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Controlled Substances Policy (#HCS-277)

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To outline standardized practices for transporting, storing, documenting, and wasting of **controlled substances** (including **narcotics**, **controlled drugs**, benzodiazepines, and other **targeted substances**) in patient care areas within **Alberta Health Services (AHS) settings**.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Exemptions

- 1.1 This Procedure does not apply to the following:
 - a) Emergency Medical Services (EMS) (refer to EMS documents and processes); and
 - b) Home Living, Supportive Living, and facilities operated by contracted Long-Term Care Service Providers (refer to the *AHS Medication Management Policy [Continuing Care]*).

2. Delivery, Receipt, Transfer

- 2.1 Only **health care professionals** and **authorized pharmacy personnel** may deliver, receive, and transfer controlled substances within AHS settings. If the pharmacy is closed, Contracting, Procurement, and Supply Management (CPSM) staff may receive and deliver controlled substances to the unit.
- 2.2 Transportation of controlled substances in a secure and safe manner includes, but is not limited to, the following:
- a) using locked delivery carts;
 - b) using opaque containers or sealable bags and ensuring that they are in the staff member's possession at all times;
 - c) travelling through non-public areas when possible and on service elevators;
 - d) delivering controlled substances at staggered, less predictable times; and
 - e) using a mechanical transportation system with security features (e.g., tube system with password access) to deliver controlled substances to the patient care area within the same site.
- 2.3 Health care professionals may requisition, pick up, and receive controlled substances from Pharmacy when supplies in the patient care area are depleted.
- 2.4 Health care professionals or authorized pharmacy personnel must return unopened controlled substances that are expired, surplus, or not required to Pharmacy.
- 2.5 Picking Up, Receiving, or Returning Controlled Substances in Patient Care Areas with a Controlled Substances Storage Unit
- a) When picking up or receiving from, or returning controlled substances to Pharmacy, the health care professional shall present their AHS identification badge and the **Controlled Substances Record**.
 - (i) Pharmacy staff must verify the ID prior to the release of the controlled substances.
 - b) The authorized pharmacy personnel or the health care professional shall document the following information for each controlled substance in the Controlled Substances Record including:
 - (i) drug name;
 - (ii) strength/concentration;
 - (iii) quantity or volume;

- (iv) dosage form;
 - (v) time of receipt;
 - (vi) whether the controlled substance was 'Issued by Pharmacy' or 'Returned to Pharmacy';
 - (vii) quantity added or subtracted; and
 - (viii) the new balance.
- c) Both the authorized pharmacy personnel and health care professional shall verify for each controlled substance, the information in Section 2.5 b) above, and then sign and date the Controlled Substances Record.
- 2.6 Transfers Within the Same Patient Care Area
- a) If transferring a controlled substance within the same care area, two (2) health care professionals shall sign the Controlled Substances Records to indicate the change of location within the care area.
- 2.7 Transfers Between Patient Care Areas Within the Same Site
- a) Transfer of controlled substances between care areas shall only occur as a last resort. This may be required in situations such as, but not limited to, the following:
- (i) when the on-site pharmacy is not open;
 - (ii) when there is no on-site pharmacy; or
 - (iii) when the required medication is not stocked in the night cupboard.
- b) If transferring a controlled substance between care areas within the same site, the following process shall be adhered to:
- (i) the health care professional from the receiving care area must bring the Controlled Substances Record from their area along with their AHS identification badge to verify their identity;
 - (ii) the health care professional of the care area transferring the controlled substance must deduct the inventory from the Controlled Substances Record in their area;
 - (iii) prior to signing both Controlled Substances Records, both health care professionals shall verify for each controlled substance to be transferred:
 - drug name;

- strength/concentration;
 - quantity or volume; and
 - dosage form.
- (iv) the information from Section 2.7 b) iii) above shall be entered into both Controlled Substances Records, along with:
- the time of receipt;
 - the care area that the controlled substance was transferred to or received from;
 - the quantity added or subtracted; and
 - the new balance.
- (v) once verified, each health care professional shall sign and date both of the Controlled Substances Records;
- upon arrival at the receiving unit, another health care professional from the receiving unit shall verify the receipt, the count of the controlled substance added, and sign the Controlled Substances Record.
- (vi) the health care professionals involved in transferring and receiving the controlled substances shall notify their Care Area Managers/designates of the transfer; and
- (vii) the Care Area Managers/designates involved in the transfer of the controlled substances must confirm the transfer occurred as recorded and document their confirmation in the Controlled Substances Record, during their next regular shift.
- 2.8 Requests from a patient care area at another site to transfer controlled substances must be referred to Pharmacy.
- a) If the regular supplier of medication to the care area is a community pharmacy, the care area's process shall be followed.
- 2.9 Patient Care Areas with an Automated Dispensing Cabinet (ADC)
- a) When the controlled substances stock in the ADC is low, Pharmacy shall be notified to replenish the stock.
- b) If Pharmacy cannot re-stock the ADC in a timely manner, the health care professional shall use the locate function on the ADC to locate the required controlled substances on a per dose basis.

3. Storage of Controlled Substances

- 3.1 Controlled substances shall be stored in an area that is only accessible to authorized AHS staff.
- a) In Corrections settings, only authorized Correctional Services staff may be given access to areas where controlled substances are stored.
- 3.2 Controlled substances must be stored in a **secure environment** that is accessible by a key or access card (see Section 4 below). Examples of a secure environment include, but are not limited to:
- a) a designated locked storage cabinet within a medication room;
- b) a medication cart controlled with a card reader keypad or an approved controlled and restricted keyway; or
- c) an automated dispensing cabinet (ADC).
- 3.3 Controlled substances that require refrigeration shall be stored securely within a locked refrigerator or a locked box in a refrigerator located in a secured or staff accessible environment as per Section 3.2 above.

4. Keys, Locking Devices, and Access Cards

- 4.1 A health care professional's access card shall remain in their possession. Access cards and unique identifying personal identification numbers (PIN) shall not be shared with others.
- 4.2 The key used to access the controlled substances storage units/cabinets shall stay on the patient care area under the supervision of the assigned health care professional or in a lock box.
- a) The code for the controlled substances key(s) that are secured in a locking device must be changed at least annually or when required.
- 4.3 All keys for controlled substances storage units/cabinets shall be accounted for at the time of the controlled substances count. This number is written in the appropriate box on the Controlled Substances Record.
- 4.4 Patient care areas must have a process for accounting for their allotted patient-controlled analgesia (PCA) and patient-controlled epidural analgesia (PCEA) keys. PCA and PCEA keys shall be securely stored and accounted for, as per site process.
- 4.5 When a health care professional ceases to work in the patient care area (e.g., due to transfer, decreased availability, termination or Care Area Manager discretion), Care Area Managers shall deactivate the health care professional's access card to medication rooms and controlled substances storage units/cabinets in a timely and systematic way.

- a) If the unit has an ADC, the health care professional's access to the ADC shall be deactivated by the appropriate authority as per site process.

4.6 Lost or Stolen Keys and Access Cards

- a) The health care professional must immediately notify the Care Area Manager or their designate, and Protective Services or appropriate authority as per site process, of lost or stolen controlled substances storage unit/cabinet keys or lost or stolen access cards to medication rooms, ADCs, and the controlled substances storage unit/cabinet.
- b) Keys:
- (i) Keys that are lost after hours and require replacing are to be reported to the Administrator On-Call. The Care Area Manager or designate is to be notified during regular business hours.
- (ii) Once notified of the lost or stolen controlled substances storage unit/cabinet keys, the Care Area Manager or designate shall:
- immediately notify on-site Facilities, Maintenance and Engineering (FM&E) or Pharmacy Services, if they are responsible for managing these keys, or if neither are available, follow their site process;
 - ensure the controlled substances storage unit/cabinet is secure and the contents remain intact;
 - ensure security of the controlled substances storage unit/cabinet until the lock can be replaced; and
 - sign for and receive a new lock, code, and/or key(s), as applicable.
- (iii) If the missing key reappears, the key shall be turned in to FM&E or Pharmacy Services, if they are responsible for managing these keys, or if neither are available, follow their site process.
- c) Access cards:
- (i) If access cards to the medication room and the storage unit/cabinet for controlled substances are lost or stolen, the health care professional shall immediately notify:
- the Care Area Manager or designate; and
 - Protective Services or the appropriate authority as per site process.

- (ii) The lost or stolen access card shall be deactivated as soon as possible.
- (iii) Once notified of a lost or stolen access card, the Patient Care Area Manager or designate shall:
 - ensure the medication room and the storage unit/cabinet for controlled substances are secure and the contents remain intact;
 - ensure security of the medication room and the storage unit/cabinet for controlled substances; and
 - sign for a new access card for the affected employee.
- (iv) If the missing access card reappears, the access card shall be turned in to Protective Services or the appropriate authority as per site process.

5. Monitoring of Controlled Substances

- 5.1 When preparing a dose of a controlled substance for administration, the health care professional shall enter the following information as required into the Controlled Substances Record or ADC:
- a) signature/electronic identification of the health care professional who withdrew the dose from the storage area;
 - b) **patient** name;
 - c) the name, strength, and dosage form of the medication dispensed;
 - d) quantity of controlled substances remaining;
 - e) authorized prescriber's name; and
 - f) any **wastage** (see Section 7 below).
- 5.2 Health care professionals shall monitor controlled substances that are being infused outside of a locked infusion pump for tampering.
- 5.3 When preparing a controlled substance for patients leaving the premises for an off-site procedure or appointment (e.g., court hearing, specialist appointment, procedure) or going on a **pass**, the health care professional shall ensure that the transaction is entered on the patient's health record and the Controlled Substances Record or into the ADC, and include the following information:
- a) signature/electronic identification of the health care professional who withdrew the dose from the storage area;

- b) patient name;
 - c) the date the dispensed medication is being sent with the patient;
 - d) the name, strength, and dosage form of the medication dispensed;
 - e) the quantity of the medication dispensed;
 - f) the route of administration and directions for use;
 - g) authorized prescriber's name; and
 - h) that teaching was provided to the patient regarding their medication (document only on the patient's health record).
- 5.4 Any unused pass medications that are returned to the patient care area when the patient returns from pass shall be documented and either:
- a) disposed of in the appropriate dedicated medication waste container; or
 - b) returned to the pharmacy as per care area process.
- 5.5 Manual Count of Controlled Substances
- a) A manual count of the controlled substances and the keys to the controlled substances storage unit/cabinet shall be performed:
 - (i) in 24-hour patient care areas, by two (2) health care professionals (an oncoming and an outgoing health care professional) at the change of each shift; or
 - (ii) in patient care areas without 24-hour care (e.g., day surgery, some urgent care centres, ambulatory clinics), by two (2) health care professionals at the end of their shift.
 - If there is only one (1) health care professional on shift and no health care professional is scheduled for the next shift, the health care professional shall count and document the controlled substances. The oncoming health care professional on the next staffed shift shall verify the count.
 - b) Both health care professionals are accountable for ensuring the counts are correct.
 - (i) The first health care professional:
 - counts and states aloud the existing number of controlled substances in each category.

- (ii) The second health care professional:
 - observes, compares and visually verifies the actual number of controlled substances in each category to the number of recorded controlled substances in each category on the Controlled Substances Record to determine if the numbers correlate; and
 - documents the final numbers as counted on the Controlled Substances Record.
 - (iii) Both health care professionals shall sign, date, and time each count on the Controlled Substances Record.
- c) For patient care areas with ADCs, two (2) health care professionals shall use the accessed/touched drawer count functionality within the ADC to perform the manual count at shift change. A total count of all controlled substances will occur weekly (or more frequently as per patient care area process).
- (i) If a health care professional discovers a discrepancy when retrieving a controlled substance from the ADC, that health care professional is responsible for resolving the discrepancy immediately or by the end of the shift.
 - (ii) For ADCs which dispense only by unit dose, a count is not necessary.

5.6 Medication Count Discrepancies

- a) In the event of a discrepancy in the Controlled Substances Record or the ADC, the following steps should be followed to resolve the discrepancy:
- (i) recount the medications as per Section 5.5 b) above where the discrepancy was noted;
 - (ii) check for mathematical errors, e.g., doses counted twice;
 - (iii) identify patients who have an order for the specific medications involved in the discrepancy (includes pre-medications);
 - (iv) review all medication records and the patient care record for those patients previously identified and compare the Controlled Substances Record or the ADC with the documentation;
 - (v) check with staff on duty to ensure all medications administered were recorded;
 - (vi) review all other medication records and patient care records to determine if unordered medication was administered; and

- (vii) notify the Patient Care Area Manager or designate if unable to resolve the discrepancy.
- b) If the Patient Care Area Manager or designate is unable to resolve the discrepancy, they shall:
 - (i) enter the discrepancy as 'unresolved' into the Controlled Substances Record or ADC, and indicate the current count;
 - (ii) report the discrepancy to site administration and Protective Services / Site Security for awareness and potentially additional investigation (if an investigation is required, refer to Section 6 below); and
 - (iii) enter the discrepancy into the *Loss or Theft Report Form for Controlled Substances and Precursors* (Health Canada) and submit the completed form to Health Canada within 10 days of discovering the discrepancy.
- c) The Patient Care Area Manager or designate shall conduct a thorough investigation of all discrepancy incidents within the week of the discrepancy occurring, and identify any recurring trends at least monthly. Trends in controlled substances discrepancies shall be reported to the Accountable Leader, and appropriate investigation and action plans will be implemented.

5.7 Completed Controlled Substances Records

- a) When a Controlled Substances Record page is completely filled, one (1) health care professional is responsible to:
 - (i) record the final tabulation at the bottom of each medication category;
 - (ii) transfer the remaining balance from the previous page onto the new record; and
 - (iii) verify the transfer of information, sign in the appropriate spots, and indicate designation.
- b) The Patient Care Area Manager or designate is responsible for:
 - (i) reviewing the completed Controlled Substances Record for signatures, general completeness and any irregularities, and signing each page as checked; and

- (ii) if there are no irregularities, sending the full Controlled Substances Record to Pharmacy. It will then be retained for five (5) years as per the AHS *Records Management Policy*.
 - If discrepancies are noted, it is the responsibility of the Patient Care Area Manager or designate to follow up with the staff working during the shift when the discrepancy occurred to resolve the discrepancy. The Patient Care Area Manager or designate shall enter the discrepancy into the *Loss or Theft Report Form for Controlled Substances and Precursors* (Health Canada) and submit the completed form to Health Canada within 10 days of discovering the discrepancy.
- c) If Pharmacy returns the Controlled Substances Record to the patient care area due to discrepancies, it is the responsibility of the Patient Care Area Manager or designate to follow up with Pharmacy.

6. Diversion

- 6.1 The **diversion** or suspected diversion of controlled substances shall be reported to Protective Services / Site Security and Pharmacy Services by the person who discovers the alleged diversion or by the appropriate Patient Care Area Manager or designate.
- a) Concerns or allegations of diversion shall be investigated by the appropriate operational leader with support from Human Resources (HR) Business Partnerships in conjunction with relevant subject matter experts such as Protective Services (e.g., Corporate Investigations Unit) or other applicable areas.
- 6.2 The Patient Care Area Manager or designate shall forward the completed *Loss or Theft Report Form for Controlled Substances and Precursors* to Health Canada for any unexplained loss or any diversion or suspected diversion, within 10 days of discovery.

7. Wastage

- 7.1 All wastage of controlled substances is to be entered into the Controlled Substances Record in the column marked 'Wastage' or the ADC, and co-signed by the staff member witnessing the disposal. Wastage is to be immediately disposed of.
- a) Two (2) health care professionals are required to waste a controlled substance.
 - (i) One (1) health care professional shall be a witness to the wastage and must sign that they witnessed the wastage on the Controlled Substances Record or the ADC.

- b) If two (2) health care professionals are not available, the wastage may be witnessed by a **health care provider** with appropriate training.
 - (i) The authorized health care provider must sign that they witnessed the wastage on the Controlled Substances Record or the ADC.
 - (ii) For wastage of controlled substances within Correctional Health, the health care professionals should follow their site process.
- 7.2 Controlled substances waste shall be disposed of in the appropriate dedicated medication waste container as per the AHS *Waste Management Policy*.
- a) To prevent the controlled substances from being retrieved, add a water and detergent mixture or an absorptive compound to the bottom of the empty dedicated medication waste container or a portable sharps container, prior to adding the controlled substances waste.
 - b) Syringes, intravenous minibags, and infusion bags shall have their contents emptied into the dedicated medication waste container prior to disposal.
 - c) If a medication waste container is not readily available, partial doses of controlled substances in vials and syringes that are not needed may be:
 - (i) disposed of in a wall-mounted sharps container (labelled for incineration); or
 - (ii) expelled into a small portable sharps container (labelled for incineration) that contains an absorptive compound.
 - d) Tablets should be crushed and put in the appropriate medication waste container. Appropriate personal protective equipment (PPE) should be worn if required. Refer to the AHS *Hazardous Medication Personal Protective Equipment (PPE) Guide*.
 - (i) Tablets that cannot be crushed shall be disposed of in a dedicated medication waste container that contains a water and detergent mixture.
 - e) When wall-mounted sharps containers are three-quarters (3/4) full or at the designated fill level, they should be removed from the wall and securely stored until they are transported from the patient care area.
- 7.3 Used controlled substances patches shall be disposed of in a dedicated medication waste container and in a manner that prevents them from being retrieved (e.g., while wearing gloves, fold the adhesive side of the patch against itself prior to disposing).

8. Controlled Substances Prepared for Patient Procedures

- 8.1 Controlled substances shall be prepared one procedure at a time.
- a) Single dose vials and ampoules shall be used for one (1) patient only. Unused contents shall not be retained for later use.
 - b) When multi-dose vials are used, the health care professional shall reduce the risk of cross-contamination by ensuring that the date that the vial was opened is indicated on the vial, that the vial is properly stored, and aseptic technique is strictly followed.
- 8.2 Controlled substances that are prepared for administration during a procedure (e.g., colonoscopy, cardiac catheterization) shall not be left unattended.
- a) Trays, carts, and kits are to be properly secured before and after procedures and monitored during procedures.
- 8.3 Prescribers, including but not limited to Physicians (e.g., Anesthesiologists, Radiologists), Nurse Practitioners, and Midwives, are responsible for:
- a) accurately recording the amount of controlled substances administered during a procedure; and
 - b) having their wastage of controlled substances witnessed and co-signed by a health care professional as per Section 7.1 above.
- 8.4 Controlled substances will be accounted for and disposed of in the appropriate medication waste container immediately following the procedure.

DEFINITIONS

Alberta Health Services (AHS) settings means any environment where treatment/procedures and other health services are delivered by, on behalf of or in conjunction with, Alberta Health Services.

Authorized pharmacy personnel means individuals providing services, or acting on behalf of Alberta Health Services, who have been granted access to pharmacy activities related to the delivery, receipt, and transfer of controlled substances. Authorized pharmacy personnel includes Pharmacists, Pharmacy Technicians, and Pharmacy Assistants.

Controlled substance means any type of drug that the federal government has categorized as having a potential for abuse or addiction and is included in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act*.

Controlled drug means a drug or preparation set out in Schedule to Part G of the *Food and Drug Regulations (FDR)*. A drug categorized federally as having higher than average potential for abuse or addiction.

Narcotic means any substance set out in the Schedule to the *Narcotic Control Regulations* (NCR) or anything that contains any substance set out in that Schedule. A substance that has a high potential to become physically and psychologically addictive or liable for abuse.

Targeted substance means a controlled substance that is included in Schedule 1 of the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR) or a product or compound that contains a controlled substance.

Controlled Substances Record means a specific record for each controlled substances storage unit/cabinet kept in the patient care area for the purpose of tracking the receipt of, administration, and distribution of controlled substances (including narcotics, controlled drugs, and targeted substances). The Controlled Substances Record is a legal document and must legally be retained as per the *AHS Records Retention Schedule*.

Diversion means the redirection of controlled substances from the legitimate distribution chain for medical use into illicit channels. Diversion may happen in various ways including:

- Administration “deviations” such as: giving less than is ordered, abuse of PRN order, substitution of actual ordered drug, give nothing at all, falsification/manipulation of forms and records.
- Theft; substitution or dilution; excessive breakage or waste.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the *Health Disciplines Act* (Alberta) or the *Health Professions Act* (Alberta), and who practices within scope and role.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

Pass means that the patient is allowed to leave the premises or facility grounds for a specified period of time, either accompanied or not.

Patient means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

Secure environment means an area or storage unit/cabinet that is locked, away from heavy or public traffic and where only authorized AHS staff have access.

Wastage means the drug amount that is discarded and not administered to any patient (e.g., from broken or partially used or contaminated ampoules, vials, syringes, IV bags tablets, capsules and adhesive patches).

REFERENCES

- Alberta Health Services Governance Documents:
 - *Controlled Substances Policy* (#HCS-277)
 - *Medication Management Policy (Continuing Care)* (#HCS-220)
 - *Records Management Policy* (#1133)
 - *Waste Management Policy* (#ESM-01)
- Alberta Health Services Resources:
 - *Hazardous Medication Personal Protective Equipment (PPE) Guide*
- Non-Alberta Health Services Documents:
 - *Loss or Theft Report Form for Controlled Substances and Precursors* (Health Canada)

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