

Frequently Asked Questions

DO I NEED A PERMIT?

1. What is dispensing?

Dispensing means the procedure which results in the receipt of a prescription drug by a patient. Dispensing includes:

- a. Interpretation of the prescription;
- b. Selection and labeling of the drug; and
- c. Measuring and packaging of the drug. These are tasks most often performed by a pharmacist.

2. May a physician dispense a prescription drug without a dispensing permit?

No, unless an exception applies. Examples of exceptions are discussed in FAQs 3 through 6.

3. Do I need a dispensing permit to give a patient free samples of a drug provided by a manufacturer?

No. There is an exception in the law permitting this activity without a permit.

4. Do I need a dispensing permit to hand out free starter dosages of 72 hours of medication or less?

No. There is an exception in the law permitting this activity without a permit.

5. Do I need a dispensing permit to hand a drug to a patient for immediate consumption, or to inject a drug?

No. This activity is called “administering” a drug. You do not need a dispensing permit to do this.

6. Do I need a dispensing permit to provide an IV infusion or inhalation therapy in my office or clinic?

A physician who directly applies therapies of any kind to the patient while the patient is in the office or clinic is “administering,” and there is no need for a dispensing permit to apply therapies.

7. Do I need a dispensing permit in order to *prescribe* controlled dangerous substances such as oxycodone, diazepam, and phentermine?

No. Prescribing is not dispensing. You do not need a dispensing permit to *prescribe* controlled dangerous substances.

8. Do I need any kind of permit in order to *prescribe* controlled dangerous substances?

Yes. In order to *prescribe* controlled dangerous substances, you need to obtain both the registration issued by the state Office of Controlled Substances Administration (OCSA) and the registration issued by the federal Drug Enforcement Administration (DEA). Neither of these registrations is handled by the Board. Contact these agencies directly to obtain these registrations. Links to these agencies' websites are:

OCSA: <https://health.maryland.gov/OCSA/Pages/home.ASPX>

DEA: <https://www.deadiversion.usdoj.gov/>

ROLE OF THE BOARD OF PHYSICIANS

9. Do these FAQs set out everything I need to know about dispensing?

No. These questions cover only some basic information about how the Board's permit program works, as well as the definition of dispensing and some basic principles.

10. Will the Board staff be able to give me advice from time to time on how the pharmaceutical laws and regulations should be applied to my dispensing operation?

No. The Board is not authorized to, nor does it, give legal advice. The Board can provide guidance only about the requirements of its own dispensing regulations found at COMAR 10.32.23. Detailed questions about how any pharmacy laws or regulations apply to your situation should not be addressed to the Board but to a person or organization knowledgeable in that area.

EDUCATIONAL REQUIREMENTS

11. Are there any formal educational requirements for obtaining a dispensing permit for the first time?

No. However, all dispensers are required to demonstrate a basic knowledge of the statutes and regulations governing the practice of dispensing prescription drugs.

12. Are there any educational requirements for renewing a permit?

Yes. A permit cannot be renewed unless you have completed ten continuing education credits over the past five years related to the preparing and dispensing of prescription drugs offered by the Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary of the Maryland Department of Health.

FEES

13. What is the fee for a dispensing permit?

The fee is \$1,050 for a five-year permit. This fee is not refundable.

14. Where does my money go?

The Board is required by §12-102.2 of the Health Occupations Article to charge a fee that will approximate the costs of the inspections performed by OCSA. The Board pays \$1,000 from each dispensing permit application to the General Fund of the State to cover the cost of OCSA's inspections and retains \$50 as a processing fee.

15. Do I need a dispensing permit for each location at which I dispense drugs?

No. Permits are issued to the dispenser and not to each dispensing location. However, you must list each location on your dispensing application, and you must keep a copy of the dispensing permit available at each dispensing location.

LEGAL AUTHORIZATION AND REQUIREMENTS

16. Where are the laws found that govern the dispensing of prescription drugs?

An extensive set of laws and regulations govern the dispensing of drugs.

- a. The Maryland Pharmacy Act, Health Occupations Article, Title 12, §12-102, authorizes dispensing by physicians and also sets out the requirements a physician dispenser must meet. The Maryland Department of Health's regulations at COMAR 10.13.01 and the Board's regulations at COMAR 10.32.23 further set out these specific dispensing requirements.

- b. Other state regulations govern labeling and packaging for controlled dangerous substances (COMAR 10.19.03.04); recording, reporting and inventory requirements (COMAR 10.19.03.05); and prescription and dispensing requirements (COMAR 10.19.03.07).
- c. Title 5 of Maryland’s Criminal Law Article and federal statutes and regulations govern the dispensing of and recordkeeping for controlled dangerous substances.

17. What general legal requirement must be met before I may dispense medications to any particular patient?

Your dispensing must be “in the public interest.” *See* Health Occupations Article §12-102(c)(2)(ii)1B. You may not dispense any medications unless and until you are granted a permit by the Board. (Remember that there are four exceptions to the requirement of a dispensing permit. These are set out in FAQs 3 through 6.)

18. What does “in the public interest” mean?

By law, “in the public interest” means that a pharmacy is not conveniently available to the patient. *See* Health Occupations Article, §12-102(a)(2).

19. Do I determine whether a pharmacy is conveniently available to each patient?

No. The patient makes that determination.

20. By signing the application, will I be attesting that I am familiar with the legal requirements for dispensing drugs and will comply with those requirements?

Yes. You will be responsible for being familiar the applicable pharmacy and dispensing laws and regulations and for complying with them.

RECORDKEEPING REQUIREMENTS; SIGNAGE

21. Are there certain recordkeeping and signage requirements with respect to the patient’s determination that a pharmacy is not conveniently available?

Yes. The requirements are as follows:

- a. A sign must be prominently displayed informing the patients that prescriptions can be purchased from the permit holder only if the patient determines that a pharmacy is not conveniently available to the patient;

- b. The sign also must describe the process for resolving incorrectly filled prescriptions, unless each patient is individually given a written document that describes the process for resolving incorrectly filled prescriptions; and
- c. For each patient for whom prescription drugs are dispensed, the patient's chart must contain a single form signed by the patient documenting that the patient has determined that a pharmacy is not conveniently available.

22. What must be included on the patient form documenting the patient's determination that a pharmacy is not conveniently available?

At a minimum, the form must:

- a. Include a statement that the patient understands that the determination of whether a pharmacy is conveniently available can be made only by the patient;
- b. Indicate the reason, as stated by the patient, that a pharmacy is not conveniently available to the patient; and
- c. Be signed and dated by the patient.

BASIC PHARMACEUTICAL INFORMATION

23. What are controlled dangerous substances?

Controlled dangerous substances (CDS) are divided into five categories: Schedules I, II, III, IV, and V.

- a. Substances in Schedule I have no accepted medical use in the United States and a high potential for harm even when taken under medical supervision. Examples of substances in Schedule I are heroin and mescaline.
- b. Substances in Schedule II have a currently accepted medical use in the United States but also a high potential for abuse which may lead to severe physical or psychological dependence. Examples of Schedule II drugs are hydrocodone and oxycodone.
- c. Substances in Schedule III have a well-documented and approved medical use in the United States, a potential for abuse less than those substances listed in Schedules I and II, and may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III substances are testosterone, ketamine and marinol.

- d. Substances in Schedule IV have a lower potential for abuse than Schedule III substances, a currently accepted medical use in the United States, and may lead to limited physical or psychological dependence relative to Schedule III substances. Examples of Schedule IV substances are diazepam, zolpidem, carisprodol and phentermine.
- e. Substances in Schedule V are currently accepted for medical use in the United States, have a low potential for abuse compared to Schedule IV substances, and may lead to limited physical or psychological dependence compared to substances in Schedule IV. An example of a Schedule V substance is Robitussin AC.

24. Are the storage and record keeping requirements for CDS the same as for other prescription drugs?

No. Federal law establishes special recordkeeping and storage requirements for CDS. In addition, Schedule II substances have special recordkeeping requirements over and above those required for Schedule III through V substances. For example, separate records must be kept of all Schedule II prescriptions, and invoices for Schedule II drugs must be kept separately. You are responsible for this aspect of dispensing.

25. Are there any special inventory requirements for keeping CDS?

Yes. There must be a biennial inventory of all CDS.

26. Must my dispensary limit access to its inventory of stored drugs?

Yes. The inventory of stored drugs must be secured at all times so that it may be accessed only by authorized personnel.

27. How long must prescriptions be kept on file?

By law, records for all prescriptions must be kept for five years. Certain payors may require a longer period of retention.

28. May I dispense drugs to anyone in the absence of a written prescription?

No. A written prescription must be provided to the patient prior to dispensing.

29. May I refill a prescription?

No. You may dispense additional drugs only if a new prescription is written.

30. May I fill prescriptions by mail with my dispensing permit?

No.

31. When must my dispensary be locked?

Your dispensary must be physically secure against access by unauthorized persons at all times.

32. Do I have to keep records of who supplied the drugs to my dispensary?

Yes. You need to keep on file the number and expiration date of your wholesale supplier's distribution permit (or pharmacy permit if you are receiving your drugs from a pharmacy) and the number and expiration date of the CDS registration issued by OCSA. You must be able to produce these records during the course of an unscheduled on-site inspection.

33. If I run out of my regular supply of a drug in my dispensary, may I gather together a manufacturer's samples and sell them?

No, you may not charge for a manufacturer's samples.

34. If a patient wants to return a medication previously dispensed, do I have to take it back?

No. It is a violation of law to take back CDS. And taking back any other dispensed medication is also prohibited except in the very limited circumstances set out in the pharmacy regulations at COMAR 10.34.10.07. That regulation does not require you to take back any drugs in any instance. You may advise patients that there are repositories around the state, including many police stations and pharmacies that accept excess drugs.

35. If a patient wants to return just the unused portion of a drug that I previously dispensed, do I have to take it back?

No. You should not take back any unused portions of any medications. You may advise patients of repositories available for this purpose.

DISPENSING FOR OTHERS

36. May I dispense drugs to fill prescriptions written by another physician?

No.

37. May I dispense drugs to fill a prescription written by a physician assistant (PA)?

Yes, in the following circumstances:

- (1) You must be the supervisor or alternate supervisor of the PA according to an approved delegation agreement with the Board;
- (2) The delegation agreement must authorize the PA to prescribe that drug;
- (3) The delegation agreement must be readily available for inspection at the site where you dispense; and
- (4) You cannot dispense a drug that you yourself cannot prescribe.

38. May I dispense a prescription written by a certified registered nurse practitioner?

Yes, in the following circumstances:

- (1) The certified registered nurse practitioner must be authorized to prescribe the drug under the Health Occupations Article, Title 8, Annotated Code of Maryland (the Maryland Nurse Practice Act);
- (2) The certified registered nurse practitioner must be working with you in the same office setting;
- (3) A record of the certified registered nurse practitioner's name, license number, and specialty must be readily available for inspection at the site where you dispense; and
- (4) You cannot dispense a drug that you yourself cannot prescribe.

DELEGATION OF DISPENSING FUNCTIONS

39. May I delegate my duties as a dispenser to another person?

Yes. You may delegate the "mechanical acts" of the dispensing process to another person, including an unlicensed person.

40. What is a "mechanical act?"

A mechanical act is an act which does not require professional judgment or medical or pharmaceutical training or the use of discretion in the filling of prescriptions.

41. What are some examples of mechanical acts?

Examples of mechanical acts are placing the completed, labeled prescription in a bag, handing the labeled and closed container to the patient, and collecting payment for the prescription.

42. Are there any dispensing activities that the Board has determined are not mechanical acts and cannot be delegated to an unlicensed person?

Yes. The following cannot be delegated to an unlicensed person:

- a. Selecting the drug;
- b. Measuring a drug, or interpreting any prescription that requires calculating dosages;
- c. Labeling the container in which the drug is dispensed;
- d. Interpretation of a prescription in order to change the route of administration, for example from tablet form to liquid form;
- e. Substitution of a drug, for example from generic to name-brand or vice-versa;
- f. Patient counseling; and
- g. Performing the final check.

43. If I delegate a mechanical act to another person, am I still responsible for the successful completion of that mechanical act?

Yes.

THE FINAL CHECK

44. What is the final check?

The final check means the verification of the accuracy and completeness of a filled prescription, including the verification of the appropriateness of the dose, the accuracy of the drug dispensed, the strength of the drug dispensed, the accuracy of the expiration date, the correct labeling, and the appropriateness of the container in which the drug is dispensed, including child-proof containers where applicable.

45. Does the final check include making sure that the expiration date is on the label?

Yes.

46. May I perform the final check by phone or video or internet communication?

No. You must perform the final check in person.

47. Must I document that I made the final check?

Yes. You must sign or initial that you made the final check.

48. May I counsel the patient about proper drug usage and possible drug side effects?

Yes. In fact, only you may counsel the patient about the use of the drug.

49. Must I record the dispensing of the prescription drug in the patient's chart?

Yes.

50. Must I inform each patient individually that the patient has the choice of filling the prescription either at a pharmacy or at my dispensary?

Yes.

INSPECTIONS

51. Am I required to allow the Maryland Office of Controlled Substances Administration (OCSA) to inspect the operations of my dispensary?

Yes. You must allow inspections at all reasonable hours.

52. Do I have to do anything when there is an inspection?

Yes. You must:

- a. Assure that the inspectors have access to your drug inventory and to all required records; and
- b. Sign the inspection report at the time of the inspection.

53. What if I do not agree with OCSA's inspection report?

Your signature means only that you have received a copy of the document.

54. What if I am not at the location when OCSA conducts the inspection?

You must designate someone to be available to sign the inspection form at each location at which you dispense, and at all regular office hours.

55. What is the possible consequence of refusing to sign an inspection report?

Refusing may be grounds for revocation of your permit.

DISPENSING FOR OTHERS

56. May I dispense drugs prescribed by others?

Yes, in certain circumstances. You may dispense a drug based on a prescription written by:

- a. A physician assistant with whom you have a delegation agreement that permits prescribing that drug; and
- b. A certified registered nurse practitioner who works with you in the same office setting and who is authorized by the Board of Nursing to prescribe that drug.

57. Are there any restrictions on dispensing the prescriptions written by these physician assistants and certified registered nurse practitioners?

Yes.

- a. You may not dispense a drug that you are not authorized to prescribe yourself.
- b. You must at all times keep available for inspection at each location where you dispense:
 - i. The names of all certified registered nurse practitioners for whom you dispense at that location; and
 - ii. The names and the delegation agreements of all physician assistants for whom you dispense at that location.
 - iii. As with any other dispensing, you are responsible for the dispensing process and must perform at least the final check before the drugs are dispensed.

58. Are there any additional special requirements when dispensing for physician assistants or certified registered nurse practitioners?

Yes. You must ascertain that the patient was informed individually by the prescriber, or you must inform the patient yourself, that the patient has the choice of filling the prescription either at a pharmacy or at your dispensary.

59. Can my dispensing location be different from my official contact address that I have listed on my Board profile?

Yes. You may dispense at a location different from your contact address. The dispensing application includes a place to list your dispensing location or locations. You may dispense only from those dispensing locations you have listed on your application.

SPECIAL REPORTING REQUIREMENTS; ADDRESSES

60. If I wish to change the location at which I dispense, do I have to notify the Board of that change?

Yes. If you change your dispensing location, you must notify the Board. This change must be done by sending an email to the Board at MDH.mbpdrugdispense@maryland.gov.

61. May I likewise change my official contact address with the Board by simply sending an email to that address?

No. Your official contact address is the address you listed on your profile on the Board's website. The law requires you to keep your official contact address updated.

62. How do I update my official contact address with the Board?

At the Board's website at www.mpb.state.md.us:

- Click on "Update your Profile" on the homepage.
- Go to "Are you a licensed practitioner and need to create/edit your profile information?"
- Enter your license number and click submit.
- Go to your personal profile and change your contact address there.

63. What are the possible consequences of failing to update my addresses?

The Medical Practice Act requires that you report to the Board any change of your address. That law provides that you may be fined for failing to do so.

The dispensing regulations require that you keep your address updated. Your dispensing permit will lapse if you fail to report any change in your address without good cause.

64. Besides keeping both addresses updated, are there any other reporting requirements?

Yes. You must report each year on the anniversary date of your permit whether you have dispensed prescription drugs in the past year. The Board will send you an email reminder of this requirement.

65. Is this simply a “yes” or “no” report?

Basically, yes.

66. What happens if I fail to submit this yearly report?

Your permit will lapse if without good cause you fail to submit the report within 15 days of your anniversary date.

67. Why is this report needed?

This report is needed so that the Office of Controlled Substances Administration can determine at which locations drugs are actually being dispensed.

68. If I report that I have not dispensed in the past year, can I ever start dispensing again?

Yes, you may start dispensing again, but only after you notify the Board at MDH.mbpdrugdispense@maryland.gov prior to resuming dispensing. Resuming dispensing without notifying the Board is grounds for revocation of the permit.

69. What if I originally applied for a permit for two locations but I dropped one of these locations? Do I have to report this?

Yes. It is important that an inactive location be removed from the record so that inspections may be carried out efficiently. This should be reported as a change of location. You may change locations twice during the period of the permit without charge.

70. Can I reinstate my permit if it lapses?

No. A lapsed permit may not be reinstated. If you wish to begin dispensing again, you must apply for a new permit, which includes paying the fee.

71. Do I have to turn in my permit if I change employers?

No. The permit belongs to the permit holder, not the employer. If you have changed employment but still wish to dispense at a different location, you must notify the Board that you are changing your dispensing location. You may change this location twice during the period of the permit without charge.

FREQUENTLY ENCOUNTERED DRUG DISPENSING ISSUES

72. What is the longest period of time that can pass before a dispensed prescription drug expires in Maryland?

A prescription drug expires on the date indicated by the manufacturer or one year from the date it is dispensed, whichever is earlier.

73. Why must I keep track of the lot number of a drug obtained from a stock bottle or other larger container?

Drug manufacturers sometimes recall their drugs because of contamination, errors in manufacturing, or discoveries of unexpected side effects. Pharmacies and dispensaries must have the capability of contacting patients to whom these drugs have been dispensed.

74. If I receive a notice from a manufacturer that a drug has being recalled, do I have any obligation toward the patient?

In most cases, no. However, if the manufacturer issues a “patient level” recall, you have an obligation to track down the patient and give the patient the information provided to you by the manufacturer. In order to be able to do this, you must have in place a system for tracking the lot numbers from which individual prescriptions have been filled.

THE PRESCRIPTION DRUG MONITORING PROGRAM

75. What is the Prescription Drug Monitoring Program (PDMP)?

The PDMP is a system of professional communication by which health care professionals share data on the dispensing of Schedule II through Schedule V controlled dangerous substances (CDS) in order to curb the incidents of overdose deaths. More information about the PDMP can be found at:

<https://bha.health.maryland.gov/pdmp/Pages/Home.aspx>

All prescribers and dispensers are required to be registered with the PDMP. Prescribers are also required to access the PDMP when prescribing CDS, unless certain special circumstances apply. Dispensers are required to report to the PDMP any dispensing of any CDS. Contact the PDMP if you are unsure about the PDMP requirements.

76. If I dispense my own prescriptions for Schedule II through Schedule V drugs, do the requirements of the PDMP apply to me in both capacities?

Yes. As a prescriber, you must be registered with the PDMP, and you must access the PDMP database when prescribing CDS. As a dispenser, you must report the dispensing of any CDS to the PDMP within 24 hours of dispensing or be subject to a \$500 fine for each violation.

77. If I dispense prescriptions written by a physician assistant or a certified registered nurse practitioner, does the PDMP apply to me?

Yes. As the dispenser, you must comply with the PDMP.