

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.37 Pharmacy Permit Holder Requirements – Wholesale Distribution and Nonresident Pharmacy Operations

Authority: Health Occupations Article, §§ 12-205, 12-403, and 12-406, Annotated Code of Maryland

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.01 Scope

This chapter establishes requirements for a pharmacy licensed by the Maryland Board of Pharmacy that:

- A. Engages in wholesale distribution; or
- B. Operates as a nonresident pharmacy.

.02 Pharmacies Issued a Waiver Permit.

A. A pharmacy that is issued a waiver permit by the Board under Health Occupations Article, §12-403(c), Annotated Code of Maryland, may engage in wholesale distribution, provided that:

- (1) The waiver pharmacy only engages in wholesale distribution with another pharmacy; and
- (2) The wholesale distribution business does not exceed 5 percent of the waiver pharmacy's annual sales.

B. Record Keeping Requirements. A waiver pharmacy that conducts wholesale distribution as set forth in §A of this regulation shall:

- (1) Maintain records of the waiver pharmacy's wholesale distribution separately from its other records; and
- (2) Make records of wholesale distribution available for inspection by the Board.

.03 Requirements for Wholesale Distribution.

A. General Requirements.

(1) A full service pharmacy may conduct wholesale distribution provided that the wholesale distribution business does not exceed 5 percent of the full service pharmacy's annual sales.

(2) A full service pharmacy may conduct wholesale distribution:

(a) With another pharmacy; or

(b) With a wholesale distributor, if the full service pharmacy reports to the Board within a week, on a form approved by the Board, of the full service pharmacy's wholesale distribution to a wholesale distributor.

B. Recordkeeping Requirements. A full service pharmacy that conducts wholesale distribution as set forth in §A of this regulation shall:

(1) Maintain records of wholesale distribution separately from its other records;

(2) Maintain records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to pharmacies; and

(3) Make records of wholesale distribution available for inspection by the Board.

.04 Requirements for Nonresident Pharmacy Operations.

A. A Maryland licensed pharmacist may [[not be employed by more than one nonresident]] *only serve as the designated pharmacist for one non-resident* pharmacy at a time.

B. A nonresident pharmacy shall:

(1) Hold a pharmacy permit issued by the Board;

(2) Have a pharmacist on staff who is:

(a) Licensed by the Board;

(b) Designated as the pharmacist responsible for providing pharmaceutical services to patients in the State; and

(c) Regularly available on-site as needed to meet Maryland patient's needs;

(3) Designate another Maryland licensed pharmacist as the pharmacist on staff within 60 days upon the loss of the current designated pharmacist on staff;

(4) Be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

(5) Maintain at all times a current reference library that is appropriate to meet the needs of:

(a) The practice specialty of that pharmacy; and

(b) The consumers the pharmacy serves;

(6) Comply with the regulations adopted by the Board establishing the types of texts required to be included in the reference libraries in each of the various practice specialty pharmacies;

(7) Maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy to:

(a) Prepare and dispense prescriptions properly; and

(b) Otherwise operate a pharmacy;

(8) Be equipped with the minimum equipment and appliances specified by the Board under this regulation;

(9) Be kept in a clean and orderly manner;

(10) Store all prescription or nonprescription drugs or devices properly and safely as set forth in COMAR 10.34.22.06;

(11) On an annual basis and within 30 days after a change of office, corporate officer, or pharmacist, disclose to the Board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescriptions for drugs or devices to persons in this State;

(12) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located and all requests for information made by the Board pursuant to this regulation;

(13) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located;

(14) Maintain records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;

(15) During the pharmacy's regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacist or an individual who:

(a) Has access to the patient's prescription records; and

(b) Is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate;

(16) Disclose the pharmacy's toll-free telephone number on a label affixed to each container of drugs or devices;

(17) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located;

(18) With regard to a prescription drug that is delivered in this State by the United States Postal Service, a common carrier, or a delivery service and is not personally hand delivered

directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient:

(a) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(b) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications;

(19) Provide information regarding the process for resolving incorrectly filled prescriptions in accordance with existing regulations by:

(a) Posting a sign that is conspicuously positioned and readable by consumers at the point where prescription drugs are dispensed to consumers; or

(b) Including written information regarding the process with each prescription dispensed; and

(20) If dispensing compounded sterile preparations to patients in the State, comply with:

(a) USP standards; and

(b) COMAR 10.34.19.

C. A nonresident pharmacy may not:

(1) Offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill;

(2) Make any agreement that denies a patient a free choice of pharmacist or pharmacy services;

(3) Participate in any activity that is a ground for Board action against:

(a) A licensed pharmacist under Health Occupations Article, §12-313, Annotated Code of Maryland;

(b) A registered pharmacy technician under Health Occupations Article, §12-6B-09, Annotated Code of Maryland; or

(c) A registered pharmacy intern under Health Occupations Article, §12-6D-11, Annotated Code of Maryland; or

(4) Allow an unauthorized individual to represent that the individual is a pharmacist, a registered pharmacy intern, or registered pharmacy technician.