

MARYLAND BOARD OF PHYSICIANS  
P.O. BOX 37217  
BALTIMORE, MD 21215-0095  
[www.mbp.state.md.us](http://www.mbp.state.md.us)  
410-764-4705; 800-492-6836, ext 4705

## INSTRUCTIONS AND APPLICATION FOR PHYSICIAN'S PERMIT TO DISPENSE PRESCRIPTION DRUGS

Please be aware that there is a difference between a *Controlled Dangerous Substance Permit*, issued by the Division of Drug Control and a *Permit to Dispense Prescription Drugs*, issued by the Maryland Board of Physicians.

A *Controlled Dangerous Substance (C.D.S.) Permit* is required to prescribe Schedule 2-5 controlled dangerous substances, as provided in Code of Maryland Regulations 10.19.03. To apply for a C.D.S. Permit, contact the Division of Drug Control at:

4201 Patterson Avenue  
Baltimore, MD 21215  
410-764-2890 or 410-764-2497

A *Permit to Dispense Prescription Drugs* from the Maryland Board of Physicians allows a physician to dispense prescription drugs to a patient only when the pharmacy is not conveniently available to the patient, as determined by the patient. To receive a permit, complete and submit the following application along with the \$50 fee.

Once your application is approved, the permit is valid for 5 years from the date of issue and can be renewed upon application to the Board prior to the expiration of the permit.

**MARYLAND BOARD OF PHYSICIANS**

PO Box 37217, Baltimore, MD 21297  
410-764-4705 or 1-800-492-6836, ext 4705

**APPLICATION FOR PHYSICIAN'S PERMIT TO DISPENSE PRESCRIPTION DRUGS**

INSTRUCTIONS	FOR BANK USE ONLY
<p>Review information sheet to determine whether you need a dispensing permit.</p> <ul style="list-style-type: none"> <li>• Complete 1-3 on this form and sign and date the application.</li> <li>• If prescriptions will be dispensed in more than one location or by more than one physician, a separate dispensing permit is required for each.</li> <li>• Permit is valid for 5 years from the date of issue.</li> <li>• Submit the completed, signed form with a check or money order for \$50 payable to the Maryland Board of Physicians. Mail to above address.</li> </ul>	<p>Date: ____/____/20____</p> <p>Check number: _____</p> <p>Amount Paid: _____</p> <p>Name Code: _____</p> <p>APPID: 32</p>

Application for (check one) \_\_\_\_\_ Initial Permit \_\_\_\_\_ Renew Permit

If renewal, Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

1. Physician license number \_\_\_\_\_

2. Physician name \_\_\_\_\_  
Last First Middle

3. Complete mailing address and telephone number for location where drugs will be dispensed. *Permit is valid only at this location.*

\_\_\_\_\_  
Facility Name & Street address

\_\_\_\_\_

\_\_\_\_\_  
City State Zip Code

\_\_\_\_\_  
Telephone number

**I HEREBY CERTIFY THAT:**

- A. I am thoroughly familiar with the statutes and regulations which govern physician dispensing of prescription drugs, including Health Occupations Article §§12-102, 12-505, and 12-604, Annotated Code of Maryland and Code of Maryland Regulations (COMAR) 10.13.01, 10.19.03.04, .10.19.03.05, and 10.19.03.07.
- B. I have read and understood the enclosed information sheet for physicians who are dispensing drugs.
- C. I will comply with the dispensing requirements set forth in COMAR 10.13.01, Regulations .01--.05 and the above-referenced statutes and regulations.
- D. I understand that I must follow the requirements listed in COMAR 10.13.01.04 regarding dispensing, labeling, record keeping, and patient notifications in order to receive and maintain a permit to dispense. Failure to comply with these requirements or other conditions included in the laws and regulations may be considered a violation of Health Occupations Article, §14-404(a)(28).

\_\_\_\_\_  
Physician's Signature

\_\_\_\_\_  
Date

# State of Maryland

## Board of Physicians — Division of Drug Control 410-764-4705 410-764-2890

### Information Sheet for Physicians Who Want to Dispense Prescription Drugs

#### Who needs a dispensing permit?

If a physician wants to *dispense* medication to his/her own patients (i.e., give a prescription drug to a patient to take at a later time), the physician must:

- Obtain a dispensing permit from the Board of Physicians  
or
- Be treating a patient and dispensing medication in a nonprofit health facility, a local or state health department facility, a health center operating on the campus of an institution of higher education, or a clinic dealing primarily with workers compensation cases.

A licensed physician in Maryland may *prescribe* (write or issue an order for medication) *and/or administer* (give to patient for immediate consumption) prescription drugs **without** a dispensing permit. A physician may also *dispense drug samples* and *starter doses* (for a period of 72 hours or less) of drugs without a permit.

#### Restrictions on Dispensing

A physician is required to:

- Dispense prescription drugs **to his or her own patients only**;
- Issue a written prescription to each patient;
- Be physically present on the premises when the prescription is filled;
- **Personally perform a final check of the prescription** to verify patient name, medication, and labeling before the prescription is provided to the patient; and
- Take the written prescription back from the patient and file it in the prescription file.

#### Notices

A physician is required to:

- Post a sign stating that prescription drugs may be purchased by the patient if a pharmacy is not conveniently available to the patient.
- Post a sign or distribute written instructions with each prescription explaining the process for resolving incorrectly filled prescriptions.

#### Label for Prescriptions Must Include:

- Name and Address of Prescriber/Dispenser,
- Patient's Name,
- Name, strength, quantity of the drug,
- Date dispensed,
- Directions for use,
- Expiration date (one year from date of dispensing or a shorter period as determined by the prescriber or as indicated on the original container),
- Special handling or storage instruction,
- For controlled drugs, the statement "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

#### Child Resistant Containers

- All prescriptions must be dispensed in child resistant containers unless the prescription requires or the patient specifically requests noncompliant packaging.

## **Other Important Information for Physicians who Dispense Drugs**

### **Patient Record**

- Insert a form in the chart of each patient to whom drugs are dispensed, indicating
  - A pharmacy is not conveniently available to the patient, and
  - The determination of “conveniently available” has been made solely by the patient;
- Patient must sign form when drugs are first dispensed to the patient.
- Each time a drug is dispensed to the patient, a notation must be inserted into the patient’s medical record.

### **Record Keeping for Dispensing Medications**

- Maintain complete record of all receipts, invoices, and dispensing transactions for all prescription drugs and controlled dangerous substances (CDS).
- Maintain a separate file for CDS Schedule II prescriptions; all other prescriptions may be placed into one other file.
- All written prescriptions must be kept for 5 years.
- Make sure that the quantity and strength of the drug prescribed (i.e., written on the prescription and in the patient’s medical record) match the amount dispensed and that the notation of dispensing in the patient record also matches.

### **Log Book**

We recommend that you maintain a separate dispensing log book in the drug room. The log should include the following information:

- The date the drug was dispensed;
- The patient’s full name;
- The drug name, strength, and dosage;
- The quantity dispensed;
- The name and initials of the dispensing physician performing the final check.

### **Inventory of Controlled Dangerous Substances (CDS)**

The licensed physician shall take an inventory of all stocks of CDS on hand on the first day he/she engages in dispensing any CDS and every 2 years thereafter. If no CDS are on hand at the initial inventory, a zero inventory should be recorded. The inventory record must be kept at the location specified on the DEA registration certificate. The inventory record shall be kept for a period of 2 years, and must include the:

- Physician’s name, address, and Drug Enforcement Administration registration number;
- Date and time the inventory (i.e., opening or close of business); and
- Signature of the person taking the inventory.

### **Storage of Medications:**

- Maintain room temperature between 59°F and 86° F.
- Maintain refrigerator temperature between 36°F and 46° F.
- Secure all prescription drugs.
- Limit access to CDS to personnel authorized by the physician.
- Establish effective controls and procedures to guard against theft and unlawful diversion of CDS.
- Notify the Drug Enforcement Administration, local police and the Maryland Division of Drug Control upon discovery of significant loss of CDS.

### **Disposal of expired prescription drugs and CDS**

- All expired and unused prescription drugs and CDS shall be separated from useable stock.
- Expired drugs must be disposed in accordance with applicable State and federal laws and regulations.

**Article - Health Occupations  
Annotated Code of Maryland**

§12-101.

(a) In this title the following words have the meanings indicated.

(b) "Authorized prescriber" means any licensed dentist, licensed physician, licensed podiatrist, licensed veterinarian, certified nurse midwife to the extent permitted in § 8-601 of this article, certified nurse practitioner to the extent permitted in § 8-508 of this article, or other individual authorized by law to prescribe prescription or nonprescription drugs or devices.

(c) "Board" means the State Board of Pharmacy.

(d) (1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

(2) "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(e) (1) "Delegated pharmacy act" means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under this title and regulations adopted by the Board.

(2) "Delegated pharmacy act" does not include:

(i) An act within the parameters of a therapy management contract as provided under Subtitle 6A of this title;

(ii) The administration of an influenza vaccination in accordance with § 12-508 of this title;

(iii) The delegation of a pharmacy act by a registered pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with § 12-301(b) of this title;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy in accordance with regulations adopted by the Board; or

(vi) The performance of other functions prohibited in regulations adopted by the Board.

(f) (1) "Device" means a device used in the diagnosis, treatment, or prevention of disease.

(2) "Device" does not include any:

(i) Surgical or dental instrument;

(ii) Physical therapy equipment;

(iii) X-ray apparatus; or

(iv) Component part or accessory of any of these items.

(g) "Direct supervision" means that a licensed pharmacist is physically available on-site to supervise the performance of delegated pharmacy acts.

(h) "Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(1) Interpretation of an authorized prescriber's prescription for a drug or device;

(2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

(i) (1) "Distribute" means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under this article, prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

(2) "Distribute" does not include the operations of a person who holds a permit issued under § 12-6C-03 of this title.

(j) "License" means, unless the context requires otherwise, a license issued to a pharmacist by the Board to practice pharmacy.

(k) "Licensed pharmacist" means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

(l) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and regulations of this State and the federal government.

(m) "Nonresident pharmacy" means a pharmacy located outside this State that, in the normal course of business, as determined by the Board, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.

(n) "Pharmaceutical care" means the provision of a patient's drug regimen for the purpose of achieving definite outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and which may include patient counseling and providing information to licensed and certified health care providers.

(o) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(p) "Pharmacy" means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

(q) "Pharmacy permit" means a permit issued by the Board to establish and operate a pharmacy.

(r) "Pharmacy student" means an individual who is enrolled as a student in a school or college of pharmacy approved by the Board or accredited by the Accreditation Council for Pharmacy Education.

(s) "Pharmacy technician trainee" means an individual engaged in a Board approved pharmacy technician training program.

(t) (1) "Practice pharmacy" means to engage in any of the following activities:

(i) Providing pharmaceutical care;  
(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;

(viii) Administering an influenza vaccination, a vaccination for pneumococcal pneumonia or herpes zoster, or any vaccination that has been determined by the Board, with the agreement of the Board of Physicians and the Board of Nursing, to be in the best health interests of the community in accordance with § 12-508 of this title;

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; or

(xi) Providing drug therapy management in accordance with § 19-713.6 of the Health – General Article.

(2) “Practice pharmacy” does not include the operations of a person who holds a permit issued under § 12-6C-03 of this title.

(u) “Registered pharmacy technician” means an individual who is registered with the Board to perform delegated pharmacy acts.

(v) “Registration” means, unless the context requires otherwise, a registration issued by the Board to perform delegated pharmacy acts under the supervision of a licensed pharmacist.

(w) “Supervision” means reviewing the work, guiding and directing the activities, and monitoring the performance of an individual.

#### §12-102.

(a) (1) In this section the following terms have the meanings indicated.

(2) “In the public interest” means the dispensing of drugs or devices by a licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently available to the patient.

(3) “Personally preparing and dispensing” means that the licensed dentist, physician, or podiatrist:

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

(ii) Performs a final check of the prescription before it is provided to the patient.

(b) This title does not limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article.

(c) This title does not prohibit:

(1) A licensed veterinarian from personally preparing and dispensing the veterinarian’s prescriptions;

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist’s, physician’s, or podiatrist’s prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest;

3. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

4. Posts 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;

(ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of § 12-505 of this title;

2. Records the dispensing of the prescription drug or device on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours;

4. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions;

5. Does not direct patients to a single pharmacist or pharmacy in accordance with § 12-403(b)(8) of this title; and

6. Does not receive remuneration for referring patients to a pharmacist or pharmacy; or

(3) A hospital-based clinic from dispensing prescriptions to its patients.

(d) This title does not prohibit:

(1) A licensed veterinarian from personally dispensing a drug or device sample to a patient of the veterinarian; or

(2) A licensed dentist, licensed physician, or licensed podiatrist from personally dispensing a drug or device sample to a patient of the licensed dentist, licensed physician, or licensed podiatrist if:

(i) The sample complies with the labeling requirements of § 12-505 of this title;

(ii) No charge is made for the sample; and

(iii) The authorized prescriber enters an appropriate record in the patient's chart.

(e) (1) This title does not prohibit a dentist, physician, or podiatrist from administering a prescription drug or device in the course of treating a patient.

(2) For the purposes of paragraph (1) of this subsection, "administering" means the direct introduction of a single dosage of a drug or device at a given time, whether by injection or other means, and whether in liquid, tablet, capsule, or other form.

(f) (1) This title does not prohibit a dentist, physician, or podiatrist from personally dispensing a starter dosage of a prescription drug or device to a patient of the dentist, physician, or podiatrist, provided that:

(i) The starter dosage complies with the labeling requirements of § 12-505 of this title;

(ii) No charge is made for the starter dosage; and

(iii) The dentist, physician, or podiatrist enters an appropriate record on the patient's chart.

(2) For the purposes of paragraph (1) of this subsection, "starter dosage" means an amount of drug or device sufficient to begin therapy:

(i) Of short duration of 72 hours or less; or

(ii) Prior to obtaining a larger quantity of the drug or device to complete the therapy.

(g) This title does not prohibit a dentist, physician, or podiatrist from dispensing a prescription drug or device in the course of treating a patient:

(1) At a medical facility or clinic that specializes in the treatment of medical cases reimbursable through workers' compensation insurance;

(2) At a medical facility or clinic that is operated on a nonprofit basis;

(3) At a health center that operates on a campus of an institution of higher education; or

(4) At a public health facility, a medical facility under contract with a State or local health department, or a facility funded with public funds.

(h) This title does not limit the right of a general merchant to sell:

(1) Any nonprescription drug or device;

(2) Any commonly used household or domestic remedy; or

(3) Any farm remedy or ingredient for a spraying solution, in bulk or otherwise.

(i) A dentist, physician, or podiatrist who fails to comply with the provisions of this section governing the dispensing of prescription drugs or devices shall:

(1) Have the dispensing permit revoked; and

(2) Be subject to disciplinary actions by the appropriate licensing board.

#### §12-505.

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

(b) In addition to any other information required by law, the label shall include:

(1) The date the prescription is filled; and

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices which shall be the lesser

of:

1. 1 year from the date of dispensing;

2. The month and year when the drugs or devices expire;

3. The appropriate expiration date for repackaged drugs or

devices; or

4. A shorter period as determined by the pharmacist;

(ii) Any appropriate special handling instructions regarding proper storage of the drugs or devices; and

(iii) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.

(c) (1) Except as provided in paragraph (2) of this subsection, the label shall indicate the same name for the drug or device as that used by the authorized prescriber.

(2) If, under § 12-504 of this subtitle, the pharmacist substitutes a drug or device product for that named by the authorized prescriber, the label shall indicate both the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed.

(d) (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device;

(ii) The date the prescription is dispensed;

(iii) An expiration date of the drug or device which shall be the lesser

of:

1. 1 year from the date of dispensing;

2. The month and year when the drug or device expires; or

3. A shorter period as determined by the authorized prescriber;

and

(iv) Any appropriate special handling instructions regarding proper storage of the drug or device.

(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:

(i) To an inpatient in a hospital or related institution;

(ii) In an emergency situation; or

(iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's practice.

(e) So long as any of the original contents remain in the container, a person may not alter, deface, or remove any label required by this section.

§12-604.

(a) The Secretary, the Board, or the agents of either, during business hours, may:

(1) Enter any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked, or offered for sale; and

(2) Inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.

(b) Any pharmacy issued a permit by the Board and subject to inspection under subsection (a) of this section shall be inspected annually.

(c) A person may not hinder an inspection conducted under this section.

**Code of Maryland Regulations**  
**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**10.13.01.01**

**.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.

**10.13.01.02**

**.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 Physician Quality Assurance, or the Board of Podiatric Medical Examiners.

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

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

**10.13.01.03**

**.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 10.32.01.11;

(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 licensee is prescribing in the public interest:

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

(2) A certificate by the applicant that the applicant:

(a) Shall comply with the dispensing requirements set forth in Regulation .04 of this chapter; and

(b) Is thoroughly familiar with the statute and regulations which govern dispensing of prescription drugs set forth in Health Occupations Article, Title 12, Annotated Code of Maryland, and COMAR 10.34.

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.

**10.13.01.04**

**.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 dispense prescription drugs only to the patients of the licensee.

D. A licensee shall comply with the labeling requirements of Health Occupations Article, §12-509, Annotated Code of Maryland.

E. A licensee shall record the dispensing of the prescription drug on the patient's chart.

F. A licensee may not have a substantial financial interest in a pharmacy.

G. A licensee shall allow the Division of Drug Control to enter and inspect the licensee's office at all reasonable hours.

H. A licensee shall, except for starter dosages or samples provided without charge, provide the patient with a written prescription.

I. A licensee shall maintain a separate file for Schedule II prescriptions. All other prescriptions shall be kept:

(1) In another file; and

(2) For 5 years.

J. A licensee shall dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. The decision whether a pharmacy is conveniently available shall be made by the patient based upon factors to be determined solely in the discretion of the patient.

K. A licensee shall maintain a single form in each patient's chart for each patient to whom prescription drugs are dispensed. At a minimum, the form shall:

- (1) Indicate that a pharmacy is not conveniently available to the patient;
- (2) State that the determination that a pharmacy is not conveniently available was made solely by the patient; and
- (3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the first time.

L. 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.

#### 10.13.01.05

##### **.05 Failure to Comply with Dispensing Requirements.**

A licensee who fails to comply with the requirements governing dispensing of prescription drugs may be subject to disciplinary action pursuant to Health Occupations Article, §4-315(a), 14-404, or 16-312, Annotated Code of Maryland.

#### 10.19.03.04

##### **.04 Labeling and Packaging Requirements for Controlled Dangerous Substances. (Title 21, Code of Federal Regulations 1302.01).**

A. Requirements governing the labeling and packaging of controlled dangerous substances pursuant to Criminal Law Article, §§5-202 and 5-604, Annotated Code of Maryland, are set forth generally by those sections and specifically by the sections of this regulation.

B. Symbol Required—Exceptions (21 CFR §1302.03).

(1) Each commercial container of a controlled dangerous substance (except for a controlled dangerous substance excepted by the Administrator pursuant to Title 21, Code of Federal Regulations, §1308.31, shall have printed on the label the symbol designating the schedule in which this controlled dangerous substance is listed. Each commercial container, if it has no label, shall bear a label complying with the requirement of this part.

(2) Each manufacturer shall print upon the labeling of each controlled dangerous substance distributed by the manufacturer the symbol designating the schedule in which this controlled dangerous substance is listed.

(3) Schedules.

(a) The following symbols shall designate the schedule corresponding to it:

Schedule	Symbol
Schedule I	CI or C-I
Schedule II	CII or C-II
Schedule III	CIII or C-III
Schedule IV	CIV or C-IV
Schedule V	CV or C-V

(b) The word "schedule" need not be used. A distinction need not be made between narcotic and non-narcotic substances.

(4) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through this carton or wrapper.

(5) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(6) The symbol is not required on a commercial container containing, or on the labeling of, a controlled dangerous substance being used in clinical research involving blind and double blind studies.

C. Location and Size of Symbol on Label (21 CFR §1302.04).

(1) The symbol shall be prominently located on:

- (a) The label or the labeling of the commercial container;
- (b) The panel of the commercial container normally displayed to dispensers of any controlled substance; or
- (c) Both.

(2) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled dangerous substance upon inspection, without removal from the dispenser's shelf.

(3) The symbol shall be prominently located on all labeling other than labels covered by this section. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled dangerous substance upon inspection of the labeling.

**D. Effective Dates of Labeling Requirements (21 CFR §1302.05).**

(1) All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule, shall comply with the requirements of §B of this regulation, on or before the effective date established in the final order for the transfer or addition.

(2) In the case of any controlled dangerous substance, the Secretary may require compliance with the requirements of §B within a period of time shorter than required by this regulation if the Secretary finds that public health or safety necessitates an earlier effective date.

(3) Until compliance is required under this regulation, the label on commercial containers containing, and the labeling of, any controlled dangerous substance, shall comply with any requirements under federal law as to labels of these substances existing before the effective date prescribed in this regulation.

**E. Sealing of Controlled Dangerous Substances (21 CFR §1302.06).** On each bottle, multiple dose vial, or other commercial container of any controlled dangerous substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper of that container a seal to disclose upon inspection any tampering or opening of the container.

**F. Labeling and Packaging Requirements for Imported and Exported Substances (21 CFR §1302.07).**

(1) The symbol requirements of §§B—D of this regulation apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of or the customs territory of the United States.

(2) The symbol requirements of §§B—D of this regulation do not apply to any commercial containers containing, or any labeling of, a controlled dangerous substance intended to export from the jurisdiction of the United States.

(3) The sealing requirements of §E of this regulation apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of or the customs territory of the United States.

**10.19.03.05**

**.05 Records and Reports Required of Registrants.**

A. Records and reports required of applicants, pursuant to Criminal Law Article, §5-306, Annotated Code of Maryland, shall be the same as required in 21 CFR 1304, as amended.

B. Inventories developed under the Federal Act under the date of May 1, 1971, and subsequent biennial inventory dates are acceptable for purposes of the Maryland Act. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every 2 years. The biennial inventory may be taken on any date which is within 2 years of the previous biennial inventory date.

C. On the effective date a substance is added to any schedule of controlled dangerous substances pursuant to Criminal Law Article, §5-202, Annotated Code of Maryland, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of that substance on hand. Thereafter, that substance shall be included in each inventory made by the registrant.

D. Each person registered as a manufacturer, distributor, dispenser, researcher, or chemical analyst shall be required to maintain inventory records, as stipulated in Title 21, Code of Federal Regulations, §1304.11, and they shall be accessible to the representative of the Secretary.

**10.19.03.07**

**.07 Prescriptions.**

A. Provisions governing the issuance, filling, and filing of prescriptions pursuant to Criminal Law Article, §§5-501—5-505, Annotated Code of Maryland, are set forth generally in those sections and specifically by the sections of this regulation.

B. Persons Entitled to Issue Prescriptions (21 CFR §1306.03).

(1) A prescription for a controlled dangerous substance may be issued only by an individual practitioner who is:  
(a) Authorized to prescribe controlled dangerous substances in the State of Maryland, in which the practitioner is licensed to practice the practitioner's profession; and  
(b) Either registered or exempted from registration pursuant to 21 CFR §1301.22(c) and 21 CFR §1301.23.

(2) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

C. Purpose of Issue of Prescription (21 CFR §1306.04).

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§5-501—5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

(2) A prescription may not be issued in order for an individual practitioner to obtain controlled dangerous substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for detoxification treatment or maintenance treatment.

#### D. Manner of Issuance of Prescriptions (21 CFR §1306.05).

(1) All prescriptions for controlled dangerous substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (for example, J.H. Smith or John H. Smith). When an oral order is not permitted, prescriptions shall be written with ink, indelible pencil, typewriter, or computer and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(2) An individual practitioner exempted from registration under 21 CFR §1301.22(c) shall include on all prescriptions issued by the individual practitioner the registration number of the hospital or other institution and the special internal code number assigned to the individual practitioner by the hospital or other institution, as provided in 21 CFR §1301.22(c), instead of the registration number of the practitioner required by this regulation. Each written prescription shall have the name of the individual practitioner stamped, typed, or handprinted on it, as well as the signature of the individual practitioner.

(3) An official exempted from registration under 21 CFR §1301.23 shall include on all prescriptions issued by the practitioner the branch of service or agency (for example—"U.S. Army" or "Public Health Service") and the practitioner's service identification number, instead of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is the practitioner's Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

E. Persons Entitled to Fill Prescriptions. A prescription for controlled dangerous substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

#### F. Administering or Dispensing of Narcotic Drugs (21 CFR §1306.07).

(1) The administering or dispensing directly, but not prescribing, of narcotic drugs listed in any schedule to a narcotic drug dependent individual for "detoxification treatment" or "maintenance treatment" as defined in 21 U.S.C. §802 shall be deemed to be within the meaning of the term "in the course of his professional practice of research" as provided in 21 U.S.C. §828(e) and 21 U.S.C. §802(21), if the practitioner is separately registered with the United States Attorney General as required by 21 U.S.C. §823(g) and complies with the regulatory standards for treatment qualification, security, records, and unsupervised use of drugs pursuant to the federal Act.

(2) A physician who is not specifically registered to conduct a narcotic treatment program may administer, but may not prescribe, narcotic drugs to an individual for the purpose of relieving acute withdrawal symptoms if necessary while arrangements are being made for referral for treatment. More than one day's medication may not be administered to the individual, or for the individual's use, at one time. This emergency treatment may not be carried out for more than 3 days and may not be renewed or extended.

(3) A physician or authorized hospital staff may administer or dispense narcotic drugs:

(a) In a hospital to maintain or detoxify an individual as an incidental adjunct to medical or surgical treatment of conditions other than addiction; or

(b) To an individual with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.