Controlled Substances

Purpose and Scope

To establish a mechanism for the distribution, administration, and security of controlled dangerous substances (CDS) in accordance with federal and state regulations, and to prevent diversion.

Policy

Spring Grove Hospital Center (SGHC) shall ensure medication designated as CDS by the Drug Enforcement Administration (DEA) are controlled per state and federal regulations, with appropriate oversight of their use and abuse potential.

Definitions

Controlled Dangerous Substances (CDS): drugs, chemicals, or substances whose manufacture, possession, and use are strictly regulated by government law due to their potential for abuse, addiction, and risk to public health. They are classified into "schedules" based on accepted medical use, safety, and addiction potential, including illicit drugs and certain prescription medications.

CDS Dose Log: a quadruplicate form (white, yellow, pink, goldenrod) used to track each individual dose of CDS dispensed for patient use; “Dose Log” herein.

Diversion: any unaccountable loss, theft, use for unintended purposes, or tampering of a drug.

Incoming Nurse: the licensed nursing staff accepting the CDS keys at shift change.

Narcotic Count Sheet: a document used by nursing staff to count CDS inventory on each unit at the end of every shift.

Outgoing Nurse: the licensed nursing staff relinquishing the CDS keys at shift change.

Procedure

1. Both the MDH Policy on Management of Controlled Substances and the procedures outlined in this policy are followed at SGHC.
2. **Obtaining CDS**
   - A. The unit nursing staff order CDS from the pharmacy in bulk, as needed, to ensure availability for administration per the patients’ medication orders.
   - B. To obtain CDS, nursing staff must complete a GRF as the requestor and fax it to the pharmacy
     - i. The original will be obtained upon delivery and attached to the faxed copy
   - C. Upon receipt of the GRF, the pharmacist verifies a patient on the unit has a valid order for the requisitioned CDS.
     - i. The green copy of the GRF is retained in the pharmacy.
     - ii. The Dose Log includes the date, the signature of the dispensing pharmacist, and a control number matching the control number placed on the bag of the CDS and GRF.
     - iii. The CDS is issued to the unit and may be used for multiple patients.
       - a. Nursing staff must record administration of each dose on the Dose Log per policy.
   - D. Only licensed nursing personnel may receive CDS.
   - E. The receiving nurse verifies CDS and quantity
     - i. Upon verification, the receiving nurse signs, prints full name, and dates the top of the Dose Log.
     - ii. The white copy of the GRF is returned to the pharmacy.
   - F. Requests for CDS received after 15:00 (3:00 PM) may not be processed until the following business day.
3. **Storage, Disposal, and Security**
   - A. CDS are stored behind two sets of locks.
   - B. Licensed nursing staff maintain one set of keys on each unit for the following:
     - i. Controlled substance cart lock
     - ii. Refrigerator lock (or lockbox within)

C. At the end of each nursing shift, the outgoing nurse and the incoming nurse jointly count all CDS, verify the quantities match the Dose Log, and document the actual quantity of each drug on the Narcotic Count Sheet.
   i. Each count sheet will include the CDS name, actual quantity, and signatures of the individuals performing the count.
   ii. In the event a nurse works two consecutive shifts in the medication room, the charge nurse will count the CDS supply at the change of shift time.
   iii. All CDS counts require two signatures.
   iv. If a discrepancy is detected, the outgoing nurse promptly informs the Unit Manager and Nursing Administration Office (NAO) manager of the discrepancy.
      a. If the discrepancy cannot be resolved, the incident is documented using an Management Variance Report (MVR) and reported to the Director of Pharmacy, or designee, by the outgoing nurse.
      b. Starting from the bottom of the Dose Log, the outgoing nurse will write the word "discrepancy" in place of the patient's name and sign for each missing dose.
      c. As appropriate, losses and abuse may be reported to the Chief Executive Officer (CEO).

D. After counting the CDS supply, and resolving and documenting any discrepancies, the outgoing and incoming nurses will sign and print their full name on the Shift Count/Key Transfer Log.

E. During monthly unit inspections, and randomly as necessary, the following are checked:
   i. All CDS are properly stored
   ii. The control numbers on the following match:
      a. Containers of CDS
      b. Dose Logs
      c. Pharmacy control log
   iii. CDS quantities are documented
   iv. The Shift Count/Key Transfer Log is properly completed

F. All waste and/or discard of CDS are documented on the Dose Log by writing "Waste" in place of the patient's name and signed by two licensed nurses.

G. All formulations of controlled substances shall be wasted in the Rx Destroyer®.
   i. Patches will be folded in half prior to disposal.

4. **Controlled Substance Dose Log**

A. The Dose Log is a quadruplicate form.
   i. Pharmacy retains the goldenrod copy
   ii. The white, yellow, and pink copies are sent to the unit upon dispensing.
      a. The white and yellow copies are returned to the pharmacy once completed or upon return of the CDS.
      b. The pink copy is retained on the unit until the pharmacy returns the yellow copy.
         (1) The yellow copy is retained on the unit for five years.

B. Dose Logs shall remain with the corresponding CDS at all times.

C. Upon removal of a CDS for administration, the nurse verifies the quantity matches the first blank line of the Dose Log.
   i. Any discrepancies noted are resolved using the process outlined elsewhere in this policy.

D. For each dose, the nurse documents the patient's name, date, and time, then signs and prints full name on the next blank line(s).

E. Upon completion of the Dose Log, the medication may be administered.

5. **Transferring Controlled Substances**
   A. To obtain a single dose of a CDS from another unit, the dose is documented as above on the Dose Log, including signatures of the issuing and requesting nurse, and the patient's unit is noted in parentheses after their name.
      i. A GRF is completed and signed by the requesting nurse, issuing nurse, and a different nurse on the receiving unit.
         a. The green copy is retained on the issuing unit, the original sent to the pharmacy and the remaining copies are retained on the receiving unit.
         b. The dose is immediately administered.

6. **Returning Controlled Substances to the Pharmacy**
   A. When a box or container of a CDS is empty, the container (if reusable) and the white and yellow copy of the Dose Log are returned to the pharmacy.
      i. The pink copy is retained on the unit until the yellow copy is returned from the pharmacy.
      ii. The yellow copy is retained five years.
   B. If no patient on the unit has an active order for the CDS, it must be returned to the pharmacy within one business day.
      i. The CDS supply and Dose Log are returned to the pharmacy via the pharmacy driver in a sealed bag with a completed GRF attached.
      ii. A GRF is completed and signed by the nurse returning the controlled substance in the same manner as when requesting the drug, except, the quantity being returned must be indicated and the pharmacy driver signs for receipt of the bag.
         a. The blue copy of the requisition and the pink copy of the Dose Log remain on the unit for the unit's records until the yellow dose log is returned to the unit from the pharmacy.
   C. Upon receiving the returned supply, the pharmacist immediately verifies and documents (on the Dose Log) that the number of remaining doses corresponds to the completed Dose Log.

7. **Pharmacy Inventory**
   A. The pharmacy maintains a perpetual inventory for CDS, which includes the date issued, date received, individual receiving or dispensing, source or destination, control or purchase order number, and quantity dispensed or received.
   B. The CDS inventory is double checked bi-weekly, upon receipt of CDS, and in accordance with federal and state regulations.

8. **Destruction of Controlled Substances**
   A. Rx Destroyers are available on all units for disposal of medications.
   B. Federal law prohibits the destruction or disposal of controlled substances except by individuals duly authorized by the DEA.
   C. Poured doses of liquids and/or partially used syringes/ampules may be disposed of by licensed nursing staff.
      i. Another licensed staff member must witness the disposal, document the amount destroyed, and co-sign the Dose Log.
   D. Expired, adulterated, contaminated, or broken containers of CDS are returned to the pharmacy.
   E. The pharmacy arranges the return or disposal of the CDS to the vendor or reverse distributor, respectively.
   F. The pharmacy maintains records of all destroyed CDS in accordance with federal and state regulations.

9. **Leave of Absence (LOA) and Discharge Controlled Substances**
   A. Providers may order CDS, except methadone, for LOA or discharge in accordance with the LOA and Discharge policy.
      i. See the Medications for Opioid Use Disorder policy for more information on methadone for LOA or discharge.
   B. CDS for LOA or discharge are stored in accordance with the procedures for controlled substances.

10. **After Hours Supplies**
   A. All after-hours CDS are obtained from the after-hours supply in accordance with the After Hour Drug Supply policy.
   B. Unused doses removed from the supply are stored in the unit's narcotic cabinet.
   C. The Dose Logs are attached to all CDS in the after-hours drug supply.
   D. All after-hours supplies of CDS will have a corresponding Dose Log.
      i. The goldenrod copy of the Dose Log must be affixed to the after-hours requisition and forwarded to pharmacy.
   E. A Notification of Transfer form must be completed whenever a patient is transferred with a CDS that is not stocked on the receiving unit, or when CDS are retrieved from the after-hours supply
      i. The original copy is sent to the pharmacy.
      ii. The yellow copy is retained in the NAO or on the sending unit.
      iii. The pink copy remains on the receiving unit.

References

1. Joint Commission Medication Management Standards MM.01.01.03 (EP 5)
2. Joint Commission Medication Management Standards MM.03.01.01 (EP 3)
3. Maryland Department of Health (MDH) Statewide Pharmacy and Therapeutics Committee Policy on Management of Controlled Substances
4. After Hour Drug Supply
5. Leave of Absence and Discharge
6. Medications for Opioid Use Disorder

Approved by

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