

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit

Authority: Health Occupations Article, §§12-205 and 12-307, Annotated Code of Maryland

.01 Settings.

A. If a setting otherwise complies with State and federal laws, a pharmacist may request Board approval to dispense or distribute at a setting that does not possess a pharmacy permit if:

(1) The dispensing or distribution occurs while the pharmacist is providing drug therapy management services in:

- (a) The office of a licensed physician;
- (b) A clinic; or
- (c) A medical facility; or

(2) The setting is:

- (a) Operated or funded by a public health authority of the State;
- (b) A medical facility or clinic that is operated on a nonprofit basis and is not otherwise required to possess a pharmacy permit; or
- (c) A health center that operates on a campus of an institution of higher education.

B. If the drug therapy management services referred to in §A(1)(a) of this regulation include the dispensing or distribution of controlled dangerous substances, the request may be approved by the Board if the physician possesses a dispensing permit issued by the Board of Physicians.

C. If a pharmacist seeks to obtain Board approval to dispense or distribute at a setting that is not set forth in §A of this regulation, the pharmacist shall apply to the Board for a waiver permit under COMAR 10.34.17.

.02 Pharmacist Approval.

A. Before a pharmacist may dispense or distribute at a setting that does not hold a pharmacy permit under Regulation .01A(1) of this chapter, the pharmacist shall submit to the Board a request for approval signed by the pharmacist, which includes:

- (1) The name and license number of the pharmacist;
- (2) The scope of services to be provided by the pharmacist at the nonpharmacy setting;
- (3) The name and address of the nonpharmacy setting where the pharmacist intends to dispense or distribute; and
- (4) A statement indicating the pharmacist's criminal history, if any.

B. If the pharmacist intends to provide drug therapy management services in a licensed physician's office under Regulation .01A(1)(a) of this chapter, in addition to the requirements of §A of this regulation, the pharmacist shall provide:

- (1) The name and license number of the licensed physician; and

- (2) Proof of an approved physician-pharmacist agreement with the licensed physician.

.03 Grounds for Denial.

The Board may deny a pharmacist's request for approval under Regulation .02 of this chapter if the:

A. Pharmacist has:

- (1) A pending or final disciplinary action before the Board; or
- (2) A criminal history; or

B. Criteria set forth in Regulations .01B or .02 of this chapter are not satisfied.

.04 Change in Information.

If any of the information set forth in Regulation .02 of this chapter changes during the effective period of the Board's approval:

A. The pharmacist shall immediately advise the Board in writing of the change; and

B. The change in information may cause the Board to withdraw or modify the Board's approval of the nonpharmacy setting.

.05 Approval During Catastrophic Health Emergency.

In the event of a catastrophic health emergency proclaimed by the Governor under Article 41, §2-202, Annotated Code of Maryland, or by the Secretary under Health-General Article, §18-902, Annotated Code of Maryland, assignment of a pharmacist to a location by the State constitutes application and approval under Regulation .02 of this chapter.

.06 Governing Laws.

A. Except as provided in §B of this regulation, a pharmacist approved by the Board to dispense or distribute at a nonpharmacy setting shall comply with the Health Occupations Article, Title 12, Annotated Code of Maryland.

B. A pharmacist approved by the Board to dispense or distribute at a nonpharmacy setting shall comply with the labeling, storage, and record keeping requirements governing the nonpharmacy setting.

.07 Term and Renewal.

A. Unless otherwise determined by the Board, the Board's approval of a pharmacist's request to dispense or distribute at a setting that does not possess a pharmacy permit is in effect until the expiration of the pharmacist's license.

B. The pharmacist shall request renewal of the Board's approval when renewing the pharmacist's license.

.08 Pharmacy Rendered Inoperable.

A. If a pharmacy for which a permit is issued is destroyed or otherwise rendered inoperable, a pharmacist may dispense or distribute from a temporary site if the permit holder:

(1) Obtains approval from the Board before continuing pharmacy operations from a temporary site; and

- (2) Ensures that the temporary pharmacy site complies with State and federal laws.

B. Under §A of this regulation, the Board may approve the operation of a pharmacy from a temporary site for a period not to exceed 60 days from the date of the original approval, unless an extension is approved by the Board before the expiration of the preceding approval.