

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 13 DRUGS

Chapter 01 Dispensing of Prescription Drugs by a Licensee

Authority: Health Occupations Article, §§12-102 and 12-102.1, Annotated Code of Maryland

.01 Scope.

This chapter defines the parameters under which a licensee may dispense prescription drugs in accordance with Health Occupations Article, §12-102, Annotated Code of Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Board" means the Board of Dental Examiners, the Board of Physicians, or the Board of Podiatric Medical Examiners.

(2) Final Check.

(a) "Final check" means the verification of the accuracy and completeness of a filled prescription order by the permit holder before the drug is dispensed to the patient.

(b) "Final check" includes the assumption of responsibility for the filled prescription, including verifying the:

(i) Appropriateness of the dose;

(ii) Accurate expiration date;

(iii) Accuracy of the drug dispensed;

(iv) Strength of the drug dispensed;

(v) Labeling that complies with Health Occupations Article, §12-505, Annotated Code of Maryland; and

(vi) Appropriateness of the container in which the drug is dispensed, including child-proof containers where applicable.

(3) "Licensee" means the dentist, physician, or podiatrist who is licensed by the appropriate Board to practice in Maryland.

(4) "Personally preparing and dispensing" means the licensed dentist, physician, or podiatrist:

(a) Is physically present on the premises where the prescription is filled; and

(b) Performs a final check of the prescription before it is dispensed to the patient.

(5) "Public interest" means the dispensing of prescription drugs by a licensee to a patient when a pharmacy is not conveniently available to the patient.

.03 Application for Dispensing Permit.

A. The licensee shall complete an application on a form approved by the appropriate Board and pay a fee in accordance with the fee schedule for:

(1) Physicians at COMAR 10.32.01.12;

(2) Podiatrists at COMAR 10.40.03; or

(3) Dentists at COMAR 10.44.20.

B. The application shall require the following information to indicate that the applicant is personally preparing and dispensing prescription drugs in the public interest:

(1) The name, address, and license number of the applicant;

(2) An attestation by the applicant that the applicant shall comply with the:

(a) Dispensing requirements set forth in Regulation .04 of this chapter;

(b) Inspection requirements set forth in Regulation .05 of this chapter; and

(c) Statutes and regulations governing dispensing of prescription drugs set forth in Health Occupations Article, Title 12, Annotated Code of Maryland, COMAR 10.19.03, and COMAR 10.34; and

(3) The address of each practice location where the applicant dispenses prescription drugs.

C. Each permit issued to a licensee expires 5 years after its date of issuance and is renewable upon timely submission of a renewal application in accordance with the requirements set forth in this regulation. The fee schedule set forth in §A of this regulation applies to all renewal applications.

D. Continuing Education Requirement.

(1) A permit holder shall complete 10 continuing education credits over a 5-year period relating to the preparing and dispensing of prescription drugs as a condition of permit renewal.

(2) The continuing education credit requirement shall be implemented in accordance with Ch. 267, §2, Acts of 2012.

E. A permit issued to a licensee shall be nontransferable.

.04 Dispensing Requirements.

- A. A licensee shall submit an application to the appropriate Board on the form that the Board requires.
- B. A licensee may not dispense prescription drugs until a written permit is received from the appropriate Board, except that a written permit is not required in order to dispense starter dosages or samples provided without charge.
- C. A licensee shall personally prepare and dispense prescription drugs.
- D. Except as provided in Health Occupations Article, §12-102(c)(2)(iii), Annotated Code of Maryland, and §S of this regulation, a licensee shall dispense prescription drugs only to the patients of the licensee.
- E. A licensee shall comply with the labeling requirements set forth in Health Occupations Article, §12-505, Annotated Code of Maryland.
- F. A licensee shall comply with the child resistant packaging requirements set forth in Health-General Article, Title 22, Subtitle 3, Annotated Code of Maryland.
- G. A licensee shall comply with drug recalls.
- H. A licensee shall record the dispensing of the prescription drug on the patient's chart.
- I. A licensee may not have a substantial financial interest in a pharmacy.
- J. A licensee shall, except for starter dosages or samples provided without charge, provide the patient with a written prescription.
- K. A licensee shall maintain for at least 5 years:
 - (1) A separate file for Schedule II prescriptions; and
 - (2) Another file for other prescriptions.
- L. A licensee shall maintain biennial inventories of all stocks of controlled substances.
- M. A licensee shall dispense prescription drugs to a patient only when the patient determines that a pharmacy is not conveniently available to the patient.
- N. In each patient's chart for each patient to whom prescription drugs are dispensed or in a format readily retrievable, a licensee shall maintain a single form which:
 - (1) Indicates that a pharmacy is not conveniently available to the patient;
 - (2) States that the determination that a pharmacy is not conveniently available was made solely by the patient; and
 - (3) Is signed and dated by the patient before dispensing prescription drugs to the patient for the first time.
- O. A licensee shall display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy is not conveniently available to the patient.

P. A licensee may not make any agreement that denies a patient a free choice of pharmacist or pharmacy services.

Q. A licensee shall post a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed.

R. A licensee shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary to prepare and dispense prescriptions properly.

S. To the extent permitted by COMAR 10.32.23, a licensed physician may personally prepare and dispense a prescription written by:

(1) A physician assistant with whom the physician has a delegation agreement that:

(a) Complies with Health Occupations Article, Title 15, Subtitle 3, Annotated Code of Maryland; and

(b) Permits the physician assistant to prescribe the drug; and

(2) A certified registered nurse practitioner who is:

(a) Authorized to practice under Health Occupations Article, Title 8, Subtitle 3, Annotated Code of Maryland; and

(b) Working with the physician in the same practice.

.05 Inspection Requirements.

A. The Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners shall report annually to the Office of Controlled Substances Administration the names and addresses of its licensees who:

(1) Are authorized to personally prepare and dispense prescription drugs; and

(2) Have reported to the appropriate Board that they have personally prepared and dispensed prescription drugs within the previous year.

B. A licensee shall allow the Office of Controlled Substances Administration to enter and inspect the licensee's practice locations at all reasonable hours.

C. The Office of Controlled Substances Administration shall:

(1) Enter and inspect the practice locations of a licensee who holds an initial dispensing permit:

(a) Within 6 months after receiving the annual report set forth in §A(1) of this regulation; and

(b) At least one more time during the duration of the permit;

(2) If a licensee who holds an initial dispensing permit has more than one practice location:

(a) Enter and inspect a practice location of the licensee within 6 months after receiving the annual report set forth in §A(1) of this regulation; and

- (b) Enter and inspect a different practice location at least one time during the duration of the permit;
- (3) If a licensee who holds a dispensing permit is seeking renewal:
 - (a) Enter and inspect a practice location of a licensee at least two times during the duration of the permit; and
 - (b) If licensee has more than one practice location, enter and inspect two different practice locations during the duration of the permit;
- (4) If the Office of Controlled Substances Administration finds a deficiency at one practice location of a licensee with multiple practice locations, require the licensee to prepare, sign, and submit an affidavit attesting that all practice locations are in or will be in compliance as a result of the inspection;
- (5) Report to the Board of Pharmacy a wholesale distributor not licensed in Maryland; and
- (6) Report the results of the inspections required under §C(1) and (2) of this regulation to the respective board of licensure.

D. A licensee shall sign and date an inspection form provided by the Office of Controlled Substances Administration relating to the requirements set forth in Health Occupations Article, §12-102, Annotated Code of Maryland.

E. A licensee shall pay a fee in an amount that will produce funds to approximate, but not exceed, the documented costs to the Office of Controlled Substances Administration for inspections, as required by the appropriate Board.

F. The Office of Controlled Substances Administration:

(1) May suspend inspections of any physician who reports pursuant to Health Occupations Article, §12-102(c)(2)(ii)4L, Annotated Code of Maryland, that the physician has not personally dispensed any prescription medications during the preceding year; and

(2) To the extent otherwise required by this regulation, shall resume inspections if that physician later reports that the physician has resumed dispensing activities.

.06 Failure to Comply with Dispensing Requirements.

A licensee who fails to comply with the requirements governing dispensing of prescription drugs shall have the dispensing permit revoked and be subject to disciplinary action by the appropriate licensing board.

Effective date: September 19, 1935

Chapter, Permits for Sale of Poisons by General Merchants, repealed effective July 10, 1989(16:13 Md. R. 1421)

Chapter, Dispensing of Prescription Drugs by a Licensee, adopted effective May 11, 1992 (19:9 Md. R. 879)

Regulation .03A amended effective March 6, 2000 (27:4 Md. R. 453)

Chapter revised effective June 22, 2015 (42:12 Md. R. 762)

Regulation .02B amended effective March 26, 2018 (45:6 Md. R. 320)

Regulation .03A amended effective March 26, 2018 (45:6 Md. R. 320)

Regulation .04D, N amended effective March 26, 2018 (45:6 Md. R. 320)

Regulation .04S adopted effective March 26, 2018 (45:6 Md. R. 320)

Regulation .05 amended effective March 26, 2018 (45:6 Md. R. 320)