

Vermont Psychiatric Care Hospital Policy and Procedure		
Medication Storage and Control		
Effective: September 2014	Revised: September 2024	Due for Review: September 2026

POLICY

All Medications are securely stored within the Vermont Psychiatric Care Hospital (VPCH) as to prevent diversion in Title 21 of the Code of Federal Regulations, US FDA mandates that pharmaceutical storage areas maintain optimal environmental levels and that the appropriate employees monitor the condition using continuous recording equipment that is traceable.

PROCEDURE

STORAGE

All areas where medications are stored must be locked or in a secured location where only authorized personnel may have access. A secure area is defined as an area in which licensed staff with appropriate privileges are working or providing hospitalized individual care. These areas must be locked when not in use. These areas may be accessed by environmental services, buildings and grounds, information systems, etc. personnel when directly and continuously supervised by authorized licensed personnel.

All controlled substances must always be locked regardless if the hospitalized individual care area is staffed or not.

Only approved formulary medications are routinely stocked or stored in the institution. Non-formulary medications which are stored, will be separated from formulary medications in the pharmacy. Unit dose non formulary items will be entered into the ADM or stored in hospitalized individual specific areas- For example -Hospitalized individual bulk medication bin or the topical bins stored in the medication rooms.

Other categories of medications, which must be stored in separate designated or uniquely identified:

- Topical Medications
- Ophthalmic medications
- Otic medications
- Injections
- Liquids
- Hazardous medications
- Controlled substances
- Expired/damaged/contaminated medications,
- Medications belonging to hospitalized individuals.
- Refrigerated Medications

All Medications must be appropriately labeled according to hospital policy. VPCH does not have any biologicals in the formulary, corrosive, or flammable products.

Pharmacy will utilize Tallman letters, High Risk labels, Look alike/Sound Alike labels, Hazardous Medication labels, Hazardous waste labels and Pregnancy warning labels.

STORAGE AREAS

Pharmacy

Access to medications will be limited to authorized personnel. All entrances to the Pharmacy will be locked. A registered pharmacist must be present whenever other authorized personnel are in the Pharmacy.

Hospitalized Individual Care Areas

- Access to medication is limited to licensed healthcare professionals, pharmacy staff, and other technical staff approved by the Director of Pharmacy and the Director of Nursing.
- Medications stored in hospitalized individual care areas will be locked in approved storage areas.
- Controlled substances will be originally stored in the ADM CII Safe in the pharmacy, then the controlled substances will be dispensed to the ADM on the hospitalized individual care areas.
- Crash bags are sealed with breakaway locks. The integrity of the seal is checked every shift.
- Medication transport to hospitalized individual care areas or medications returned to pharmacy will be by hand delivery (via locked transport bag).

STORAGE CONDITIONS

Medications intended for hospitalized individual use are stored in accordance with manufacturer's instructions and Federal and State laws and regulations or according to specific authoritative, medical/scientific references.

- Refrigerator temperature range: 2.2 degrees C (36 deg F) and 7.7 degrees C (46 deg F)
- Room temperature range: 15 degrees C (59 degrees F) to 30 degrees C (76 degrees F)
- Freezer temperature range: -10 degrees C (14 degrees F) to -30 degrees C (-22 degrees F)
- Relative Humidity levels- below 60%

The Pharmacy Medication refrigerator's temperature is checked during regular business hours. It is recorded and continual records kept. Pharmacy will use a Datalogging Traceable Thermometer system to track the highs and lows of the refrigerators to capture data outside of normal operating hours. All refrigerators' temperatures will be kept for 3 years. Any temperatures outside the correct temperature range will result in the medications to be quarantined and not available for hospitalized individual use. Investigation into the manufacturer's guidelines will occur and Pharmacy will proceed with the manufacturer's recommendations. Pharmacy will investigate the physical cause of the temperature fluctuations – and that will be remedied immediately.

There are no refrigerators stored on the Nursing units.

VPCH does not house any medications that require freezer storage.

Humidity in the Pharmacy will be constantly monitored. Regulations from the Vermont Board of Pharmacy and USP guidelines require all medications must be stored in a humidity less than 60%. Pharmacy monitors humidity with a tractable system EasyLog-temperature humidity data logger. Daily monitoring will occur and will be recorded/ included with the temperature log. All data must be kept for 3years. Any data outside the recommended requirements, the Director of pharmacy will notify the proper VPCH building officials to rectify any problems.

EXPIRATION DATING and EXPIRED MEDICATIONS

Medications will be labeled with a one-year expiration date or the manufacturer's expiration date, whatever is the less. Whenever repackaging medication. Multidose vials will have a 28 day expiration unless the manufacturer's date is less. Single dose vials must be used with one hour of opening or manipulating the vial.

Medications will be removed from general stock just prior to their reaching expiration (beyond use) date. Medications which are reconstituted /manipulated so that the manufacturer's original expiration date no longer applies will be labeled with a new expiration date. Stability and sterility will be considered in determining this date, as well as manufacturer recommendations, literature references. Beyond Use data will be placed on all labels prior dispensing to the Nursing Units.

Expired medications will be removed from stock and will be subjected to:

- 1- on-site destruction utilizing the Cactus Smart Sink pharmaceutical waste disposal system,
- 2- direct return to the manufacturer or wholesaler,
- 3- turned over to a reverse distribution vendor.

Waste and reverse distribution vendors must be State and federally licensed and approved by the Vermont Board of Pharmacy. The company must be in good standing with all State and Federal rules and regulations.

MANAGEMENT OF MEDICATION RETURNS:

Medications which are no longer required for hospitalized individual care, or which are no longer suitable (deteriorated/damaged) should be disposed of:

1. Utilizing the Cactus Smart Sink/ RCRA containers or after consultation with a member of the Pharmacy staff,
2. May be returned to the Pharmacy or placed in the locations designated for medications to be returned to pharmacy.
3. Controlled substances should be returned /disposed of as described in policy III-03.3 Controlled Drug Distribution.

Medications returned to pharmacy will be inspected to determine if they are suitable for re-dispensing. Medications to be re-dispensed must be in date, in the original unopened packaging


and must have been stored under appropriate environmental conditions. Returned medications which are expired/contaminated will be segregated as described above. Reasons for the returns of hospitalized individual specific medications will be investigated, whenever reasons are not clear.

SPECIAL CONSIDERATIONS

- Look-alike/Sound-alike medications will be stored in a fashion to prevent mix-ups. – special labels are attached to the bins and special warnings in the ADM screen
- High Alert medications will be stored in a fashion to draw attention to the potential dangers- High alert stickers will be placed on the meds and/or bins.
- Medications and chemicals are labeled appropriately.
- Medications in hospitalized individual care areas are maintained in the most ready-to-administer form (manufacturer’s unit dose or repackaged by pharmacy).
- All medication storage areas are inspected monthly (see policy III-09.2 Unit Inspection) to assure medications are stored correctly.
- Medications for external use will be labeled as external use only.
- Hazardous medications- labeled with hazardous labels, Black box warning, and/or pregnancy caution labels.

References

Joint Commission M.M. 03.01.01

Approved by	Signature	Date
Emily Hawes, Commissioner, Vermont Department of Mental Health		9/25/2024