	Management of Controlled Substances			
Halton Healthcare GEORGETOWN · MILTON · OAKVILLE	Program/Dept:	Pharmacy	Document Category:	Pharmacy
	Developed by:	Medication Safety Committee	Original Approval Date:	June 1995 August 2001 January 2015
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1.0 Purpose

Compliance with federal and provincial regulatory requirements for the recording, handling, storing and distribution of controlled substances is required.

The published document *Management of Controlled Drugs and Substances in Hospitals and Healthcare Organizations* outlines fundamental principles for compliance which apply to all patient care areas:

Compliance with:

- Controlled substances are securely stored and handled throughout the medication management system, from the point of ordering to the time of administration or destruction.
- Accurate and complete records of all transactions involving a controlled substance are maintained in a timely manner. Meeting this requirement entails keeping records at the points of ordering, receiving, prescribing, dispensing or issuing, administration, and destruction.
    - All manual documentation is made in indelible ink.
    - There is a clear chain of signatures showing transfer of responsibility at each transition point.
    - Records can be easily audited.
    - All staff members check for completeness and accuracy of the records for which they are responsible, immediately resolving any discrepancies that are identified.
- Segregation of duties is implemented for critical functions with significant opportunities for diversion, such as procurement, receiving, and distribution.
- Only authorized staff handle, prescribe, or have access to controlled substances.
- Controlled substances are stored in restricted areas, such as locked rooms, dispensing cabinets, or fridges.
- Authorized staff do not share passwords or other means of ordering or accessing a controlled substance. Passwords are changed frequently according to facility policies. Users should log off immediately when systems are not in use.

2.0 Scope:

The policy applies to all staff licensed to handle controlled substances at all sites of Halton Healthcare as well as the person in charge of the hospital**.**

Accountability is defined in federal legislation whereby the person in charge of the hospital is responsible for ensuring that regulatory requirements are met. Specific responsibilities may be delegated at an operational level. The Pharmacy Department has responsibility for procurement, receipt, initial storage and distribution of controlled substances to patient care areas. Other healthcare providers such as nurses and physicians also have specific accountabilities.

3.0 Policy:

3.1 Inpatient Care Areas Controlled Substance Supply

a) Controlled substance inventory levels are established for each specific patient care area by Pharmacy in collaboration with the respective Patient Care Manager and are reviewed as required based on factors such as patient need and utilization.
b) All controlled substances kept in the patient care area will be stored in a secure dispensing cabinet.
c) If needed, a supply of controlled substances will be issued by Pharmacy for patients leaving the Hospital on an approved Leave of Absence. The Pharmacy Department requires a written physician's order prior to dispensing medication for a patient (Refer to *Leave of Absence Prescriptions (LOA) Policy and Procedure*). The narcotic/controlled LOA medication(s) will be picked up in Pharmacy by the RN or RPN who will sign the Pharmacy perpetual count record for the LOA medication. (At the GH site, Pharmacy delivers the LOA and the RN or RPN sign the delivery record for the LOA medication). Any unused drug will be returned to Pharmacy for destruction.
d) When a patient's own controlled substance supply must be used during his/her hospital stay as the medication is not on the Hospital Formulary and no other alternative medications are available, the nurse will store and administer the patient's own medication (see Patient's Own Medication policy)
e) All staff administering controlled substances to patients are responsible for ensuring that dispensing cabinet transactions are processed according to dispensing cabinet specific procedures.
f) The Patient Care Manager or delegate is responsible for ensuring proper and accurate completion of the required electronic documentation on the dispensing cabinet.
g) Any cabinet discrepancy must be investigated and resolved prior to shift change by the Charge Nurse. Automated Dose Reconciliation reports by patient care area will be provided by Pharmacy on a daily basis to identify unresolved discrepancies.
h) An incident report needs to be initiated for any unresolved discrepancies documenting the discrepancy and the actions taken to resolve the discrepancy. If the loss remains unresolved 7 days after discovery, the Patient Care Manager will notify the Director or Manager of Pharmacy who will complete a Health Canada Loss or Theft report.
i) Pharmacy and Nursing staff will routinely perform random audits of narcotic storage, administration and documentation practices and report these findings to the Medication Safety Committee.

3.2 Procedural Areas

a) The principles of responsibility and accountability related to receipt, distribution and use of controlled substances are the same as for the inpatient care areas.
b) Anesthetists are solely responsible for preparing, administering, documenting and monitoring the use of controlled substances in the operating room or labor and delivery.
c) The use of dispensing cabinets in the core area of the operating rooms by anesthetists for access to controlled substances at all three sites is followed. The anesthetist is to complete documentation of use by patient on a daily basis. Unused vials and wastage is to be accounted for by the anesthetist and reviewed by Pharmacy.
d) When an anesthetist is not in the immediate vicinity controlled substances that have been dispensed but not used should be secured. Lock boxes are to be utilized by the anesthetist for secure storage between procedures.

e) When controlled substances are removed from central stock in the dispensing cabinet by the anesthetist for use in the operating room or other procedural area a daily record must be maintained that includes the following information:

- Date and time of removal
- Name and signature of practitioner to whom controlled substance is allocated
- Destination including number of procedural room
- Drug name, dose and quantity of controlled substance(s)

3.3 Pharmacy

a) A licensed dealer (e.g., manufacturer or distributor) shall supply a hospital with a controlled substance only if the dealer has first received an order from an individual who is authorized to place orders on behalf of the hospital.
b) Controlled substances will only be ordered by Pharmacy managers registered with the Ontario College of Pharmacists as authorized to order controlled substances.
c) Separation of duties for ordering and receiving controlled substances.
d) When an ordered item is on back order, the licensed dealer should notify the pharmacist, and the order should be cancelled. If the drug is available in a reduced quantity, a new order should be placed for the amount available. Once the drug is available in the required quantity, the pharmacy should order the drug. Group purchasing organizations can help to establish contractual expectations with licensed dealers, which will help in proactively managing or mitigating a drug shortage.
e) Signing and dating of orders will be done electronically through licensed dealers' online security portals. Each individual authorized to order controlled substances shall have a unique access code. Such access codes shall not be shared or used by others.
f) The Pharmacy Department will investigate shipments that are lost in transit. However, it is the responsibility of the shipper to report such losses in transit to Health Canada. Refer to Health Canada's guidance document *Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis* for further guidance.
g) Shipments will be delivered directly to Pharmacy and will be received in the hospital information system as soon as possible after receipt. If doing so is not practical, the packages should be stored in a designated secure area within the pharmacy until they can be processed.
h) Once the packages are opened, the balance of the information necessary for the receipt is included in the following areas of record:
    - Paper copy of invoice for filing:
        - confirmation of drug name (brand and generic), strength and formulation
        - quantity (number of doses, vials or other applicable units that should match those
        - documented on the purchase order)
        - lot number(s) and expiration date(s)
        - cross reference of purchase order number with invoice number
        - recording of any noted discrepancies or damage
        - date and signature of receiver as well as their OCP number
    - HIS (Hospital Information System), Meditech, is updated to include the following details:
        - review of discrepancies
        - confirmation of quantities received as well as pricing information
        - input invoice number and date of receipt

  - change quantities reflecting receipt when discrepancies are noted
  - receive purchase order in Meditech from which inventory quantities will be updated to reflect the addition to the drug inventory
  - only staff with specialty training are able to perform this review and input and would not be the same as the staff member documenting on paper as outlined above
- CSM (Controlled Substance Management) software/hardware for controlled substance management located in the controlled substance secure storage area is managed as follows:
  - drug name, strength, formulation and quantity reviewed prior to placing into CSM cabinetry by an additional staff member (Checker Technician) working independently of the Inventory Technician and the CSM Technician
  - CSM software updated with drug quantity and expiry matching drugs physically received
  - CSM hardware cabinetry accessed in an itemized sequence to enable the user to place received medication into its appropriate secure storage location
  - report of receipt printed and attached to paper record of purchase order and invoice for Pharmacy Manager review and signature prior to filing
  - only staff with specialty training are able to perform this task

3.4 Documentation of Fractional Dosages and Wastage

a) If the ordered dosage is a fraction of the supplied drug, document the amount given to the patient on the dispensing cabinet. Verify the remaining amount with a second nurse and have the second nurse witness on the dispensing cabinet.
b) The second nurse will visually witness and verify the wastage has been placed into the commercially available medication denaturing agent before adding his/her signature. The amount wasted will be noted in the dispensing cabinet. The second nurse will also verify the drug label and confirm that the amount wasted and the actual drug matches the documentation.
c) All pharmaceutical waste containers will be utilized for wastage.
d) Tablets removed from secure or unit dose packaging and not administered (e.g. ½ tabs or refused doses) must be documented and destroyed as wastage. **DO NOT** return to the package.
e) Wastage of all controlled substances must be witnessed and documented by two independent regulated health professionals.
f) Preparation and disposal of controlled substances should occur in an open or observable area specifically designated for the preparation of drugs.
g) For administration of a single dose, excess drug that must be discarded should be wasted before administration of the dose at the patient's bedside.

3.5 Unusable Controlled Substances

a) A controlled substance may become unserviceable for various reasons. Health Canada defines unserviceable stock as products that are unusable, expired, or that cannot be dispensed. When a controlled substance or its container is damaged in the patient care area (e.g., a vial is broken, a tablet is dropped on the floor), it should be destroyed in the presence of a witness, with documentation by two regulated health professionals.

3.6 Delivery from Pharmacy to Patient Care Area

a) The delivery of controlled substances to patient care areas shall be performed using secure methods. Transport will be through non-public areas and on service elevators utilizing closed opaque containers.
b) Until drugs are delivered and accepted by staff in the patient care area, Pharmacy retains responsibility for them.
c) The drug, strength, dosage form and quantity transferred to the patient care area from Pharmacy is electronically reconciled between the dispensing cabinet and the electronic vault located in Pharmacy. These reports are reconciled at end of shift. Outstanding discrepancies are reviewed by the Pharmacy Manager.

4.0 Roles/Responsibilities

1. Maintenance of controlled substance administration records for substances stocked in that area are the responsibility of the unit Patient Care Manager. Each RN/RPN is responsible and accountable for the appropriate handling, administration, storage and documentation of controlled drugs. The Patient Care Manager (or their delegate) is responsible for monitoring these processes in the patient care area to ensure compliance with regulations.
2. All controlled substances are the responsibility of Pharmacy until the drugs are stocked in the dispensing cabinet by a Pharmacy Technician. After stocking is completed, a second check is performed via the dispensing cabinet exception report to identify any stock discrepancy. These discrepancies are monitored by the Pharmacy Manager.
3. Once the drugs have been stocked in the dispensing cabinet, the responsibility for the drugs is then transferred to the Patient Care Manager in the patient care area.

5.0 Definitions

Controlled substance – Any drug or substance found in Schedules I, II, III or IV of the *Controlled Drugs and Substances Act.,* including narcotics, amphetamines, methylphenidate, barbiturates, benzodiazepines, anabolic steroids, and other such drugs.

Procedural areas – Operating room and perioperative areas, interventional radiology, labor & delivery, intensive care unit, emergency department, specific ambulatory care areas such as endoscopy.

Unserviceable stock – Any drug product in the pharmacy inventory that is unusable, expired, or that cannot be dispensed. In the hospital setting, this term does not apply to partial or unusable doses outside the pharmacy.

Unusable drugs – The combined total of unserviceable stock (in pharmacy inventory) and any drugs outside the pharmacy that cannot be administered to a patient. This may encompass partial doses, as well as other forms of wastage.

- expired or recalled drugs
- drugs that have been "poured" (opened or otherwise made ready for administration) but have been discontinued, refused by the patient, or otherwise not administered;
- overfill in vials
- partial doses (e.g., partial tablets, or drug remaining in vials or ampules)
- drug remaining in infusion bags, syringes, or cassettes
- drug remaining in transdermal delivery systems
- drugs that were specially compounded and cannot be used for a different patient;

- drugs from outside of the facility (e.g., patient's own medications for which disposal has been requested)
- other unusable drugs (e.g., drugs that have fallen on the floor, were spit out by the patient, or were prepared for the wrong patient)

6.0 Related Documents

Utilization Automated Dispensing Cabinets
Narcotics, Controlled Drugs and Targeted Substances Destruction
Patient's Own Medication

7.0 Key Words

Narcotic, discrepancy, controlled, waste, wastage, expired, partial dose

8.0 Reviewed by/Consultation with

Medication Safety Committee

9.0 References

Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention. Canadian Society of Hospital Pharmacists, 2019. (Update to 1990 Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals published by Health Canada)

Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals', Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs of Targeted Substances, Government of Canada, Effective Date May 18, 2018