Team Name: Pharmacy Compounding Team Team Lead: Regional Compounding Supervisor Approved by: Director – Pharmacy	Reference Number: CLI.6010.PL.074 Program Area: Pharmacy Policy Section: General
Issue Date: August 9, 2023 Review Date: Revision Date:	Subject: Receipt, Storage and Internal Transport of Pharmaceuticals

POLICY SUBJECT:
Receipt, Storage and Internal Transport of Pharmaceuticals (Non-Hazardous and Hazardous)

PURPOSE:
To ensure appropriate receipt and storage of non-hazardous and hazardous pharmaceuticals.

To reduce staff exposure to hazardous pharmaceuticals during receipt and transport of hazardous pharmaceuticals.

To maintain a clean environment and reduce the introduction of external contamination or particulate count in the clean room.

BOARD POLICY REFERENCE:
Executive Limitation (EL-02) Treatment of Clients
Executive Limitation (EL-03) Treatment of Staff

POLICY:
RECEIPT:

- All pharmaceuticals, including Special Access medications and Investigational drugs, are properly stored immediately upon receipt. Commercial pharmaceuticals must follow manufacturer instructions for storage.
- Upon receipt, all pharmaceuticals must be inspected for damage by staff performing the unpacking.
- All procedures for the receipt of Hazardous Products listed in this directive must be followed.
- Receipt of pharmaceuticals must take place outside of controlled areas (clean room and anteroom).

STORAGE:

- Room storage temperature for pharmaceuticals must be maintained as follows (where possible due to infrastructure):
    - Drug conservation temperature 15 to 30 degrees Celsius
    - Except for
        - Controlled Room (Cleanroom and Anteroom) 15 to 20 degrees Celsius
        - Controlled room temperature for non-sterile compounds 20-25 degrees Celsius
    - Room temperature must be monitored daily in pharmaceutical storage areas such as the pharmacy warehouse, pharmacy satellite or main pharmacy. These logs must be retained for 5 years.
    - Pharmacy staff must follow procedures in this directive for room temperature excursions.
    - All pharmacy storage areas must have a procedure and documentation for review of Expiry Dates and Beyond Use Dating. This documentation must be retained for 5 years.
    - Compounded products that have exceeded their Beyond Use Date (BUD) must be discarded immediately.
    - Compounded products containing controlled substances must follow controlled substance destruction procedures.
    - Pharmaceuticals to be destroyed or returned to vendor (unusable, expired or damaged) must be safely stored in a location separate from other medications in inventory to avoid unintentional dispensing of these medications.
    - Storage of instructional inactive devices for teaching purposes must be segregated in distinct storage containers clearly labelled as such.
    - After storage and before use, all pharmaceuticals must be inspected for evidence of deterioration.
    - Hazardous pharmaceuticals, as listed in the SHSS Safe Handling Chart, must be stored separately from non-hazardous pharmaceuticals.
    - Hazardous pharmaceuticals must be stored in a well-ventilated room (described below) or in a dedicated biomedical refrigerator or freezer (where possible due to infrastructure).
        - Area separate from unpacking area
        - Dedicated room (also permitted in the clean room)
        - Negative pressure relative to adjacent rooms
        - At least 12 air changes per hour, with all air exhausted to the exterior
        - Shelving with lips to prevent drugs from falling and breaking
        - Proper signage for hazardous products
        - Sufficient ventilation
    - If hazardous products are stored in the cleanroom, the facility must ensure that air exhausts are placed so that they will remove particles generated within the storage area and refrigerator so that an ISO Class 7 Clean room is maintained.
- If required, fill out a Safety Event Report (ORG.1810.PL.001.FORM.01) and submit it to the Pharmacy Manager/Site Lead.

INTERNAL DELIVERY:

- Delivery of pharmaceuticals from pharmacy to patient care units within a facility must occur by pharmacy staff, patient care unit staff and transport/ mailroom staff.
- Delivery of narcotics must follow regional Narcotics and Controlled drugs policy (CLI.6010.PL.015).
- Delivery of commercial pharmaceuticals from the pharmacy to the patient care area must ensure maintenance of storage temperature during delivery process.
- Delivery by pharmacy staff directly to the refrigerator in a timely manner must be done.
- Delivery of compounded products, which require refrigeration, must be delivered directly to the refrigerator on the patient care unit by the pharmacy staff or trained delivery staff. Exception: First doses/ emergency doses / stat doses may be delivered directly to patient care areas via hospital staff for prompt administration to the patient.
- Delivery of hazardous compounded products must follow the procedures in the Safe Handling of Hazardous Medications (Cytotoxic and Non-Cytotoxic) policy (CLI.6010.PL.021).
- Tamper evident seals must be used for all compounded products if there is a possibility of reuse. Reuse of compounded products must occur only when tamper evident seals are secure and appropriate storage requirements can be verified at all times prior to reuse.
- When a needle is attached to a compounded sterile product during transport from pharmacy to a patient care area, the item must be transported inside a rigid container to protect the needle and the person transporting it.
- If required, fill out a Safety Event Report (ORG.1810.PL.001.FORM.01) and submit it to the Pharmacy Manager/ site lead.

DEFINITIONS:

Pharmaceuticals: include commercial medications (DIN or NPN), raw materials for non-sterile compounding, repackaged medications, (sterile or non-sterile), and compounded medications (sterile or non-sterile). Unless otherwise stated by alternate information, from Health Canada or Study Protocols, Special Access Medications and Investigational Drugs will be included in this directive.

Temperature Excursion: Any temperature reading outside of the recommended ranges based on the storage requirements of the product.

PROCEDURE:

RECEIPT OF HAZARDOUS PHARMACEUTICALS:

- Consult the Safe Handling of Hazardous Medications (Cytotoxic and Non-Cytotoxic) policy (CLI.6010.PL.021). for more information related to handling of hazardous pharmaceuticals.
- For the receipt of all hazardous pharmaceuticals (undamaged)
    - Two pairs of ASTM International – approved gloves must be worn for unpacking.

- Unpack and discard shipping container and packaging inside container that has not come in contact with the vials/ bottles (such as cartons, bubble wrap, foam, filling materials) in the regular garbage.
- Decontaminate outer surface of vial/ bottle (use facility approved disinfectant)
- If the vial is to be stored in the individual packaging, decontaminate the outer surface of the individual packaging. It is important to note that the vial will need to be decontaminated once removed from its packaging.
- Discard outer pair of gloves when all vials/ bottles have been decontaminated.
- Transfer hazardous pharmaceuticals to the hazardous product storage area.
- Decontaminate the receiving area work surface
- Discard decontaminated wipes and gloves as hazardous waste

- Packaging materials are considered chemically contaminated and must be discarded in a hazardous (cytotoxic) waste container if:
  - A spill has occurred inside the container, box or outside bag
  - The manufacturer's boxes or individual packaging has been in direct contact with vials containing hazardous products.
- If hazardous product arrives potentially damaged and unpacking is required, the following Personal Protection Equipment (PPE) is required:
  - Two pairs of ASTM International – approved gloves
  - Gown approved for the compounding of hazardous sterile preparations
  - Hair, face, beard and shoe covers
  - Goggles, a face shield, and a half face piece respirator*

  *staff must be fit tested with a respirator in order to perform this clean-up
- When a hazardous pharmaceutical arrives damaged, staff may choose one of the following options:
  - Seal the package without opening it, contact supplier. If package is to be returned to supplier, seal inside an impervious container and label as hazardous. If a return is declined, dispose of as hazardous waste.
- If required, fill out an Safety Event Report (ORG.1810.PL.001.FORM.01) and submit it to the Pharmacy Manager/ site lead.

TRANSPORTATION COVER LETTER – Special Requirements i.e. Refrigerated, Narcotic etc.

- The Medication Transportation Cover Letter (CLI.6010.PL.074.FORM.01) is to be filled out and faxed to the receiving site ahead of sending the package in order to ensure receiving site is aware of the package.
- Must be filled out by receiving site once the package has been received;
  - Check if the temperature indicator is within range (refrigerated) and initial. If an excursion has occurred, consult Packaging and Transport of Pharmaceuticals – Facility to Facility policy (CLI.6010.PL.073) and its supporting documents.
  - Narcotics must be signed for and double signed if received by nursing staff.
  - Fax the completed form back to the originating site to confirm receipt of the package.

ROOM TEMPERATURE EXCURSIONS:

- Temperatures between 25 to 30 degrees Celsius may be approaching non-compliance. Staff must notify a manager. The manager must connect with facility services to discuss possible remediation. The discussion and plan must be documented by the manager where possible due to infrastructure.
- For temperatures less than 15 or greater than 30 degrees Celsius:
    - Staff must:
        - Immediately notify a manager
        - Segregate medications during assessment process
        - Note exact length of time of the excursion
        - If a manager is not available, contact Facility Management for immediate remediation
    - The manager must:
        - Contact Facility Management for immediate remediation
        - Confirm length of time of the excursion
        - Determine if medications are to be moved, continue to be segregated or can be used.
        - Perform an assessment of risk in relation to drug conservation medication impacts.
        - Connect with Drug Information as required to support plan
        - Document remediation and plan

SUPPORTING DOCUMENTS:

CLI.6010.PL.074.FORM.01 Medication Transportation Cover Letter

REFERENCES:

CLI.6010.PL.073 Packaging and Transport of Pharmaceuticals – Facility to Facility policy

ORG.1810.PL.001.FORM.01 Safety Event Report

WRHA. June 2020. Receipt, Storage and Internal Transport of Pharmaceuticals (Non-Hazardous and Hazardous). 900.06.33. Date Accessed: November 26, 2021.

PMH. Feb. 2019. Receipt, Storage and Internal Transport of Pharmaceuticals (Non-Hazardous and Hazardous). PPG-01650. Date Accessed: November 26, 2021.