

# Massachusetts Board of Registration in Pharmacy

## Policy No. 2011-01: Proper Storage of Refrigerated and Frozen Medications in a Pharmacy

The Massachusetts Board of Registration Pharmacy (Board) establishes this policy to ensure the proper storage of refrigerated and frozen medications in Board licensed pharmacies. Board regulation 247 CMR 9.01(5) requires that “While on duty, a pharmacist shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.” The duties of a Pharmacist Manager of Record include the “maintenance of necessary pharmaceutical equipment” to conduct pharmacy practice in accordance with current *United States Pharmacopeia* (USP) standards and the establishment, implementation and monitoring of policies and procedures in the pharmacy that maintain the professional practice standards in the dispensing of pharmaceuticals, which includes proper storage of refrigerated and frozen medications in the pharmacy. (247 CMR sections 6.01(5)(a)5., 6.02(2) and 6.07(1)(a))

Following review of pharmacy refrigeration systems, the Board has determined that Board licensed pharmacies must meet ALL the below listed conditions to ensure proper storage of refrigerated and frozen medications. Accordingly, each Board licensed pharmacy must:

1. Develop policies and procedures to ensure proper refrigeration equipment is available and of adequate size to maintain medication stability and safety;
2. Utilize either: (a) combination refrigerator/freezer; or (b) a stand alone refrigerator or freezer that has self-defrosting compartments;
3. Ensure proper refrigerator temperature (36° to 46°F/ 2° to 8°C) and freezer temperature (14° to -13°F/ -25° to -10°C) is maintained at all times through the use of a daily temperature log or certified thermometer equipped with an audible out of range alarm for monitoring of both refrigerator and freezer compartments;
4. Develop an action policy and procedure to respond to any out of range temperature reading to ensure the integrity of stored medications;
5. Develop and monitor a policy that **NO** food or beverage products may be stored in the refrigerators or freezers; and
6. Educate pharmacists and other pharmacy personnel regarding the importance of proper storage of refrigerated and frozen medications.
  - ✓ Review the Board’s *Best Practice Recommendation #26*: Develop policies and procedures to ensure the proper storage of refrigerated and frozen medications. Provide ongoing education on the importance of proper storage of medications requiring refrigeration.
7. Review current refrigeration standards established by Centers of Disease Control and Prevention, USP and the Massachusetts Department of Public Health, Division of Epidemiology and Immunization.

### Best Practice Recommendation #26 and Refrigeration Standards

#### Policy No. 2011-01 Implementation/Compliance Dates

- July 1, 2011 Pharmacies storing vaccines
- January 1, 2012 New or relocating pharmacy applicants
- January 1, 2013 Pharmacies licensed as of April 1, 2011

AUTHORITY: M.G.L. c. 112, §§ 24 – 42A; 247 CMR 2.00 – 16.00  
Adopted by the Board of Registration in Pharmacy: March 08, 2011

PHARMACY REFRIGERATION SELF-INSPECTION FORM

Board of Registration in Pharmacy Regulations 247 CMR sections 6.01(5)(a)(5), 6.02(1), 6.02(2), 9.01(1) and 9.01(5)	YES	NO
<p>REFRIGERATORS AND FREEZERS ARE MAINTAINED WITHIN PROPER RANGE (<b>Refrigeration at 36° to 46°F/2° to 8°C; Freezer at 14° to -13°F/-25° to -10°C USP recommended range</b>) IN ACCORDANCE WITH MANUFACTURER RECOMMENDED MEDICATION STORAGE REQUIREMENTS.</p> <p>1. TYPE* _____ REFRIG TEMP _____ FREEZER TEMP _____</p> <p>2. TYPE _____ REFRIG TEMP _____ FREEZER TEMP _____</p> <p>3. TYPE _____ REFRIG TEMP _____ FREEZER TEMP _____</p> <p>4. TYPE _____ REFRIG TEMP _____ FREEZER TEMP _____</p> <p><b>*Refrigerator/Freezer Type:</b> Combination refrigerator/freezer (C)                      Stand alone refrigerator ----- (SR)                      Stand alone freezer ----- (SF)</p>		
PHARMACY REFRIGERATORS AND FREEZERS ARE KEPT CLEAN, ORGANIZED, AND DEFROSTED.		
PHARMACY UTILIZES A CERTIFIED THERMOMETER WITH AN OUT OF RANGE ALARM. If NO, next listed item is required.		
PHARMACY UTILIZING A CERTIFIED THERMOMETER WITHOUT AN ALARM UTILIZES A DAILY TEMPERATURE LOG.		
REFRIGERATED INVENTORY IS ORGANIZED TO ALLOW FOR PROPER AIR FLOW. NO CARDBOARD OR SOLID PLASTIC SHELVING IS UTILIZED (impedes proper air circulation).		
NO FOOD OR BEVERAGES ARE STORED IN A REFRIGERATOR OR FREEZER UTILIZED FOR MEDICATION STORAGE.		
REFRIGERATORS AND FREEZERS PROVIDE ADEQUATE SPACE FOR AMOUNT AND TYPE OF MEDICATIONS STORED BY THE PHARMACY. NO MEDICATIONS ARE OVERSTOCKED.		
<b>COMMENTS</b>		

Signature of Pharmacist completing Self-Inspection Form \_\_\_\_\_ Date \_\_\_\_\_

**DO NOT MAIL COMPLETED SELF-INSPECTION FORM TO THE BOARD.**