

 Lakeridge Health	Controlled Substances – Policy and Procedures	
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<input checked="" type="checkbox"/> Harmonized	Document Applies to: Lakeridge Health (LH) Clinical Staff and Physicians involved in the handling and/or administration of Controlled Substances	
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Introduction

The Federal Controlled Drugs and Substances Act, Food and Drugs Act and associated Regulations regulate how hospitals are to handle controlled substances including narcotics (Narcotic Control Regulations), controlled drugs (Food and Drug Regulations) and benzodiazepines (Benzodiazepines and Other Targeted Substances Regulations). A hospital is directed to develop its own control measures to ensure that the requirements of the Acts and Regulations are met. It is a hospital's responsibility to institute and enforce control measures. In addition, other medications with a high risk of harm and/or diversion have been identified that warrant additional controls beyond legislative requirements.

The extensive use of controlled substances within a hospital, combined with the complex system of distribution and the many individuals involved in the system who have access to these drugs, provide ample opportunity for diversion. The key to minimizing such diversion is to ensure that there are sufficient checks and balances in place, that clear responsibility and accountability for these drugs is established and that such responsibility is transferred as the drugs move through the system.

The inventory of controlled substances anywhere in the hospital is subject to inspection at any time by an inspector of Health Canada's Office of Controlled Substances. The intent of this inspection is to ensure that every controlled substance that enters the hospital is fully documented until it is administered to the patient, wasted, destroyed or transferred out of the hospital.

Policy

All Controlled Substances must be securely stored to minimize theft and diversion.

All Controlled Substance transactions must be promptly and accurately recorded to ensure compliance with legislation.

The identity of the prescriber of all Controlled Substance orders must be identifiable by Pharmacy Services and the Regulated Health Care Provider (RHCP) administering the medication.

Diversion of any controlled substance is a serious offence and will be thoroughly investigated with appropriate follow up and notifications as required by legislation.

Policy and Procedures Sections:

[Storage and Access of Controlled Substances](#)

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Definitions

Controlled Substance: Any medication defined as such in the Controlled Drugs and Substances Act or as identified by Pharmacy Services or Clinical Programs as being controlled.

Controlled Substance Record: A paper form used to document all manual controlled substance transactions on the patient care unit and the current quantity of each medication remaining on the unit following each transaction. Also referred to as a Narcotic Record.

Transaction: Any action that involves a transfer of accountability of a controlled substance. This includes delivery of a medication from Pharmacy Services, transfer of a medication to or from another patient care unit, patient administration, wastage, transfers within Pharmacy Services, or returns to Pharmacy Services.

Controlled Substance Discrepancy: a difference between the physical count of a controlled substance on a patient care area and the expected count based on documented transactions since the last documented count.

Controlled Substance Count: the recording of the current number of units of every controlled substance currently stocked on a patient care unit. For automated dispensing cabinets (e.g. MedSelect) or similar locations this may involve counting only those medications that are immediately accessible.

Identifiable Signature: A signature that allows for the clear identification of the individual which may include initials, professional designation or electronic signature within the Computer Information System (CIS).

Storage and Access of Controlled Substances

Policy

Controlled substances are to be stored in a minimum of a double locked system and are only to be accessed by a RHCP while on shift. Access when not scheduled to work is prohibited. Generic access codes and sharing of access (badge and/or codes) is prohibited.

Pharmacy Services staff will not have individual access to patient care unit/department electronic carts or non-electronic carts/storage locations; nurses or other RHCPs will be required to provide access to these locations on request. Automated Dispensing Cabinets (ADCs) will have shared nursing and pharmacy staff access to permit dispensing and restocking.

Access to physical keys and/or programming of electronic codes that allow access to controlled substances will be the responsibility of the patient care unit manager (e.g. Patient Care Manager) or delegate. This responsibility includes:

- Removing access for staff members that are no longer assigned to or employed at the unit or site.
- Assigning access codes upon hire or transfer to unit or site:
 - Code assigned must adhere to Lakeridge Health (LH) standards as outlined in the Manager's Narcotics and Controlled Substances Toolkit.
- Quarterly review of all staff with access to the unit or site to identify individuals that no longer require access
- Ensuring physical keys, where applicable, are carried by a RHCP when not stored in a locked location
- Determining and distributing information regarding backup keys and downtime procedures in case of power loss.

If a RHCP suspects that his/her personal electronic access code has been compromised, the Manager or delegate must be contacted immediately. All reasonable steps must be taken to ensure that the compromised code is removed from all affected equipment as soon as possible and that controlled substance counts are conducted, as appropriate, to ensure that no medication has been diverted.

Students will not have access to controlled substance storage.

Controlled substance storage locations are to be used for authorized medications only.

Procedures

Physical Key Procedures:

- If physical keys are misplaced:
 - Notify the Charge Nurse and Manager/delegate immediately to coordinate a search.
 - Complete an incident report in the incident reporting system
 - Complete a Count of all medications upon the return of the keys. If there is suspicion that the key may have been copied, the Manager will arrange to change the locks on the narcotic storage area as soon as possible.
- If the physical keys leave the hospital:
 - the RHCP responsible is to notify the Charge Nurse and Manager/delegate immediately and return the keys as soon as possible

- Complete a narcotic incident report in the incident reporting system
- The Manager will determine if replacing the locks is warranted.
- Patient's Own Controlled Substance Storage:
 - Refer to *Patient's Own Medication – Policy and Procedures*.

Controlled Substance Records

Policy

Controlled Substance Records must be used for all transactions not involving an Automated Dispensing Cabinet (e.g. MedSelect) to record all required legislated Controlled Substance information.

The Controlled Substance Record is to be used within clinical areas to:

- Record all deliveries of controlled substances received from Pharmacy Services
- Record transfers of controlled substances between patient care units
- Record returns to Pharmacy Services of controlled substances
- Maintain a record of all “current counts” of controlled substances stored in the clinical area (see Controlled Substance Counts)
- Record and account for controlled substances administered to patients including the name of the medication, the name of the patient receiving the medication and the dose of medication received by the patient (see Administration, Wastage and Documentation)
- Record wastages of controlled substances (see Administration, Wastage and Documentation)

Pharmacy Services will maintain a record of all transactions within the Pharmacy either manually or electronically.

Procedure

- Daily Usage on the Patient Care Unit:
 - Record the details of all Counts, deliveries, transfers and returns on the Controlled Substance Record using red ink. Record all other information using black ink.
 - Ensure all information written on the Controlled Substance Record is legible. If an error is made, draw a line through the entire entry and initial then write the correct entry on a new line. Do not write over or otherwise obscure a number (e.g. with correction fluid) to correct it.
 - Document transactions involving Controlled Substance liquids as outlined in [Appendix A](#). Initiate an incident report if the volume lost in measuring is more than 5% of the supplied amount (e.g. more than 5 mL lost for a 100 mL bottle).
 - Initiate a new Controlled Substance Record daily at a time designated for each patient care area (e.g. 0700) unless otherwise scheduled (e.g. weekly) and when full.
- Initiation of a new Controlled Substance Record:
 - Controlled Substance Records are supplied through the contracted printing service.

- When starting a new Record, record the following information:
 - The current date
 - Patient care unit name
 - Medication cart number (where applicable)
 - "Transcribed Count" (written on the first line under *PATIENT OR COUNT* which records the current count for each drug from the last Count or transactions on the previous Record).
 - For scheduled initiation of a new Record: signatures in the *SIGNATURE* and *COSIGNATURE* columns of the two RHCPs performing the count and transcription. Signatures must be identifiable.
 - For new Records initiated when the previous Record is full: signature in the *SIGNATURE* column of only the RHCP transcribing the previously documented amounts.

- For new Records initiated when the previous Record is full, attach the completed Record to the new Record, retain until the scheduled count at the end of the designated shift/day/week, and forward to Pharmacy together.

- Upon completion of a Controlled Substance Record (i.e. current count transcribed to a new Record), the two RHCPs completing the count will review the sheet(s) to identify any omissions or discrepancies (as outlined in [Controlled Substances Discrepancy on a Patient Care Unit](#)).

- Promptly forward completed Controlled Substance Records to Pharmacy.

- If a Controlled Substance Record is returned by Pharmacy Services due to omissions or discrepancies, refer to Controlled Substance Discrepancy section (as outlined in [Controlled Substances Discrepancy on a Patient Care Unit](#)).

- Pharmacy Services
 - Monitor the receipt of Controlled Substance Records from patient care areas to ensure they are received as scheduled (daily or as per established schedule). If not received in a timely fashion, contact the patient care area to ensure a new Record is initiated and that the completed Record is forwarded to Pharmacy.

 - Review each received Record (generally within 4 hours of receipt) for the following:
 - need to re-stock
 - discrepancies or omissions
 - appropriate/reasonable usage (any excessive amounts of drug used are compared with previous records or the patient's profile)

Controlled Substances Counts

Policy

A Controlled Substances Count for non-electronic access controlled locations (e.g. medication cart drawer) is required for all controlled substances at least twice per day when the location is being accessed by staff.

A Controlled Substance Count for electronic access controlled locations (e.g. MedSelect drawer) is required every time the location is accessed.

Procedure

Non-Electronic Access Controlled Locations:

- Complete a Controlled Substance Count at the beginning/end of each major shift (either every 12 hours or every 8 hours) as defined by the Manager. For those areas open less than 24 hours (e.g. outpatient clinics), complete a Count at the beginning and end of each day where the controlled substances are accessed.
- The nurse coming on-shift conducts the physical count and the nurse going off-shift records the count on the Controlled Substance Record. For those areas open less than 24 hours (e.g. outpatient clinics), both nurses are from the same shift.
- Record the words “Count” or “Current Count” in red ink under the “PATIENT OR COUNT” column along with the time and date.
- Compare the physical count for each medication to the previously recorded quantity and resolve any discrepancies (via recounting or investigating any transactions since the last count). If a discrepancy cannot be immediately resolved, escalate as outlined in the [Controlled Substance Discrepancy](#) section.
- Record the physical inventory count on the Controlled Substance Record for each medication currently stocked.
- Following the completion of the count, both nurses sign the Record with identifiable signatures.
- Review each transaction on the Controlled Substance Record for completeness (missing signatures, etc.) prior to forwarding to Pharmacy.

Controlled Substances Transactions with Pharmacy Services

Policy

Delivery and return of controlled substances from Pharmacy Services will be determined based on reasonable usage and any back-up stock requirements for the unit. Pharmacy Services staff will travel to the patient care area to complete these transactions.

The responsibility and accountability for controlled substances is transferred to the patient care area once the physical product has been transferred and the transaction has been signed on the Controlled Substance Record or recorded electronically.

Procedures

- For locations using requisitions from Pharmacy, ensure all requisitions are received in Pharmacy before 1200 hours.
- Transfers for non-electronic access control locations (e.g. medication carts)

- Prior to completing a transfer, verify the identity of both the Pharmacy staff member and the receiving RHCP (e.g. nurse). If required, request and verify using photo identification stating their status at Lakeridge Health.
- Record each transaction on two lines of the Controlled Substance Record:
 - On the first line record “Pharmacy Issue” or “Pharmacy Return” under the “PATIENT OR COUNT” column with the quantity/quantities of drug(s) being transferred (issued or returned) being recorded under the appropriate drug column(s).
 - On the second line record “Adjusted Total”, as calculated according to the last recorded transaction and confirmed with a physical count.
- The nurse and pharmacy technician completing the transaction both sign the Record to complete the transaction
- The staff member receiving the medication(s) is then responsible for securing the medication(s) in the appropriate location

Controlled Substances Transactions between Patient Care Units

Policy

Controlled Substances transactions between patient care units are only permitted when Pharmacy Services are not available on-site (i.e. outside of Pharmacy operating hours). Quantities transferred are limited to the amount required until Pharmacy reopens.

Medications transferred out from a patient care unit must be recorded on the unit’s Controlled Substance Record (where applicable) or dispensed directly to the intended patient if stored in an Automated Dispensing Cabinet.

Medications received from another patient care unit must be recorded on the receiving unit’s Controlled Substance Record prior to administration to the patient.

Procedures

- Sending Unit using Controlled Substance Records (Same Hospital Site)
 - Receiving Unit nurse travels to the Sending Unit with the Receiving Unit Controlled Substance Record
 - The Sending Unit nurse records the transfer on the Sending Unit Controlled Substance Record indicating “Transferred to” and the name of the receiving unit under the “PATIENT OR COUNT” column with the quantity of medication under the appropriate medication name. On a second line, record “Adjusted total” as calculated according to the last recorded transaction.
 - Both nurses sign the Sending Unit Controlled Substance Record entries.
 - The Receiving Unit nurse records the transfer on the Receiving Unit Controlled Substance Record indicating “Received from” and the name of the receiving unit under the “PATIENT OR COUNT” column with the quantity of medication under the

- appropriate medication name. On a second line, record “Adjusted total” and the updated quantity as calculated according to the last recorded transaction.
- Both nurses sign the Receiving Unit Controlled Substance Record entries.
 - Sending Unit using Automated Dispensing Cabinet (MedSelect) (Same Hospital Site)
 - Receiving Unit nurse travels to the Sending Unit with the Receiving Unit Controlled Substance Record.
 - The Sending Unit nurse accesses the Automated Dispensing Cabinet using the name of the patient requiring the medication and dispenses the required number of items.
 - The Receiving Unit nurse records the transfer on the Receiving Unit Controlled Substance Record indicating “Received from” and the name of the receiving unit under the “PATIENT OR COUNT” column with the quantity of medication under the appropriate medication name. On a second line, record “Adjusted total” and the updated quantity as calculated according to the last recorded transaction.
 - Both nurses sign the Receiving Unit Controlled Substance Record entries.
 - Sending Unit and Receiving Unit at Different Hospital Sites
 - Receiving Unit nurse to contact the Sending Unit to request the medication and provide the requested quantity and the patient’s name, if applicable.
 - The Sending Unit nurse either records a transfer as [above](#) (with a second nurse co-signing the transaction) or as [New Record](#) above.
 - The Sending Unit nurse prints a copy of the *Lakeridge Health Controlled Substance Site to Site Transaction Record* from the Wave and completes the required information.
 - The Sending Unit nurse prepares the medication for transfer by placing in a sealed envelope with a signature across the flap. This envelope is then placed in a second package that identifies the destination but does not identify the contents (e.g. paper bag).
 - The Receiving Unit nurse then co-ordinates transportation via a Lakeridge Health contracted courier or taxi service.
 - On arrival of the medication, the Receiving Unit nurse completes the *Lakeridge Health Controlled Substances Site to Site Transaction Record* and forwards to the receiving site’s Pharmacy Department.
 - The Receiving Unit nurse records the transfer as per Procedure 1.4 above with a second nurse co-signing the transaction.

Administration, Wastage and Documentation

Policy

In addition to the patient's Medication Administration Record (MAR), every controlled substance administered to a patient must be recorded on a Controlled Substance Record or electronic record.

Wastage of controlled substances must be witnessed and co-signed at time of wastage. For liquid controlled substances (e.g. injectable or oral liquids), the co-signature of a witness indicates acknowledgement that a labeled vial/syringe/bottle is being wasted and does not validate the contents of the labelled vial/syringe/bottle.

RHCP's who are responsible for administering controlled substances must ensure the medication is fit for administration (e.g. check expiry date or Beyond Use Date) prior to administration.

Pharmacy Services is responsible for identifying medications stocked on patient care units that are nearing expiry and removing and/or replacing as appropriate.

Procedures

- The RHCP administering a medication, records the following information:
 - Time of administration
 - Patient name (complete first and last name)
 - Prescriber name
 - Dose, as ordered (e.g. 50 mcg, 10 mg, 5 mL, 1 tablet, etc.)
 - Waste amount (if applicable)
 - Calculated adjusted amount remaining, if applicable, by direct count or by subtracting the amount used from the previously recorded quantity. See [Appendix A](#) for documentation of narcotic liquids on paper records.
 - RHCP's identifiable signature
 - Witnessing RHCP's identifiable co-signature as necessary for wastage
- The RHCP is to request and ensure a co-signature is recorded electronically or on the paper Controlled Substance Record, as per the *Independent Double Checking of Medications – Policy and Procedures*, and when:
 - There is wastage of a partial dosage form (e.g. half tablet, partial ampoule)
 - Medication poured but not administered (e.g. patient refusal)
 - Accidental breakage or spillage occurs. See [Appendix A](#) for documentation of spillage for narcotic liquids.
- Health care professional students record the information in the above procedure on the paper Controlled Substance Record and each transaction is then co-signed by their preceptor. Electronic documentation is recorded under the preceptor.
- The RHCP is to request and ensure a co-signature is recorded on the patient's MAR when:
 - There is wastage of a partially administered parenteral dose (e.g. mini bag, cassette)
 - A controlled substance patch (e.g. fentaNYL, buprenorphine) is removed
- The RHCP is to record an additional reason or comment when:

- Medication poured but not administered (e.g. patient refusal)
- Accidental breakage or spillage occurs. See [Appendix A](#) for documentation of spillage for narcotic liquids.
- Controlled Substances are to be wasted in a white pharmaceutical sharps container that is secured to the wall. Empty containers/tubing/syringes may be disposed of in white pharmaceutical bins.
- Contact Pharmacy Services to retrieve any Controlled Substances identified as expired or otherwise unfit for administration.

Controlled Substances Discrepancy on a Patient Care Unit

Policy

Controlled substances discrepancies identified on a patient care unit will be investigated promptly upon discovery.

Procedures

- Upon discovery of a controlled substance discrepancy, all RHCPs who had access to the controlled substance storage area since the last count are to remain on the unit until the discrepancy is resolved or until permission to leave is given by the manager or delegate.
- The RHCP discovering the discrepancy will spend no more than 30 minutes reviewing the Controlled Substance Record(s), patient Medication Administration Records (MARs) and medication orders to resolve the discrepancy.
- If the discrepancy cannot be accounted for after 30 minutes, the discovering RHCP will report to the unit manager or delegate and initiate an incident report (e.g. We Care).
- The manager will identify all RHCPs who had access to the controlled substance storage area during the shift. The manager will also compile a list of all patients on the unit who had an active order for the medication(s) associated with the discrepancy.
- Review the Controlled Substance Record and verify that every RHCP and patient involved in transactions with the medication(s) associated with the discrepancy were in fact present on the patient care area during that shift.
- Review the MAR of every patient currently ordered the drug in question to ensure that no administrations occurred that were not recorded on the Controlled Substance Record.
- Review the MAR of every patient that received a controlled substance during the shift to confirm that each documented medication is appropriately recorded.
- If the discrepancy remains unresolved, the manager will conduct a further investigation and notify the site Pharmacy Manager. Pharmacy Services, as appropriate, will assist with the investigation. Discrepancies involving more than 2 drugs or when there is a recurring discrepancy are escalated to the responsible Program Director or Administrator-On Call. Other discrepancies are escalated as appropriate.

- The Pharmacy Director or designate will report any significant loss of narcotics or controlled drugs (as outlined in legislation) to the Office of Controlled Substances' Compliance, Monitoring & Liaison Division within 10 days of discovery of the loss. Complete and submit a "Loss or Theft Report Form for Controlled Substances and Precursors" (<https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/loss-theft-controlled-substances-precursors/loss-theft-report-form-controlled-substances-precursors.pdf>) along with any relevant additional information in an accompanying letter.
- The Program Director and Pharmacy Director will determine whether the involvement of the police is required.

Physician Administration of Controlled Substances

Policy

The identity of the prescriber of all Controlled Substance orders must be identifiable by Pharmacy Services and the RHCP providing the medication.

As per the Benzodiazepines and Other Targeted Substances Regulation and the Narcotic Control Regulations:

Pharmacy (or RHCP receiving the order) must not fill an order for a targeted substance if the authorized prescriber's identity cannot be confirmed.

As per the College of Nurses of Ontario:

Verbal orders can only be accepted during an emergency situation or when the Prescriber cannot document his/her orders, e.g. in the operating room. Verbal orders must be documented and signed by the Prescriber as soon as reasonably possible and/or at the end of the case. Refer to the regional *Medical Orders Policy*.

Procedures

- Physician Access and Storage (e.g. Operating Room, Endoscopy)
 - Physicians are to take custody of controlled substances by accessing or signing out the medications from the appropriate controlled substances inventory (Automated Dispensing Cabinet or on the Controlled Substances Record) either for an individual patient or for multiple cases.
 - For transactions involving a Controlled Substances Record:
 - On the first line, record "TRANSFERRED TO" and physician name, under the "PATIENT OR COUNT" column, and record the quantity/quantities of drug(s) being issued under the appropriate drug column(s).
 - On the second line, record "ADJUSTED TOTAL", as calculated according to the last recorded transaction.
 - Physician to sign the Controlled Substance Record.
 - Physicians are to ensure that every controlled substance in their custody is stored in a double-locked location when not in their direct possession (e.g. in between OR cases).
- Physician Administration and Documentation

- Physicians administering controlled substances are to record following on an approved Administration Record:
 - Patient name, first and last
 - Dose administered and/or medication removed with adjusted total
 - Any wastage (co-signature required)
 - Identifiable physician signature
- Physician Return
 - For transactions involving a Controlled Substances Record:
 - On the first line, record “RETURNED FROM” and physician name, under the “PATIENT OR COUNT” column, and record the quantity(ies) of drug(s) being returned under the appropriate drug column(s).
 - On the second line, record “ADJUSTED TOTAL”, as calculated according to the last recorded transaction.
 - Physician to sign the Controlled Substance Record.
 - For Automated Dispensing Cabinets, return any unused controlled substances to the External Return Bin with the completed Administration Record.

References

Narcotic Control Regulations (2017). C.R.C., c. 1041

Food and Drug Regulations (2017). C.R.C., c 870

Benzodiazepines and Other Targeted Substances Regulations (2017). SOR/2000-217

College of Nurses of Ontario (2017). Practice Standard: Medication. Retrieved from http://www.cno.org/globalassets/docs/prac/41007_medication.pdf

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College of Physician and Surgeons of Ontario (2017). Policy Number 7-16: Prescribing Drugs

Committee on Security in Drug Distribution, (March 1998). Principles and Guidelines Security in Drug Distribution for Narcotic and Other Psychoactive Drugs. Drug Control Unit, Health Canada

Healthy Environments and Consumer Safety Branch, Health Canada. Corporate Regulatory Compliance and Enforcement Advisor, B. Lafontaine (Jan 5, 2014 electronic communication)

Appendix A: Documentation of Controlled Substance Liquids

For each dose administered, write the balance (previous volume minus the volume administered) in milliliters (mL) in the appropriate column. Oral syringes are available from Stores/Materials Management to measure liquid medications.

Surplus Volume

If an amount remains in the bottle after the full volume has been accounted for, document the remainder as wastage and dispose of in the presence of another Registered Health Care Professional (RHCP). This wastage requires two signatures.

Example: Codeine liquid 5 mg/mL, 1x part bottle + 1x 100 mL full bottle

TIME	PATIENT OR COUNT	DOSE	CODEINE LIQUID	SIGNATURE	COSIGNATURE
1300	Jimmy Smith	30 mg	113 mL	Nurse 1	
1430	John Brown	35 mg	106 mL	Nurse 2	
1700*	Jimmy Smith	30 mg	100 mL	Nurse 1	
1700	Surplus Wastage	2 mL	100 mL	Nurse 1	Nurse 2

* At this time, there is a full 100 mL bottle and a part bottle containing approximately 2 mL of surplus volume. Waste and account for the surplus amount prior to using the new 100 mL bottle.

Deficit in Volume

If the amount of liquid medication in the bottle has been used and the Record still indicates that an amount should be remaining, account for the missing volume prior to using the next bottle. This documentation requires two signatures.

Example: Codeine liquid 5 mg/mL, 1x part bottle + 1x 100 mL full bottle

TIME	PATIENT OR COUNT	DOSE	CODEINE 5 mg/mL Liquid	SIGNATURE	COSIGNATURE
1300	Jimmy Smith	30 mg	113 mL	Nurse 1	
1430*	John Brown	45 mg	104 mL	Nurse 2	
1430	Lost in Measuring	4 mL	100 mL	Nurse 2	Nurse 1
1700	Jimmy Smith	30 mg	94 mL	Nurse 1	

* At this time, there is a full 100 mL bottle but the part bottle is now empty despite the count showing that 4 mL remains. Account for the missing amount prior to using the new 100 mL

Documentation of Spillage of Liquid Controlled Substances

If a liquid medication is accidentally spilled, two RHCPs will verify the remaining amount, document "Spill" on the Controlled Substance Record and the volume wasted, then record the verified amount remaining on the second line. Both RHCPs then sign for the wastage.