

**TOWN OF MASHPEE  
BOARD OF HEALTH**

**REGULATION TO PROMOTE  
OPTIMUM PHARMACEUTICAL CARE  
IN THE TOWN OF MASHPEE**

In response to medication distribution issues, regarding continuing quality improvement initiatives that could be implemented in all pharmacy practice settings to promote optimum pharmaceutical care, the Board of Health believes that adoption and institution of this regulation will result in improved performance, increased patient safety and enhanced pharmacy medication delivery and storage systems in general.

In accordance with the provisions of Chapter 111, Section 31, of the Massachusetts General laws, the following regulation is set forth by the Town of Mashpee, Board of Health.

**SECTION 1. Pharmacists**

- A. The Pharmacist is responsible for oversight of all medication, drugs and vaccine storage and handling.

**SECTION 2. Pharmacists or their designated employee(s) shall inspect the following on a weekly basis:**

- A. The expiration date on all medication stock bottles
- B. Inspect the expiration date on all medication containers in the refrigerator or freezer.
- C. Identify short dated items with a colored label indicating expiration date.

**SECTION 3. Pharmacists' or their designated employee(s) shall comply with the following:**

- A. All outdated medication, drugs, vaccine stock with an expiration date that does not allow sufficient time for dispensing by the pharmacy or use by the patient shall be segregated from other medication, drugs, vaccine stock and either prepared for return to the manufacturer or destroyed and documented.
- B. All Pharmacies with refrigeration and/or freezer units utilized to store medication, drugs and vaccine shall record the temperature of the interior of the refrigeration and/or freezer unit with a liquid thermometer, compared with a Standard calibrated at the National Institute of Standards and Technology (NIST).

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All medication, drugs and vaccines with the exception of Varicella vaccine must be stored refrigerated at 2° to 8°C (35° to 46°F). Varicella vaccine must be stored frozen at  $\leq -15^{\circ}\text{C}$  ( $\leq 5^{\circ}\text{F}$ ). The Pharmacist or designated employee shall maintain a daily temperature log for the refrigeration and/or freezer unit twice daily, once between 7:00 a.m. and 10:00 in the morning and once between 3:00 p.m. and 5:00 p.m. in the afternoon. The temperature log shall be posted in close proximity to the refrigeration area for convenience and shall be submitted to the Board of Health on a monthly basis.

- C. Medication, drugs and vaccines shall **not** be stored on the refrigerator or freezer door.
- D. Expiration dates shall be reviewed on all products prior to completing the filling and dispensing of medication, drugs and vaccine.

### SECTION 4. Temperatures Out Of Range:

- A. If the Pharmacist or designated employee recognizes the refrigerator temperature is out of range as stated in Section 3(B) of this regulation, the Pharmacist or designated employee shall:
  - 1.) Contact the Board of Health immediately to report the last recorded temperature and the current temperature of the affected refrigerator.
  - 2.) Contact the manufacturer of the medication, drugs and/or vaccine regarding their storage requirements.
- B. If the Pharmacist or designated employee recognizes the freezer temperature is out of range as stated in Section 3(B) of this regulation, the Pharmacist or designated employee shall contact the Board of Health immediately. The Pharmacist or designated employee will be required to report to the Board of Health the lot number of the medication, drugs and vaccine affected, the warmest temperature the medication, drugs and vaccine was exposed to and the duration of the time the medication, drugs and vaccine was out of range.

### SECTION 5. Power failures:

- A. In the event of an extended building power failure, vaccines will be packed in insulated containers with cool packs. The Pharmacist or designated employee shall contact the Board of Health immediately. An agent of the Board of Health shall transport the vaccine to a pre-arranged authorized site for proper storage.

### SECTION 6. Variances:

The Board of Health in any particular case may vary the application of any provision of this

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regulation, when, in its opinion:

1. Such action is in the public interest and not inconsistent with the intent and purpose of the regulation
2. Strict enforcement would cause undue hardship and manifest injustice.

### **SECTION 7. Penalties:**

Any owner/operator who fails to comply with the provisions of this regulation will result in the levy of fines of not less than \$100.00 per day per offense but not more than \$300.00 per day per offense. Each day's failure to comply with the provisions of this regulation shall constitute a separate violation. Further, the Board of Health, after notice to and after public hearing thereon, may suspend, revoke or modify any license or permit issued for due cause.

### **SECTION 8. Severability:**

If any provision of this regulation is declared invalid, the other provisions thereof shall not be affected.

### **SECTION 9. Effectiveness:**

This regulation is adopted by the Board of Health, upon publication in a newspaper of general circulation, within the town of Mashpee.

Per Order Of,  
Mashpee Board of Health

MaryRose Grady, Chairman  
L. Glenn Santos Co-Chairman  
Steven R. Ball, Clerk