

# Title 10

## MARYLAND DEPARTMENT OF HEALTH

### Subtitle 34 BOARD OF PHARMACY

#### 10.34.14 Opening and Closing of Pharmacies

Authority: Health Occupations Article, §§12-205 and 12-513, Annotated Code of Maryland

##### **.01 Definitions**

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
  - (1) “Closing of a pharmacy” means a licensed pharmacy will cease operations for more than 7 consecutive days, except when:
    - a) A licensed pharmacy is destroyed or otherwise rendered inoperable, and the licensed pharmacy is moving its operations to a temporary site in accordance with the Board’s regulations; or
    - b) A licensed pharmacy is undergoing a change of ownership:
      - i. That will not result in any cessation of pharmacy operations at the location; and
      - ii. The anticipated new pharmacy permit holder has submitted a change of ownership application to the Board at least 30 days prior to the change of ownership transaction.
  - (2) “Operational pharmacy” means a pharmacy that is actively compounding, dispensing, or distributing prescription or nonprescription drugs or devices in accordance with Health Occupations Article, §12-101(p), Annotated Code of Maryland.

##### **.02 Opening a Pharmacy.**

- A. To apply for pharmacy permit, an applicant shall:
  - (1) Submit an application to the Board on the form that the Board requires;
  - (2) Pay to the Board an application fee set by the Board in COMAR 10.34.09; and
  - (3) Submit to an opening inspection, at which time the applicant shall have, at a minimum, the following:
    - a) If applicable, a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity;
    - b) A refrigerator, solely for the storage of medications requiring refrigeration, with a thermometer or a temperature monitoring device;
    - c) Additional equipment to enable the pharmacy to prepare and dispense prescriptions properly consistent with the pharmacy’s scope of practice;
    - d) Hot and cold running water;
    - e) A library of current reference sources, consistent with the pharmacy’s scope of practice, that is accessible to appropriate personnel;
    - f) A current edition of Maryland Pharmacy Laws;
    - g) A security system in accordance with COMAR 10.34.05.02; and
    - h) A pharmacist on the premises during the opening inspection, if prescription drugs are present.
- B. A pharmacy may not be located in a residence.
- C. A permit holder who has been issued a pharmacy permit by the Board shall, within 60 days following the initial issuance of the pharmacy permit, have and maintain an operational pharmacy.
- D. The Board shall inspect a pharmacy after the initial issuance of a pharmacy permit to ensure that the pharmacy is an operational pharmacy.

- E. If a pharmacy is not an operational pharmacy within 60 days following the initial issuance of a pharmacy permit, the Board shall notify the permit holder of the Board's intent to rescind the pharmacy permit.
- F. A permit holder who has been notified of the Board's intent to rescind the pharmacy permit under this regulation shall return the permit to the Board within 10 days of notification, unless the permit holder submits documentation satisfactory to the Board to show that the pharmacy is an operational pharmacy.
- G. If a pharmacy permit has been rescinded under this regulation, the permit holder may reapply if application requirements are met.
- H. The Board may waive any of the requirements set forth in this regulation.

**.03 Notification of Closing of a Pharmacy.**

- A. At least 14 days before a licensed pharmacy's anticipated date of closing, the pharmacy permit holder shall:
  - (1) Notify the:
    - a) Board in writing by certified mail, return receipt requested, or hand delivery to the Board's office, of the day on which the licensed pharmacy will close;
    - b) Office of Controlled Substances Administration by certified mail, return receipt requested, of the day on which the licensed pharmacy will close;
    - c) Public by conspicuously posting a notice inside the pharmacy and on the pharmacy's website of the anticipated day on which the pharmacy will close; and
    - d) Pharmacy's customers who pick up a new or refilled prescription via written and verbal communication of the anticipated day on which the licensed pharmacy will close; and
  - (2) Request a closing inspection date.
- B. The notice shall contain the:
  - 1) Anticipated date of closing;
  - 2) Name and location of the pharmacy to which the closing pharmacy will transfer patient prescriptions and records; and
  - 3) Manner in which a patient may request the closing pharmacy to send the patient's prescriptions and records to an alternative pharmacy of the patient's choice.
- C. Upon notification by the pharmacy permit holder of the proposed date on which a licensed pharmacy will close, the Board or its agent shall schedule a closing inspection to be performed within 14 days, excluding federal and State holidays, of the pharmacy's closing.

**.03-1 Notification by Pharmacy Permit Holder of Anticipated Sale of Pharmacy Operations.**

- A. At least 30 days before a licensed pharmacy's sale or transfer of its pharmacy operations at the permitted establishment, the pharmacy permit holder shall:
  - (1) Notify the:
    - a) Board in writing by certified mail, return receipt requested, or hand delivery to the Board's office; and

- b) Office of Controlled Substances Administration by certified mail, return receipt requested; and
  - (2) Request a closing inspection of the pharmacy permit holder's pharmacy inventory and records.
- B. The notice shall contain:
  - (1) The anticipated date of the pharmacy permit holder's sale or transfer of its pharmacy operations; and
  - (2) The name of the anticipated purchaser or transferee of the pharmacy permit holder's pharmacy operations.
- C. Upon notification by a pharmacy permit holder of the proposed date on which the licensed pharmacy's operations will be sold or transferred, the Board or its agent shall schedule a closing inspection of the pharmacy permit holder's inventory and records to be performed within 14 days, excluding State and federal holidays.
- D. In the event the purchaser or transferee of the pharmacy's operations is not issued a new pharmacy permit by the Board on or prior to the date of the sale or transfer of the pharmacy operations that results in the cessation of pharmacy operations, the existing pharmacy permit holder shall immediately provide notice to the public, posted outside the pharmacy and on the pharmacy's website, including:
  - (1) The anticipated day on which pharmacy operations may resume; and
  - (2) The pharmacy permit holder's contact information for patients who wish to transfer prescriptions or records to another licensed pharmacy of the patient's choice.

#### **.04 Required Information and Procedure.**

- A. At the closing inspection of a licensed pharmacy, the pharmacy permit holder shall provide to the Board, or the Board's agent, information and documentation required by Regulation .05 of this chapter.
- B. The pharmacy permit holder shall remove or completely cover indications that the premises was a pharmacy within 30 days after the date the licensed pharmacy ceases to operate as a pharmacy.
- C. The pharmacy permit holder shall notify prescription drug suppliers to the pharmacy, before ceasing to operate as a pharmacy, of the date that the location will cease to operate as a pharmacy.
- D. The pharmacy permit holder shall notify the public of the date that the pharmacy will cease to operate as a pharmacy by that date.
- E. The pharmacy permit holder shall notify the public of the location to which the patients' records have been transferred, by the date the pharmacy ceases to operate.
- F. If patient records are not transferred, the pharmacy permit holder shall notify the public of the:
  - (1) Location of the patient records;
  - (2) Method by which the patient records shall be maintained; and
  - (3) Procedure by which patients and other authorized individuals or entities may access the patient records.
- G. The pharmacy permit holder shall comply with all federal and State laws and regulations.
- H. If the Board's agent performs the closing inspection, the Board's agent shall obtain information and documentation required by Regulation.05 of this chapter.

#### **.05 Information and Documentation Due at the Closing Inspection.**

Information and documentation due at the closing inspection shall include:

- A. The exact date on which the pharmacy ceased to operate as a pharmacy;
- B. A copy of the inventory required by the Drug Enforcement Administration;
- C. The pharmacy permit and Maryland Department of Health controlled dangerous substance registration for cancellation;
- D. The names, address, telephone numbers, and Drug Enforcement Administration registration numbers of the persons or business entities to whom any prescription drugs in stock were returned or transferred under Regulation .05 of this chapter and for any prescription files or patient records transferred;
- E. If prescription drugs are destroyed pursuant to Regulation .06 of this chapter, and Regulation .07 of this chapter does not apply to the prescription drugs, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the:
  - (1) Date, place and manner in which the prescription drugs were destroyed;
  - (2) Names, addresses, and telephone numbers of the persons responsible for destroying the prescription drugs; and
  - (3) Name, dosage unit, and quantity of each type of prescription drug destroyed;
- F. If any patient records which are not required to be maintained by law, or other documents containing patient information are destroyed, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:
  - (1) That the documents were destroyed;
  - (2) The date of the destruction of the documents;
  - (3) The name and address of the person who destroyed the documents;
  - (4) That the records or other documents were destroyed in a manner so as to avoid breaches of patients' confidentiality; and
  - (5) The identity of the records destroyed; and
- G. If any patient records or other documents containing patient information are transferred, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:
  - (1) The date, time, place to which and manner in which the records or other documents were transferred;
  - (2) The names, addresses, and telephone numbers of the persons responsible for transferring the records or other documents;
  - (3) That the records or other documents were transferred in a manner so as to avoid breaches of patients' confidentiality; and
  - (4) The identity of the records transferred.

**.06 Disposition of Prescription Drugs Other than Controlled Dangerous Substances.**

With the exception of controlled dangerous substances, prescription drugs in stock shall be disposed of by one or more of the following means:

- A. Returning them to a distributor or manufacturer; or
- B. Transferring them to another licensed pharmacy, authorized prescriber, or other person or entity approved by the Board or the Division of Drug Control.

**.07 Disposition of Controlled Dangerous Substances.**

The pharmacy permit holder shall comply with the procedures set forth in this chapter in addition to those set forth in COMAR 10.19.03.10C-E governing the disposal of controlled dangerous substances.

