

Frequently Asked Questions

DISPENSING PRESCRIPTION DRUGS BY A PHYSICIAN ASSISTANT

1. What is dispensing?

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

- a. Interpreting the prescription;
- b. Selecting and labeling of the drug; and
- c. Measuring and packaging of the drug.

These are tasks most often performed by a pharmacist.

2. What authorization does a Physician Assistant need to dispense drugs?

In order to dispense drugs, a Physician Assistant must have, as part of a delegation agreement, both: (1) prescriptive authority; and (2) Board approval of the advanced duty of dispensing drugs.

3. Do I need Board approval of the advanced duty of dispensing drugs to give a patient free samples of a drug provided by a manufacturer?

No. A Physician Assistant who has prescriptive authority may dispense free manufacturer's sample packets of prescription drugs they prescribe. Board approval of the advanced duty of dispensing drugs is not required for this duty.

4. Do I need Board approval of the advanced duty of dispensing drugs in order to hand out free starter dosages of 72 hours of medication or less?

No. A Physician Assistant who has prescriptive authority may dispense starter doses of medication prescribed by that Physician Assistant without Board approval of the advanced duty of dispensing drugs.

5. What is "administering" a drug?

Handing a single dose of a drug to a patient for immediate consumption, or injecting a drug, is called "administering" a drug.

6. Do I need Board approval of the advanced duty of dispensing drugs to administer a drug?

No. Administering a drug is not dispensing. If your delegation agreement gives you prescriptive authority, you may administer a drug that you have the authority to prescribe without further Board authorization.

7. Do I need Board approval of the advanced duty of dispensing drugs to provide an IV infusion or inhalation therapy in my office or clinic?

No. A Physician Assistant who directly applies therapies of any kind to the patient while the patient is in the office or clinic is “administering,” not dispensing. A Physician Assistant who otherwise has the authority, through a delegation agreement, to prescribe in this manner does not need any further authorization from the Board.

8. Do I need Board approval of the advanced duty of dispensing drugs in order to *prescribe* controlled dangerous substances such as oxycodone, diazepam, and phentermine?

No. Prescribing is not dispensing. You do not need Board approval of the advanced duty of dispensing drugs to *prescribe* controlled dangerous substances. You do, of course, need prescriptive authority under a delegation agreement to do so.

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

Yes. First, you need to be delegated prescriptive authority in your delegation agreement. In addition, if you wish 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

10. 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 dispensing program works, as well as the definition of dispensing and some basic principles.

11. 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 the dispensing operation at which I work?

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.

REQUIREMENTS

12. What do I need in order to apply for Board approval of the advanced duty of dispensing drugs?

In order to apply for this advanced duty, you must have:

- (1) Practiced under the supervision of your primary supervising physician (PSP) for at least 90 days;
- (2) Operated for one year under a delegation agreement that grants you prescriptive authority;
- (3) Dispensed prescription drugs at least 25 times under the direct, in-person supervision of your PSP who possesses an active dispensing permit; and
- (4) Demonstrated to your PSP a basic knowledge of the statutes and regulations governing the practice of dispensing prescription drugs.

In addition, the Physician Assistant's PSP must have an active dispensing permit, and a Physician Assistant must meet the requirements in the regulations such as good moral character.

13. Do I need a separate Board approval for each location at which I dispense drugs?

No, but you may dispense only at those locations on your Board-approved delegation agreement and where your primary supervising physician is authorized to dispense.

LEGAL AUTHORIZATION AND REQUIREMENTS

14. Where can I find the laws that govern the dispensing of prescription drugs?

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

- a. The Maryland Pharmacy Act, Health Occupations Article, §12-102, among other statutory provisions and Board of Pharmacy regulations, authorizes dispensing by physicians and also sets out the requirements for dispensing. 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.

15. 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.

16. 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).

17. Does my primary supervising physician determine whether a pharmacy is conveniently available to each patient?

No. The patient makes that determination.

18. By signing the application for advanced duties, 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 with the applicable pharmacy and dispensing laws and regulations and for complying with them.

RECORDKEEPING REQUIREMENTS; SIGNAGE

19. 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 patients that prescriptions may 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 to 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.

20. 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

21. What are controlled dangerous substances (CDS)?

CDS are divided into five categories: Schedules I, II, II, 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.

22. 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.

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

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

24. 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.

25. 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.

26. May I refill a prescription?

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

27. May I dispense prescriptions by mail order?

No.

28. May I dispense a prescription that my primary supervising physician is not authorized to prescribe?

No.

29. May I dispense a prescription that my primary supervising physician is not authorized to dispense?

No.

30. May I dispense a prescription that my alternate supervision physician has written?

No.

31. May I dispense a prescription written by another Physician Assistant who is supervised by the same primary supervising physician as me?

No.

32. When must my dispensary be locked?

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

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

No. You are not required 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. Taking back dispensed medication is prohibited except in the very limited circumstances set out in the pharmacy regulations at COMAR 10.34.10.07.

34. 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 are not required to take back any unused portions of any medications. You may advise patients of safe medication disposal boxes that are available in most pharmacies for this purpose.

DISPENSING FOR OTHERS

35. May I dispense drugs to fill prescriptions written by a physician who is not my primary supervising physician?

No.

36. May I dispense drugs to fill a prescription written by anyone other than myself or my primary supervising physician?

No.

DELEGATION OF DISPENSING FUNCTIONS

37. May I delegate my duties involved in dispensing to another individual?

No.

THE FINAL CHECK

38. 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.

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

Yes.

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

No. You must perform the final check in person.

41. Must I document that I completed the final check?

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

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

Yes. In fact, only you or your primary supervising physician may counsel the patient about the use of the drug.

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

Yes.

44. 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

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

Yes. A permit holder must allow inspections at all reasonable hours. If you are delegated dispensing pursuant to a Board-approved delegation agreement for advanced duties, the requirements that apply to the permit holder will also apply to any Physician Assistant dispensing under the primary supervising physician's permit.

DISPENSING FOR OTHERS

46. May I dispense drugs prescribed by anyone besides myself or my primary supervising physician?

No.

FREQUENTLY ENCOUNTERED DRUG DISPENSING ISSUES

47. What is the longest period of time that can pass before a 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.

48. 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 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.

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

In most cases, no. However, if the manufacturer issues a “patient level” recall, you have an obligation to notify 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 a system for tracking the lot numbers from which individual prescriptions have been filled.

THE PRESCRIPTION DRUG MONITORING PROGRAM

50. 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.

51. If I write prescriptions for Schedule II through Schedule V drugs and dispense those 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 3 calendar days of dispensing or be subject to a \$500 fine for each violation.

THE APPLICATION FOR THE ADVANCED DUTY OF DISPENSING

52. Will the application require me to demonstrate that I have good moral character? If so, how?

Yes. You will be required to answer the same or similar questions you answered in order to obtain your license, such as whether you have been convicted of any crimes or are currently under arrest. These are “yes” or “no” questions that cover the period of time since you last applied for or renewed your license.

53. Are there any situations that will automatically disqualify me from being approved for the advanced duty of dispensing?

Yes. The advanced duty of dispensing will not be approved if your license is currently suspended, on probation, if you have been sanctioned in Maryland or any other jurisdiction for certain violations related to drug use or misuse, or if your CDS or DEA registration has been revoked, suspended, or surrendered under certain circumstances. In addition, you must demonstrate that you are of good moral character at the time of your application.