

This policy sets out requirements for pharmacy managers on cold chain management and their responsibilities under the *Pharmacy Operations and Drug Scheduling Act* (“PODSA”) Bylaws sections 18(2)(c)(ii), 18(2)(e), 18(2)(l), 18(2)(v), 18(2)(ee)(i), 23.1(1), 24(1), 25(2)(g), and 29(1)(a-c).

**DEFINITIONS:**

In this policy,

“**drug**” means a drug that requires cold chain management according to the required storage temperature range;

“**cold chain management**” means the processes used to maintain a drug within the required storage temperature range, starting at the manufacturer and ending with release of the drug to the patient, which includes transporting, handling and storage of the drug;

“**temperature excursion**” means an event in which a drug is exposed to a temperature outside of the required storage temperature range; and

“**cold storage equipment**” means the equipment (i.e., refrigerator or freezer) used to maintain a drug within the required storage temperature range. The recommended temperature range for a refrigerator is between +2°C to +8°C and for a freezer is between -25 °C to -10 °C.

**POLICY STATEMENTS:**

For a drug that requires cold chain management, the pharmacy manager must ensure the following:

1. the drug is maintained in accordance with the manufacturer’s requirements and any other applicable requirements;
2. the pharmacy is equipped with cold storage equipment that
  - a. must be purposed for drugs only,
  - b. must maintain only one temperature range enclosed by a door with an air-tight seal (a standard “bar” fridge (combination fridge/freezer with one exterior door) is not acceptable as it does not maintain even temperatures), and
  - c. is equipped with a digital thermometer or temperature monitoring system;
3. temperatures of the cold storage equipment are monitored and recorded
  - a. manually at least twice each working day, preferably at opening and closing of the pharmacy, documenting the current temperature, and the minimum and maximum temperatures reached since the last temperature recording, or
  - b. automatically with a temperature monitoring system that
    - i. records temperatures at a frequency that can determine current temperatures, and minimum and maximum temperatures reached at least twice a day, and
    - ii. monitors and notifies pharmacy staff when a temperature excursion occurs;

4. establish written policies and procedures that include processes
  - a. to ensure proper cold chain management,
  - b. to record temperatures of the cold storage equipment in accordance with section 3,
  - c. to determine and document actions taken when a temperature excursion occurs, and
  - d. for regular maintenance that ensures functionality of cold storage equipment and documenting those processes;
5. all pharmacy staff are trained on the policies and procedures necessary to maintain cold chain management; and
6. the following documentation must be retained and easily retrievable for at least three years
  - a. the temperature records of the cold storage equipment required by section 3, and
  - b. the documentation resulting from
    - i. actions taken when a temperature excursion occurs, and
    - ii. regular maintenance that ensures functionality of the cold chain equipment.