

NOTES FROM 8/4/2022

DISCUSSION DRAFT ONLY – Does not represent the opinion of the Administration, the Department or the Board
Discussion Draft for 8/22/2022 PH Rules Workshop

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**Chapter 41: SALE OF NONPRESCRIPTION DRUGS THROUGH VENDING MACHINE
OUTLETS (NEW)**

Summary: This chapter sets forth requirements for licensing, management and safe operation of vending machine outlets.

1. DEFINITIONS. As used in this chapter, the following terms are defined as follows:

- 1. Nonprescription drugs.** “Nonprescription drugs” has the same meaning as in 32 M.R.S. 17302-A(20).
- 2. Vending machine.** “Vending machine” means any automated mechanical device operated by a vending machine outlet licensee from which nonprescription drugs are dispensed to a consumer after a form of payment is inserted or otherwise made into the machine.
- 3. Vending machine outlet.** “Vending machine outlet” means any pharmacy licensed by the Board pursuant to 32 M.R.S. § 13751(E).

2. LICENSURE.

- 1. License Required.** Only vending machine outlets may operate one or more vending machine(s) in accordance with the terms and conditions set forth in this chapter. A vending machine outlet is solely responsible for all vending machines the licensee operates, and shall name a pharmacist in charge to oversee the activities and operation of each of its vending machine outlets. (JB NOTE - Delete: 8/4/2022 Cassandra suggested eliminating to require a PIC.)
- 2. Limited Authorization.** A vending machine outlet license only authorizes operation of vending machines for one (1) physical location where one or more vending machines are located. Any person desiring to operate a vending machine outlet shall obtain from the board a vending machine outlet license for each physical location where one or more vending machines outlets are located.
- 3. Non-transferrable.** A vending machine outlet license issued under this section is not transferable.
- 4. Application.**

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- a. A person seeking a vending machine outlet license shall submit an application on a form provided by the board and pay any fees as set forth in Chapter 10 of the rules of the Office of Professional and Occupational Regulation.

- b. Any application shall include a detailed description of the intended location of each vending machine within the physical structure. Each vending machine shall be assigned a specific physical location within a physical structure that is:
 - i. weather-tight;
 - ii. well-ventilated;
 - iii. moisture-controlled environment;
 - iv. well-lighted; and
 - v. protected from direct sunlight.

- c. In addition to the prohibited locations described under 32 M.R.S. § 13792(H), a vending machine outlet may not be located [for discussion: any additional restrictions? IF NONE, THIS CAN EASILY BE ELIMINATED...]

3. VENDING MACHINE REQUIREMENTS

- 1. **Nonprescription Drugs Only; Limits.** Only nonprescription drugs may be sold or dispensed from a vending machine. Any single vending machine may sell or dispense no more than twelve (12) different nonprescription drugs.

- 2. **Compliance with Manufacturer Recommendations.** Nonprescription drugs dispensed by a vending machine shall be:
 - a. Stored in accordance with manufacturer recommendations, including those that require a stable temperature;

 - b. Sold only in the manufacturer’s clearly labeled, original, unbroken, tamper-proof and expiration-dated packaging; and

 - c. No older than the manufacturer’s expiration date.

A nonprescription drug outlet shall not purchase or receive nonprescription drugs from a source not licensed with the Board.
SHOULD BE EASILY DECIDED WHETHER THIS IS NECESSARY OR JUST RELY ON THE FACT THAT PURCHASES ARE MADE APPROPRIATELY SIMILAR TO WHAT A RETAIL PHARMACY DOES ... THIS IS NOT IN THE CURRENT RULE FOR RETAIL PHARMACIES.

- 3. **Machine Labeling.**

Commented [NJ1]: Intended to require licensed wholesalers or distributors to provide nonprescription drugs? Is this how such drugs are distributed in practice? Is this consistent with regulation of retail pharmacies?

Commented [TM2R1]: Good question.

Commented [BGL3R1]: For Board Discussion

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1. Each vending machine outlet must have an obvious and legible statement on the machine that advises the consumer to check the expiration date of the product before using the product.
2. Each vending machine must also have a label clearly identifying:
 - a. the owner of the machine;
 - b. the vending machine's serial number;
 - c. the license number and name of the vending machine outlet licensee that operates the machine;
 - d. the telephone number and mailing address at which the consumer may contact the Board; and
 - e. a toll-free telephone number at which the consumer may contact the machine owner and, if different, the vending machine outlet licensee that operates the machine.
4. Provides a toll-free telephone number at which the consumer may contact the pharmacist in charge and/or pharmacy technicians who are available 24 hours a day 7 days a week to ask questions about the medication.
5. ~~Provides a toll free telephone number at which the consumer may contact the vending machine outlet licensee and/or pharmacist in charge during regular business hours 7 days a week to ask questions about medication; and~~
(JB – NOTE: By eliminating the PIC in Section 2(1) above, this section is no longer a viable option. With this section out...section 4 would prevail.

4. Expired Drugs

Under no circumstances may expired drugs be sold or dispensed from a vending machine. It is the sole responsibility of each vending machine outlet licensee to ensure products are in date and that expired drugs are promptly removed upon expiration.

4. PROCEDURE FOR RELOCATING OR RETIRING A VENDING MACHINE

Before relocating or retiring any vending machine outlet previously covered by a vending machine outlet license, the vending machine outlet licensee shall notify the Board in writing of that relocation or retirement. The notice shall include the following: license number; vending machine's serial number; action planned (relocation or retirement); if relocating, the intended new location; and if retiring a vending machine, the manner of disposition of the nonprescription drug contents of the vending machine.

5. RETURN OF NONPRESCRIPTION DRUGS TO VENDING MACHINE OUTLET

Commented [NJ4]: Which do you want?

Commented [TM5R4]: Question for board. (Good question.)

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After a consumer has taken a nonprescription drug from a vending machine, no nonprescription drug item shall be accepted for return or exchange for resale unless the following conditions have been met: 1) it is in the original, unopened container; and 2) the container has not been subjected to contamination or deterioration.

6. INSPECTION

Each vending machine outlet is subject to inspection by a Board designee. The vending machine outlet licensee or its agent shall provide access to the contents of the vending machine immediately upon request from the Board's designee.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13751, 13792(2)

EFFECTIVE DATE:

DRAFT

Commented [RK6]: Would there be any way to know for certain that the item came from the vending machine?

Commented [BGL7R6]: Similar to drug returns to the pharmacy – question for the Board to determine if this should be kept, adjusted or deleted altogether