribing physician name, medication name, prescription #, quantity, and line for pharmacist and nursing signature. This receipt is printed twice so it can be matched up once the nurse gives the medication to the patient.
4. Count out the amount prescribed using a counting tray.
5. Place medication in a safety cap prescription vial.
6. Place prescription label on the vial.
7. Place the prescription with other prescriptions the patient is getting (if any) on the counter to be checked by the central pharmacist or other available pharmacist.
8. Pharmacist checks prescription and files the processed prescription accordingly. Schedule II prescriptions will be filed separately from the Schedule III, IV and V prescriptions.
9. Deliver medication to unit and have the nurse sign the receipt. The second receipt will be left with the nurse so that he/she can sign it again along with the client receiving the prescriptions for verification and then sent to pharmacy for filing.

**WHITING FORENSIC HOSPITAL
PHARMACY POLICY AND PROCEDURE MANUAL**

**SECTION VI: CONTROLLED SUBSTANCE
CHAPTER 6.10: INVENTORY VERIFICATION COUNT**

POLICY: The contents of the controlled drug CII Safe are reconciled daily upon use and the entire inventory of controlled drugs is inventoried once a month (usually at the end of the month) between a pharmacy technician and a pharmacist. All discrepancies are reported to the Pharmacy Unit Supervisor.

PROCEDURE: The standard day for counting and reconciling the controlled drug medications in the CII Safe is usually done at the end of the month on the day of the last week of the month that is the least busy and depending on staffing.

1. The pharmacist and technician will work together counting the inventory in the CII Safe. One person will count and the other will verify what the CII safe has on hand. Each pharmacist may not conduct more than one count over a 2 month period (i.e. cannot do consecutive monthly counts). A Reconcile Inventory Report will be printed with the correct count and both pharmacist and pharmacy technician will sign it. This report will be kept on file for future use.
2. A separate record/folder of all stocks of controlled substances on hand will be kept in a different folder marked "Biennial Inventory" for inventories done biennially (or more often if required by law/regulations), that is on odd numbered years. The biennial inventory will be done to coincide with the date of the general physical inventory which is within four days of the last day of June.
3. If a count is wrong the CII safe will prompt the person at the computer to recount quantity. It gives you two chances.
4. If the count is wrong a second time, the CII safe will print out a discrepancy report for further investigation.
5. If the discrepancy cannot be reconciled, then the pharmacy supervisor will adjust the count and fill out an incident report with explanation if possible.
6. If large quantities are unaccounted for, the CT. Drug Control Division will be notified.

**WHITING FORENSIC HOSPITAL
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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.11: OVERSTOCK RETURNED**

POLICY: Controlled substances in stock in the automated medication carts that are no longer required for patient care and are considered to be overstock are returned to the controlled drug CII Safe in the pharmacy following all required state and federal regulations. There is a clear paper trail maintained.

PROCEDURE:

1. Overstocked controlled drugs are identified by the pharmacist, nurse, or pharmacy technician
2. The pharmacy technician is notified to unload the control drug from the patient care unit.
3. The technician returns the controlled drug to the drug control technician in the pharmacy, who then returns it to the CII safe, and adds the correct quantity back into the stock.
4. After returning the controlled drug(s), a transaction report is printed out, a witness signs it, and it gets filed for future use.

Reviewed 03 April 2018

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SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.11B: OVERSTOCK RETURNED (Back-up Policy)

POLICY: Controlled substances in stock in the patient care areas that are no longer required for patient care and are considered to be overstock are returned to the controlled drug vault in the pharmacy following all required state and federal regulations. There is a back-up system in place that provides a clear paper trail should the Pyxis 4000 automated medication carts go off-line.

PROCEDURE:

1. Overstock controlled drugs with the corresponding proof of use sheets (POUS) are given to the pharmacist or pharmacy technician by the nurse at the usual controlled drug delivery time. Alternatively the nurse may contact the pharmacy by telephone or fax and request a pharmacist or pharmacy technician pick up the overstock.
2. The controlled drugs are returned to the pharmacy by the pharmacy technician. The controlled substances and the POUS's are forwarded to the drug control technician to be returned to the CII Safe.
3. The drug control technician verifies the POUS and drug to make sure they match and the quantity is correct.
4. On the POUS, circle the returned amount in red and write in red "returned to pharmacy inventory stock on MM/DD/YY" and then initial.
5. In the controlled drug inventory book find the page corresponding to the drug being returned.
 - a. Verify date, POUS number, ward, amount returned (added to inventory), new total inventory amount and initial.
 - b. Return the drug to the inventory in the CII Safe
 - c. Match the POUS to the stub and file.

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**SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.12: OUTDATED/RETURNED**

POLICY: Controlled substances in stock in the automated medication carts that are outdated are returned to the controlled drug vault in the pharmacy following all required state and federal regulations. There is a clear paper trail maintained.

PROCEDURE:

1. The pharmacy technician unloads the medication from the medstation, adjusting the count.
2. The technician returns the controlled drug to the drug control technician in the pharmacy, who then returns it to the CII safe in the pharmacy by selecting the return button, quantity to return, and patient care unit it was returned from.
3. By selecting the expire button, entering quantity, and reason for destruction the medication can then be placed in the “pending destruction bin” for destruction at a later date or destroyed immediately. Whether it is destroyed immediately or at a later date, a second pharmacist will be needed to co-sign in the CII Safe as a witness.
4. If the medication is required for patient care, then the cart is refilled with good dating medication and the medication is just outdated from the medstation and not unloaded.
5. Any controlled medications in liquid form other than in sealed unit dose cups, being returned to the pharmacy from the patient care unit will NOT be returned to the CII Safe. All bulk liquid medications will be wasted by appropriate pharmacy personnel and documented.

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SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.12B: OUTDATED/RETURNED (Back-up Policy)

POLICY: Controlled substances stock in the automated medication carts that are outdated are returned to the controlled drug vault in the pharmacy following all required state and federal regulations. There is a back-up procedure in place that provides a clear paper trail should the automated medication carts go off-line.

PROCEDURE:

1. Outdated controlled drugs with the corresponding proof of use sheets (POUS) are given to the pharmacist or technician by the nurse at the usual controlled drug delivery time. Alternatively, the nurse may contact the pharmacy by telephone or fax and request a pharmacist or technician pick up outdated controlled drugs.
2. The controlled drugs and POUS are forwarded to the drug control technician in the pharmacy.
3. The drug control technician verifies the POUS and matches the drug and the quantity for accuracy.
4. On the POUS circle the returned amount in red and write in red "to be destroyed, MM/DD/YY" and then initial.
5. The controlled drug is either returned the CII Safe and place in the pending destruction bin for later destruction or expired through the CII Safe with medication, quantity, and patient care unit it is returned from with a second pharmacist cosigning in the CII Safe as a witness.
6. If the CII Safe is down, the POUS and the medication will be locked up in the pharmacy vault for destruction when automation is back up.

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SECTION VI: CONTROLLED SUBSTANCES CHAPTER 6.13: DESTRUCTION OF DRUGS

POLICY: Controlled substances in pharmacy stock that are outdated or otherwise unusable may be destroyed under certain circumstances. Controlled substance destruction by the pharmacy services unit follows all required state and federal regulations. There is a clear paper trail maintained.

PROCEDURE:

1. The following controlled drugs are routinely destroyed:
 - a) outdated (not returnable via Rx Returns)
 - b) returned temporary visit or discharge medications
 - c) confiscated patient medication
 - d) pre-packaged controlled drugs that are crushed
2. An entry is made in the Confiscated Controlled Drug Destruction Log notebook for each drug being destroyed with the following:
 - a) date
 - b) ward
 - c) medication name and strength
 - d) quantity being destroyed
 - e) patient name if any
 - f) pharmacy
 - g) destruction code (s=sink, t=toilet, b=biohazard waste, o=other)
 - h) pharmacist signature
 - i) second pharmacist signature as a witness
3. The controlled drugs can now be destroyed or saved in the pending bin for EXP destruction
4. Whiting Forensic Hospital currently has a contract with EXP Pharmaceutical Services Corp. for the disposal of both non-hazardous schedule and non-schedule medications. Some of these medications are returnables in which a credit is given via the Credit Assurance Program. All non-returnables are processed for waste disposal.
5. Small quantities (usually ½ a tablet to a few tablets) are disposed of as noted in #2 on the nursing unit itself. Larger quantities are disposed of via the EXP services company.

Chapter 6.13a Destruction of Fractional Doses of Controlled Substances

Order Entry: On the Performance order entry screen, for tablets, the pharmacist will enter fractional doses of tablets, not as milligrams. For example: An order is written for clonazepam 0.25mg bid. In order to enter this dose, clonazepam 0.5mg is chosen from the Performance medication list. Since one-half of the tablets (0.25mg) will be given, the pharmacist will enter as the dose 0.5 TAB. In the REMARKS field the equivalency will be entered as 0.5 TAB= 0.25mg. The nurse, with a witness will destroy the remaining ½ tablet.

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SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.14: MONTHLY WARD CHECKS (Procedure used when automated medication carts are down)

POLICY: All proof of use sheets (POUS) in use in the patient care areas are reconciled against unmatched POUS stubs on file in the pharmacy as part of the back-up controlled drug distribution system used when the automated medication carts are off-line. This process is completed at least monthly in each patient care area.

PROCEDURE:

1. Ensure all proof of use sheets (POUS) in the pharmacy are matched and filed.
2. Take unmatched stubs and sort stubs by building and then by unit
3. Process stubs as described below one building at a time.
4. Go the nursing station on each unit and ask the nurse for the control drug book.
5. For each POUS in the control drug book find the matching stub by comparing the drug and control number.
6. On each stub matched put a check mark, date, and initial.
7. Reconcile all unmatched stubs and POUS using the following steps.
 - a. Recheck POUS
 - b. Check with nurse for any POUS not in the control drug book
 - c. Return to pharmacy and check POUS file cabinet for miss-matched stub for that drug
 - d. Check other units in the same building
 - e. Notify supervisor if A-D do not rectify the problem
8. Return the stubs to the drug control technician in the pharmacy for further investigation.

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SECTION VI: CONTROLLED SUBSTANCES
CHAPTER 6.15: END OF MONTH PROCESS

POLICY: Controlled drugs are inventoried monthly between a pharmacist and pharmacy technician, usually the last week of the month.

PROCEDURE:

1. One person stands at the computer with the quantity the safe has and the other person stands at the CII Safe and does the actual counting of the medication being inventoried. Both witness the actual counting of the medication.
2. If the quantities match, the OK is selected and the next medication comes up to be inventoried.
3. If the quantity does not match, the computer will prompt you for a second count.
4. If it is still wrong then a discrepancy sheet will print out for further investigation.
5. This process continues until the entire contents of the CII safe are inventoried.
6. A CII count sheet and a CIII-CV count sheet will be printed out for signing by the pharmacist and controlled drug technician.
7. These are filed away in the inventory binder.
8. At the end, if any discrepancies exist, this is when they are investigated and resolved.