

# Appendix 4

## Controlled Substances Procedure

UPMC PRESBYTERIAN SHADYSIDE  
POLICY AND PROCEDURE MANUAL

POLICY: CP-38  
INDEX TITLE: Care of Patients

SUBJECT: Controlled Substances (CS)  
DATE: March 3, 2004

CORRESPONDING PROCEDURE:  
Controlled Substance - Pro-CP-38

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I. POLICY

It is the policy of UPMC Presbyterian Shadyside (UPMCPS) to address all aspects of the controlled drug system including procurement, storage, access, security, control, handling, operational procedures, destruction and waste, and investigation and reporting of discrepancies. The Federal Drug Enforcement Agency (DEA) and the Pennsylvania State Board of Pharmacy regulate the possession, handling, administration and record keeping of controlled substances. Pharmacy, Nursing, Medical staff and Medical Department managers are jointly responsible for the implementation of this policy and related procedure to assure appropriate and effective medication control.

II. DEFINITIONS

Controlled Substances (CS) are divided into 5 Schedules:

Schedule I (CI)      Drugs that have no accepted medical use in the United States and have a high abuse potential.

Schedule II (CII)    Drugs which have a high abuse potential with severe psychological or physical dependence liability. Examples are opioids, amphetamines, phenmetrazine, methylphenidate, and the barbiturates such as secobarbital, pentobarbital and amobarbital, by themselves or in combination.

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Schedule III (CIII)	Drugs which have an abuse potential less than Schedule I and II. Examples are certain barbiturates, glutethimide, nalorphine, benzphetamine, chlorphentermine, phendimetrazine and paregoric.
Schedule IV (CIV)	Drugs with an abuse potential less than those listed in Schedule III. Examples are phenobarbital, chloral hydrate, ethchlorvynol, meprobamate, and paraldehyde.
Schedule V (CV)	Drugs with an abuse potential less than Schedule IV and contain limited quantities of certain CS generally for antitussive or antidiarrheal purposes. Examples are guaifenesin with codeine syrup and Diphenoxylate HCl/Atropine sulfate.
DEA	Drug Enforcement Administration is an arm of the Department of Justice created to administer the enforcement of the Comprehensive Drug Abuse Prevention and Control Act of 1970.
Valid ID	A UPMCPS hospital badge with photograph or a University of Pittsburgh ID containing a photograph.
Discrepancy	When the recorded inventory does not match the physical inventory.
Discrepancy Resolution	When the cause of the discrepancy has been discovered and all of the CS have been accounted for.
AMS Discrepancy Resolution	The recording of the discrepancy resolution in the AMS (automated medstation).
Patient Care Unit	Refers to UPMCPS inpatient units and UPMCPS based ambulatory care clinics.

Department	Refers to UPMCPS ancillary departments
Physician	Includes licensed dentists and others who by virtue of their qualifications and credentials are authorized under federal and state laws to prescribe CS.

**III. PERSONS AUTHORIZED TO HANDLE CS**

A. All authorized persons listed in this section must ensure that CS are secured at all times and never left unattended. Secured means that the CS is locked, in view or with the authorized person at all times. If CS meds are carried on the person they may not leave the unit unless transporting a patient.

B. Persons authorized to prescribe CS are:

**1. Licensed physicians registered with the DEA:**

- (a) All discharge or outpatient prescriptions must be signed by a physician who is registered with the DEA or by a physician who has a hospital assigned DEA number.
- (b) A copy of the physician DEA license is kept in the Medical Staff Office for all UPMCPS physicians credentialed.
- (c) A copy of the physician's signature is kept in the Health Information Management Department.
- (d) The Department of Pharmacy manager/director will routinely request a copy of the physician DEA numbers from the Medical Staff Office.

**Licensed physicians not registered with the DEA:**

Physicians not registered (interns, fellows, residents, foreign-trained physicians) must have their CS orders countersigned by a physician who is registered with the DEA or obtain a hospital assigned DEA number (see corresponding procedure).

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2. Allied Health Professionals (CRNP's PA's, Nurse Midwife) may prescribe as is permitted by the respective practice acts in the Commonwealth of Pennsylvania, the collaborative agreement with the supervising physician and as approved by the credentialing and privileging process at UPMC Presbyterian Shadyside.
  3. Every effort shall be made to maintain staff DEA numbers in a secure manner.
  4. Physicians and Allied Health Professionals should not prescribe CS for themselves or for members of their immediate family.
- C. Individuals authorized to administer CS are registered nurses (RN), licensed practical nurses (LPN), graduate nurses (GN), student nurses, certified physician assistants, CRNP's, nurse midwives, and licensed physicians.
- D. Individuals authorized to dispense CS are registered pharmacists and licensed physicians.
- E. Other Persons authorized to handle CS.
1. Pharmacy technicians under the direct supervision of the pharmacist are authorized to assist in the delivery of CS.
  2. Departments without nurses may designate specific individuals to pick up CS from the pharmacy with pharmacy approval and with valid ID.

**IV. PROCUREMENT, SUPPLYING AND RECEIVING CS**

Pharmacy procurement of DEA Class II CS

The person who signed the most recent application for DEA registration will grant power of attorney to all registered pharmacists designated with ability to procure CS.

V. STORAGE AND SECURITY CONTROL

A. Storage of CS within the Pharmacy

1. All Schedule II and selected Schedule III-V CS will be stored in the main pharmacies in a secured, controlled access cabinet or in the CS room/vault in the pharmacy.
2. The remaining Schedule III - V CS will be stored in open stock in the main pharmacies.
3. Pharmacy personnel designated by the Pharmacy Director or Manager will be given access to the vault area and inventory control system.
4. All areas of the department that compound preparations that contain CS (Central Pharmacy, IV Room, Satellite areas) must maintain a perpetual inventory through the use of the CS Record in order to create an audit trail as well as for documentation of usage and waste.
5. CS used to compound patient items must be logged out of the vault area and logged into the area that is preparing the item via the CS Record. After signing the medication needed from the vault for the appropriate pharmacy area, it must be signed into the log that is located in the area compounding the medication. At the time the medication is compounded, the patient name, date, room number, amount of drug used and wasted must be documented. The signatures of two pharmacy employees are required for this documentation to be complete.

B. Storage of CS in Patient Care Areas

1. All Schedule II and selected high abuse scheduled III, IV, and V CS located in patient care areas will be stored by one of three methods:
  - (a) AMS Medstation
  - (b) A centrally located CS cabinet
  - (c) A secured medication drawer

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2. CS cabinets and drawers must be double locked. If the actual storage area does not have two locks, the room may provide the second lock as long as there is limited access to the area on all shifts. Limited access is defined as access only by those individuals authorized to handle CS.
3. Any Schedule III, IV, or V CS printed on the CS Record or AMS must also be stored by one of the three methods listed above.
4. Any Schedule III, IV, or V CS not printed on the CS Record or AMS will be dispensed to the patient in a 24 hour supply and stored in the patient's specific medication bin/drawer or in the AMS station.
5. After each transaction, the cabinet or medication drawer must be locked. After each AMS transaction, the nurse must sign off the system, preventing anyone else from accessing drugs under his/her I.D. and password.

**C. Security Control**

1. Access to CS is controlled by means of an electronic card reader, AMS security code or keys.
2. Card readers and/or AMS security codes are not to be shared with anyone else.
3. CS keys or key sets must be handled in the same manner and security as with CS medication.
4. Keys/Key sets must be accounted for at change of shift.
5. Keys must not be given to anyone not authorized to prescribe or handle CS.



6. Key access and control - CS Infusion Devices (PCA and epidural pumps)
  - (a) PCA/Epidural keys are to be secured and stored in an AMS pocket or must be in the possession of a caregiver at all times. The PCA/epidural keys will be accessed using established procedures.
  - (b) Keys must be accounted for at change of shift when CS medications are counted and must be handled as such.
  - (c) PCA keys must be returned to AMS drawer when not in possession of the caregiver, using established procedures.

VI. STOCKING, DISPENSING, AND MONITORING

- A. The Pharmacy Department is to ensure that there is an adequate supply of CS in the patient care areas to enable timely patient care interventions and continuity of care.
- B. Pharmacy Daily CS Count Procedure:
  1. The pharmacy department will have a process in place to manually reconcile the actual inventory counts with the expected inventory counts, which are in the perpetual inventory software. This reconciliation will occur with each transaction or via end of shift activity report determinations.
  2. All differences between physical and expected counts are to be resolved prior to end of shift by examining requisition activity and prior physical counts for the CS in questions.
  3. If a discrepancy cannot be resolved **refer to SECTION X, PROCEDURE, RESOLVING AND REPORTING DISCREPANCIES** of this policy.
- C. Hospital-based ambulatory areas not using an AMS will perform an actual physical count of all CS daily to ensure there are no discrepancies, unless the department is closed for business (should note this on audit sheet).

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If a discrepancy cannot be resolved refer to **SECTION X, PROCEDURE, RESOLVING AND REPORTING DISCREPANCIES** of this policy.

- D. CS Weekly AMS Audit
1. An inventory of the CS on automated units must be performed once a week. Two nurses performing the audit will verify all CS in their inventory.
  2. The completed report should be forwarded to the appropriate designated Administrative Director for monitoring and follow-up. Audits will be forwarded to the Pharmacy Director.
- E. Performing CS Physical Counts (Non-AMS Units/ Departments)
1. Performing CS Physical Counts (Non-AMS Units/ Departments)
    - (a) Physical inventory counts of CS shall be performed daily by a physician, registered nurse, or licensed practical nurse, and must be verified by a witness.
    - (b) The inventory record must include the following information:
      - (1) date
      - (2) time of audit
      - (3) actual physical count of each CS
      - (4) Signature/initial of physician, registered nurse, licensed practical nurse, graduate nurse, or witness
    - (c) The unit forwards the record daily or as otherwise required (i.e. in residential treatment facility) to the pharmacy. To ensure that the figures brought forward were accurately transcribed, the record is compared to the previous 24 hour record for the same unit and is verified for mathematical accuracy.

**VII. ADMINISTRATION AND DOCUMENTATION**

- A. Administration and documentation must conform with regulatory requirements as outlined in the corresponding procedure.
1. CS are not to be vended for another caregiver unless it is an emergent situation and the nurse vending will be physically present at all times to account for the use of the CS.
  2. CS are not to be kept on the nurse/caregiver except in cases where the nurse is actively involved in care at the patient bedside (titrating dose) or is transporting the patient.
  3. Medications must be charted within one hour of removal from the AMS or CS cabinet/drawer.

**VIII. ACCOUNTABILITY IN THE ANESTHESIOLOGY/OPERATIVE CARE AREAS**

- A. Satellite Pharmacy (Presbyterian Campus)
1. The Pharmacy department provides CS to the Anesthesia Department for use in the operating room and to other areas Anesthesia provides services to. The OR Pharmacist is responsible for maintaining an accurate audit trail of all CS provided to these areas.
  2. If at any time during the case the Anesthesia Provider must leave their room, the CS signed out must remain on their person or must be secured in some manner.
  3. If the case tray changes hands during the case, the change of ownership for the CS must be documented on the CS Record of Waste receipt in the case tray. A verification of the CS in the box must be done at this time and both parties must sign record.

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4. The Anesthesia Provider involved in the discrepancy may be asked to submit a written explanation of the events leading to the discrepancy within 48 hours. The explanation is submitted to the Medical Director of Anesthesiology/OR or CRNA Chief. A copy of the statement will be retained by the pharmacy.
- B. Accountability in the Anesthesiology/Operating Room (OR) and Ambulatory Surgical Center (ASC) (**Shadyside Campus**)
1. The Pharmacy department provides CS to the Anesthesia Department for use in the operating room and ASC areas. The OR Pharmacist is responsible for maintaining an accurate audit trail of all CS provided to these areas.
  2. The CS cart will have at least one key secured locked drawer. Only employees of the Pharmacy will have access to the keys to open such drawer/s. The narcotic contents of this drawer will provide an additional supply of CS that may be needed in acute episodes. The OR Pharmacist audits the content of this drawer each day.
  3. Under no circumstances are CS to be removed from the OR or ASC Areas. CS are to be carried by the Anesthesiology staff during the participation in a procedure, and are not to be left in a room between cases or at the end of the day.

**IX. PRESCRIPTION PADS**

- A. Schedule II Prescription Pads
1. Schedule II prescription blanks will be controlled in the same manner as with schedule II medications.
  2. A perpetual inventory will be maintained in the CS vault, AMS, or CS cabinet.
  3. Dispensing and auditing will be the same process as with schedule II medications.

4. Physician Procedures

- (a) Prescriptions for Scheduled II CS must be written only on a CII prescription blank. All other blanks contain the words "Not Valid for Schedule II Drugs".
- (b) Alternatively, physicians may use the automated "Easy Script" system for providing CS prescriptions which requires a physician log in code which is equivalent to the authority for prescribing Schedule II Drugs.

X. DESTRUCTION AND WASTE

A. Wasting CS on AMS Units

- 1. Any CS removed from the Medstation unit which is not completely administered to a patient MUST be wasted.
- 2. CS waste is documented in the Medstation by two nurses, the nurse wasting the medication and a witness. The witness must view the drug being wasted/discarded into sink or toilet. Running water must follow waste. Tablets must be crushed if they are too large to be discarded in a sink drain. Any exception to the waste method must be documented under waste in the AMS system (i.e., ampule fell out of hands, medication spilled on the floor.)

B. Recording Waste or Refusal for Non-AMS Units/  
Departments

- 1. Any partial quantity of CS remaining after administration of a single dose must be immediately recorded and wasted in the presence of a witness. The witness must view the drug being wasted/discarded into sink or toilet. Running water must follow. Tablets must be crushed if they are too large to be discarded in a sink drain. Any exception of that waste method must be documented under waste on the CS Record.

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2. Each dose of the CS that is wasted or refused is to be recorded on the appropriate CS Perpetual Inventory Record by the nurse. The record must include:
  - (a) time of wastage or refusal and method of waste if different than described in Section H. 3.a)
  - (b) patient first and last name
  - (c) patient room number or floor number
  - (d) nurse and witness signatures
  - (e) drug wasted or refused and quantity
  - (f) amount remaining in stock

**C. Wasting and/or Disposal of Topical CS Dosage Forms**

1. When the prescribed dosing interval (for example 72 hours in the case of a fentanyl transdermal patch) has elapsed since application, the nurse should remove the patch from the patient, fold the patch or topical dosage form in on itself with adhesive sides touching, and dispose in a sharps container.
2. When the topical dosage form is discontinued in less than the prescribed dosing interval, after application, the drug wastage must be documented per the procedure outlined in the previous section on "**Destruction and Waste**".

**XI. RESOLVING AND REPORTING DISCREPANCIES****A. AMS Units**

1. The staff member should resolve the discrepancy as soon as it is identified. Discrepancy reports are to be run as needed to ensure prompt resolution.
2. If diversion is suspected the Pharmacy Director or Executive Director will involve the Vice President of Patient Care and will notify, when appropriate, the DEA, the Pennsylvania Attorney General, and the Pennsylvania Department of Health as required by law.

3. The Pharmacy Director will report the incident to the appropriate State Licensing Boards as required by the State Pharmacy Act.

**XII. SUSPECTED CONTROLLED SUBSTANCES TAMPERING**

- A. Any evidence of CS tampering is to be reported immediately to the clinical director or department head. A written or electronic Initial Investigation Event Report (IIER) must be completed and notification to the pharmacy within 24 hours. The CS in question shall be returned to the pharmacy following proper return procedures.

**XIII. BIENNIAL INVENTORY**

- A. A complete inventory count of all controlled drugs will be conducted at least every two years. The inventory record will be maintained for 2 years or as required by law.

**XIV. DOWNTIME**

- A. The Pharmacy Department, in collaboration with nursing and ISD staff, will oversee the development, on-going review, and appropriate revision of procedures to be used when a malfunction or failure in the AMS medstation occurs.

**SIGNED:** John Innocenti  
Senior Vice President & Chief Operating Officer

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