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Board of Registration in Pharmacy

Policy 2020-05: Refrigerated and Frozen Medication Storage

The Massachusetts Board of Registration Pharmacy ("Board") establishes this policy to set forth required conditions for the proper storage of refrigerated and frozen medications in Board licensed pharmacies.

In order to properly store refrigerated and frozen medications, pharmacies shall:

I. Handle and store all medications and vaccines according to medication package inserts and the latest CDC guidelines for vaccine storage.

II. Assure that cold chain (temperature-controlled supply chain) processes are maintained at all times, including during delivery and shipping.

III. In accordance with USP <1079>, maintain the following refrigerator and freezer temperatures:
   1. Refrigerator: between 36ºF to 46ºF (2ºC to 8ºC); and
   2. Freezer: between -13°F and 14°F (between -25°C and -10°C)

IV. Develop a policy and procedure to handle the maintenance, monitoring, and cleaning of the equipment (i.e., refrigerator, freezer, thermometer) as recommended by the manufacturer. Additionally, establish a back-up plan to assure proper storage of refrigerated or frozen medications in the event of a power failure or other unforeseen event.

V. Utilize a combination refrigerator / freezer, standalone refrigerator, or standalone freezer. A unit that contains a freezer compartment within the refrigerator space, such as a dorm-style refrigerator, is not permitted.

VI. Freezer units must be frost-free with an automatic defrost cycle. However, for highly temperature sensitive medications, a pharmacy may utilize a freezer unit without an automatic defrost cycle. A manual process must be used to monitor and remove frost buildup.

VII. Utilize thermometers that have a certificate of calibration testing from an accredited laboratory and are calibrated according to the manufacturer's

suggested timeline. See the CDC's recommendations on thermometer selection and placement: https://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html

VIII. Review and document temperatures of each unit at least twice daily. On any days the pharmacy may be closed, the pharmacy must have a mechanism in place to identify any temperature excursions. Each temperature log must identify the corresponding refrigerator or freezer unit, identify the reviewer (e.g. name or initials), and be readily retrievable upon request. Consider using a continuous recording device with alarm capabilities to include remote notification of excursions.

IX. As recommended by the CDC, promote good air circulation around the outside of the unit:

1. allow for space on all sides and top;
2. allow at least 4 inches between unit and wall;
3. do not block motor cover; and
4. make sure there are at least 1 to 2 inches between bottom of unit and floor.

X. Unit must not be overstocked, and inventory must be organized to allow for proper air flow. Cardboard or solid plastic shelving must not be utilized as they would impede proper air circulation.

XI. Store refrigerated or frozen hazardous drugs in accordance with USP <800> or Board regulations, whichever is stricter.

XII. Store biologics in a separate unit, or at the bottom of the unit, to reduce the risk of contamination to other products.

XIII. NOT store food or beverage products in refrigerators or freezers used for medications.

XIV. Containers of water may be used for temperature stabilization as long as they are labeled "Do NOT Drink".

XV. To address excursions, develop a policy and procedure with an action plan to include such steps as:

1. Document and record the excursion (e.g., value, duration, time of day, etc.)

2. Conduct an assessment of the excursion (i.e., length and magnitude) and quarantine products as necessary.

3. Contact manufacturers of refrigerated / frozen products to confirm safety and efficacy after exposure to inadequate storage conditions.

4. All visibly altered or damaged inventory (i.e., visible particulate, refrigerated product that has been frozen), and any product(s) which cannot be confirmed safe and effective by the manufacturer must be removed from active inventory.

5. Document confirmation or evidence of safety and effectiveness of products prior to returning to active inventory and ensure this documentation is readily retrievable upon request.

6. In the event that an unsafe or ineffective product was administered or dispensed to a patient, the patient and patient's health care provider must be notified.

Please direct any questions to: **Pharmacy.Admin@mass.gov**