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 in accordance with federal and State laws.

These are tasks most often performed by a pharmacist.

2. Do I need Board approval to dispense prescription drugs?

In order to obtain the full authority to dispense drugs, a Physician Assistant must have, as part of a delegation agreement, both: (a) Prescriptive authority; and (b) Board approval of the advanced duty of dispensing prescription drugs.

3. What is full dispensing authority?

Full dispensing authority means the authorization to conduct the entire process of dispensing prescription drugs, including the final check.

4. 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 the Physician Assistant prescribes. Board approval of the advanced duty of dispensing prescription drugs is not required for this duty.

5. 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 prescription drugs, assuming that the supervising physician approves.
6. 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.

7. 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 includes prescriptive authority, you may administer a drug that you have the authority to prescribe without further Board authorization, assuming your supervising physician approves.

8. 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 Board-approved delegation agreement, to treat a patient in this manner does not need any further authorization from the Board.

9. Do I need Board approval of the advanced duty of dispensing drugs in order to prescribe controlled dangerous substances (CDS) 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 CDS. You do, of course, need prescriptive authority under a Board-approved delegation agreement to do so. Also see Question 10.

10. Do I need any further authorization in order to prescribe controlled dangerous substances (CDS)?

Yes. First, you need to be delegated prescriptive authority in your Board-approved delegation agreement. In addition, if you wish to prescribe CDS, you need to obtain both the registration issued by the Maryland 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/

11. Do I need Board approval of the advanced duty of dispensing drugs if I am delegated only parts of the dispensing process?

No. Your primary supervising physician may delegate to you parts, but not all, of the dispensing process without obtaining Board approval of the advanced duty of dispensing prescription drugs.

12. Which parts of the dispensing process may my supervising physician delegate to me without obtaining Board approval of the advanced duty of dispensing?

Your primary supervising physician may delegate to you, without obtaining Board approval of the advanced duty of dispensing, all parts of the dispensing process except the final check. See questions 44 to 50 for a description of the final check. Full dispensing authority, which includes the final check, may be delegated only after Board approval of the advanced duty of dispensing prescription drugs.

ROLE OF THE BOARD OF PHYSICIANS

13. 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.

14. 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.
15. What requirements must I meet to qualify for Board approval of the advanced duty of dispensing prescription drugs?

In order to qualify for this advanced duty, you must have: (a) Practiced under the supervision of your primary supervising physician (PSP) for at least 90 days; (b) Operated for at least one year under a Board-approved delegation agreement that grants you prescriptive authority; (c) Dispensed prescription drugs at least 25 times under the direct, in-person supervision of your PSP who possesses an active dispensing permit; and (d) 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 any additional regulatory requirements, such as good moral character.

16. Do I need a separate Board approval for each location at which I intend to dispense prescription drugs?

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

17. Will the Board’s 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.

18. 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 Maryland CDS or Drug Enforcement Administration registration has been revoked, suspended, or surrendered under certain circumstances.
LEGAL AUTHORIZATION AND REQUIREMENTS

19. 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 authorize dispensing by physicians and set 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. The Board’s regulations regarding Physician Assistants are at COMAR 10.32.03.

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.

20. What general legal requirement must be met before I may dispense prescription drugs to any particular patient?

Your dispensing must be “in the public interest.” See Health Occupations Article, §12-102(c)(2)(ii)1B.

21. 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).

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

No. The patient makes that determination.
23. By signing the application for the advanced duty of dispensing prescription drugs, 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.

24. 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.

25. May I refill a prescription?

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

26. May I dispense prescriptions by mail order?

   No.

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

   No.

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

   No.

   RECORDKEEPING REQUIREMENTS

29. Are there certain record keeping requirements with respect to the patient’s determination that a pharmacy is not conveniently available?

   Yes. 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.

30. 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 clearly explaining to the patient 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.

31. **Must this form be completed every time the patient is given a prescription?**

   No, but each time a prescription is written, the patient must be given a choice as to where to fill the prescription.

32. **Are there certain record keeping requirements with respect to the patient’s written prescription?**

   Yes. All medical charts or records require a notation of any prescriptions written or dispensed by a physician assistant in accordance with Health Occupations Article, §15-302.2, Annotated Code of Maryland.

**BASIC PHARMACEUTICAL INFORMATION**

33. **What are controlled dangerous substances (CDS)?**

   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 of 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.

34. Are the storage and record keeping requirements for controlled dangerous substances (CDS) the same as for other prescription drugs?

No. Federal law establishes special record keeping and storage requirements for CDS. In addition, Schedule II substances have special record keeping 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.

35. Are there any special inventory requirements for keeping controlled dangerous substances (CDS)?

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

36. Must the 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.

37. When must the dispensary be locked?

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

38. Do I have to accept a previously dispensed drug that a patient wishes to return?

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

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**

40. May I dispense drugs to fill prescriptions written by a physician other than my primary supervising physician, such as my alternate supervising physician?

No.

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

No.

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

No.

**DELEGATION OF DISPENSING FUNCTIONS**

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

No.
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, video, or internet communication?

No. You must perform the final check in person.

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

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

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

Yes.

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 where to fill the prescription?

Yes.

INSPECTIONS BY THE MARYLAND OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION (OCSA)

51. Is my primary supervising physician required to allow OCSA to inspect the operations of the dispensary where I work?

Yes. A permit holder must allow OCSA inspections at all reasonable hours.
52. Am I required to allow OCSA to inspect the operations of the dispensary where I work?

Yes. OCSA can enter and inspect a dispensing facility at all reasonable hours. You, your primary supervising physician (PSP), or your PSP’s designated representative must be available at all times to sign an acknowledgment that the inspection took place.

FREQUENTLY ENCOUNTERED DRUG DISPENSING ISSUES

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

A prescription drug expires on the earliest of these three dates: (a) The date indicated by the manufacturer; (b) One year from the date the drug is dispensed; or (c) The date indicated by the prescriber.

54. 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.

55. If I receive a notice from a manufacturer that a drug has been 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.
56. What is the 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 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

57. Does the PDMP place obligations on both prescribers and dispensers?

Yes. All prescribers and dispensers are required to be registered with the PDMP.

Prescribers also are 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.

58. 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 24 hours of dispensing or be subject to a $500 fine for each violation.