

Oregon Medical Board Oregon Board of Pharmacy



Drug Dispensing Training Program
for Physician Assistants
2012

Why this Training?

- A supervising physician or supervising physician organization may apply to the Oregon Medical Board (OMB) for authority for a physician assistant (PA) to dispense certain prescription drugs. (2012 Oregon Law Chapter 34)
- By law, the PA must complete a training program jointly adopted by the OMB and the Oregon Board of Pharmacy (OBOP) prior to being granted general dispensing authority.
- At the end of the training program, you, the PA, will be asked to attest with your signature that you completed this training. You must send your attestation to the OMB.

What is Dispensing?

“Dispense” or “dispensing” means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.



Supervising Physician Requirements

Prior to dispensing any prescription drug, a qualified PA must be granted dispensing authority by the OMB. This requires:

- The supervising physician or supervising physician organization must register each facility from which the PA will dispense with the OBOP as a Supervising Physician Dispensing Outlet (SPDO);
- The supervising physician must submit a plan for drug delivery and control, an annual report on the PA's dispensing, and a list of drugs or classes of drugs the PA will dispense;
- Dispensing duties must be properly delegated in the Practice Agreement.

Supervising Physician Dispensing Outlet (SPDO)

- Each SPDO must have a designated supervising physician and must retain a pharmacist licensed in Oregon for consultation purposes.
- The supervising physician and the consulting pharmacist must develop and maintain policies and procedures to address all aspects of drug dispensing, including but not limited to acquisition, storage, integrity, security, access, disposal and recordkeeping.
- If an outlet has a change in their supervising physician or consultant pharmacist, it must appoint a new individual and notify the Board of Pharmacy in writing within 15 days.

Controlled Substance Registration

Prior to dispensing a Controlled Substance, the PA and the SPDO must obtain a controlled substance registration with the U.S. Drug Enforcement Administration and with the Oregon Board of Pharmacy.



Physician Assistant Dispensing Qualifications

- The PA must have prescribing privileges; and
- The PA must be in good standing with the OMB and the National Commission for the Certification of Physician Assistants (NCCPA).

Limitations on Dispensing

Under this dispensing law:

- The PA may only dispense the drugs or classes of drugs listed in the Practice Agreement.
- The PA may not dispense Schedule II-IV Controlled Substances.

Drug Samples

- Distribution of properly packaged and labeled pharmaceutical manufacturer's drug samples is not "dispensing."
- PAs may personally provide FDA-approved drug samples to their patients.

The Six "Rights" of Drug Dispensing

Verify Correct:

Patient

Drug

Dose

Dosage Form

Directions
for Use

Information

Drug Utilization Review

- Prior to dispensing a medication, a drug utilization review (DUR) must be performed by the PA including, at a minimum, potential drug interactions, drug allergies and duplicate drug therapy.
- As part of the DUR, the physician assistant must:
 - Evaluate the patient's current condition; and
 - Review the patient's current record.

Counseling

Prior to dispensing a medication, the physician assistant must provide:

- Professional advice to the patient or the patient's agent regarding the safe and effective use of the drug for the purpose of assuring appropriate therapeutic outcomes.
- Oral counseling to the patient concerning all prescriptions, unless circumstances indicate another form of counseling would be more effective.

Labeling

A prescription container must be labeled with:

- Name of patient;
- Name of prescriber;
- Date of dispensing;
- Name, address and phone number of the clinic;
- Name, strength and quantity of the drug;
- Unique identifier (number);
- Directions for use;
- Initials of the person dispensing;
- Cautionary statements, if any, as required by law;
- Manufacturer's expiration date; and
- Prescription Identification Label (PIL).



Prescription Identification Label (PIL)

Any dispensed medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description (Prescription Identification Label or PIL), including color, shape and any identification code that may appear on tablets and capsules.



Drug Containers

- Drugs must be dispensed in new containers that comply with the current provisions of the Poison Prevention Packaging Act and with the current U.S. Pharmacopoeia National Formulary (USP NF) monographs for packaging, storage and labeling.
- Drugs must be prepackaged by a pharmacy or manufacturer registered with the Oregon Board of Pharmacy.

Written Patient Information

When dispensed, a drug must be accompanied by written patient information that contains at least the following information:

- Drug name and class;
- Common uses of the drug;
- Proper use and storage;
- Common side effects;
- Precautions & contraindications; and
- Significant drug interactions.

Written Patient Information Cont.

When dispensed, and when required by the FDA, a drug must be accompanied by the appropriate Medguide available on the FDA website.

<http://www.fda.gov/drugs/drugsafety/ucm085729.htm>

Required References

The current updated edition of at least one standard pharmaceutical reference must be accessible. For example:

- Drug Facts & Comparisons
- American Hospital Formulary Service: *Drug Information*
- United States Pharmacopeia, Drug Information (USPDI)
- Micromedex

Drug Storage Area Must Have:

- Proper sanitation;
- Temperature control;
- Moisture control;
- Adequate ventilation; and
- Any other condition recommended by the manufacturer.



Security of Drugs

- Drugs must be stored in a securely locked cabinet or designated drug storage area when not in use and accessible only to authorized personnel.
- Drugs must be located in an area that prevents access by unauthorized individuals.



Previously Dispensed Drugs

- Previously dispensed drugs may not be accepted for return or reuse.
- A previously dispensed prescription may be refilled only if it is personally dispensed by the PA or supervising physician after consultation with the patient.

Drug Disposal

Drugs that are recalled, outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs until they are:

- Returned to your registered wholesaler for destruction; or
- Sent to a Reverse Distributor; or
- Taken to a collection location for unwanted and unused drugs.

Drug Disposal Cont.

The outlet must maintain a list of sites in Oregon where drugs may be disposed. The updated list of locations is available on the Board of Pharmacy website at

www.pharmacy.state.or.us/pharmacy/Imports/ORUnwantedDrugDropOffSites.pdf

Expedited Partner Therapy

When a drug is dispensed in the practice of an *Expedited Partner Therapy* treatment protocol, a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice. The partner's name may be omitted from the label and from the records.

Who is Responsible for Records?

- The Supervising Physician, in collaboration with the Consulting Pharmacist, is responsible for maintaining recordkeeping and drug security.
- The PA is responsible for documenting his or her actions in the appropriate record.

Recordkeeping

All drug dispensing & purchasing records must be:

- Maintained at the facility;
- Kept separate from the patient chart;
- Recorded legibly in ink or electronically;
- Retained on site for three years;
- Made readily available for review by the Board of Pharmacy and the Medical Board.



Dispensing Record

A dispensing record must be maintained separately from the patient chart. The record must include the following:

- Name of patient;
- Drug name (either the brand name or generic name with manufacturer or distributor);
- Dose, dosage form and quantity;
- Date dispensed; and
- Initials of person dispensing prescription.

Records of Purchase

- Records of drug purchases shall be maintained at the facility and readily available for Board of Pharmacy inspection.
- Purchases of controlled substances must be maintained separately from other purchases.
- Include Oregon Board of Pharmacy license number of distributor.
- If a distributor is not registered with the Board of Pharmacy, they are not allowed to distribute drugs into or within Oregon.

Consulting Pharmacist

YOUR CONSULTING PHARMACIST IS A VALUABLE RESOURCE

The consulting pharmacist is available to you for questions or concerns on matters of drug availability, drug therapy and procedures for drug acquisition, storage, integrity, security and dispensing. Call on your pharmacist whenever you have questions or concerns.

Prescribing and Dispensing Errors

- The Supervising Physician and Consulting Pharmacist must establish a Quality Assurance (QA) procedure. All prescribing and dispensing errors must be addressed through the established QA procedure.
- Prescribing and dispensing errors should be reported to the FDA's *MedWatch* or the ISMP's Medication Error Reporting Program, *MERP*.

Required Reading

The following is a list of required reading. You will be asked to attest that you have read these.

- 2012 Oregon Laws Chapter 34
<http://www.leg.state.or.us/12orlaws/0034ss.pdf>
- OAR Chapter 855, Divisions 19, 41 (sections 0017 through 0103), and 43: *Pharmacy Administrative Rules*
http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_tofc.html
- OAR Chapter 847, Division 050: *Physician Assistant Administrative Rules*
http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_847/847_050.html

Required Reading Cont.

- 21 CFR 1306: *Prescriptions*
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title21/21cfr1306_main_02.tpl
- Food Drug & Cosmetic Act: *Chapter V Part A – Drugs & Devices (Sections 501-506C only)*
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugandDevices/default.htm>
- Poison Prevention Packaging Act: *A Text for Healthcare Professionals*
<http://www.cpsc.gov/cpsc/pub/pubs/384.pdf>

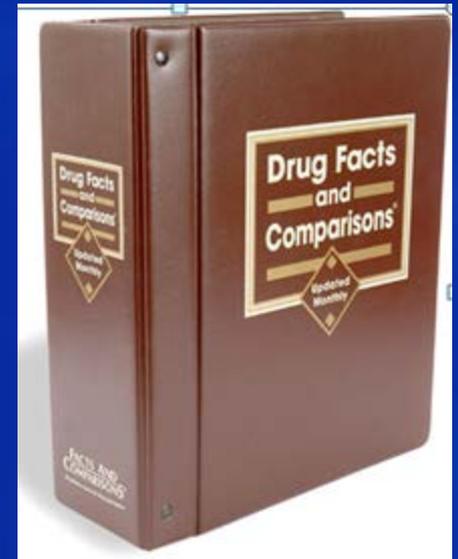
Required Reading Cont.

- ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling
<http://www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx>
- Academy of Managed Care Pharmacy: *Drug Utilization Review*
<http://www.amcp.org/workarea/downloadasset.aspx?id=9296>
- Pequat Pharmaceutical Network (PRxN): *What are Drug Utilization Reviews?*
<http://www.prxn.com/docs/PRxn%20DUR.pdf>

Additional Resources

These additional resources are reference materials that you may want to read or have available for reference:

- Drug Facts & Comparisons
- *USPDI*
- Micromedex
- Epocrates
- LexiComp
- Clinical Pharmacology
- List of Error Prone Abbreviations, Symbols & Dose Designations – *Institute for Safe Medication Practices (ISMP)*



Additional Resources

Cont.

- Practitioner's Manual: *An Informational Outline of the Controlled Substances Act*
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf
- Pharmacist's Manual: *An Informational Outline of the Controlled Substances Act*
http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

Additional Resources

Cont.

- Food & Drug Administration Website
<http://www.fda.gov/>
- Drug Enforcement Administration Website
<http://www.justice.gov/dea/>
- ISMP Safety Alert (Newsletter)
<http://www.ismp.org/newsletters/default.asp>
- ISMP Website
<http://www.ismp.org/default.asp>
- Oregon Patient Safety Commission
<http://oregonpatientsafety.org/>

Proceed to Self Test

Self Test

- This self test is designed to provide you an opportunity to review and test your recall of the presented material.
- Take time to read each question and answer. Review the material as necessary. The test will not be turned in or graded.
- You will be asked to attest that you have answered the self-test questions.

Self Test

1. Prior to dispensing a Controlled Substance, the PA and SPDO must obtain a controlled substance registration from both the OBOP and DEA.
 - A. True
 - B. False

2. PAs or their auxiliary staff may deliver a dispensed medication to the patient.
 - A. True
 - B. False

Self Test

3. The PA must complete a DUR on each patient prior to dispensing any medication to a patient.
 - A. True
 - B. False

4. The law requires a PA to complete a training program developed by:
 - A. Oregon Board of Pharmacy
 - B. Oregon Medical Board
 - C. A & B
 - D. None of the above

Self Test

5. A prescription container must be labeled with all of the following except:
 - A. Date of Dispensing
 - B. Manufacturer's Expiration Date
 - C. Prescription Identification Label
 - D. Name of Consulting Pharmacist
 - E. Cautionary Statements, if any, as required by law

Self Test

6. Describe what is included in prospective drug utilization review (DUR).
7. Explain what Patient Medication Counseling means.
8. What is the Institute for Safe Medication Practice (ISMP), and what does the ISMP do?

Self Test

9. Describe the SPDO dispensing and drug purchasing recordkeeping requirements.
10. Review the SPDO requirements for drug security and disposal.

***When complete, proceed to
Attestation/Certification Statement.***

ATTESTATION/CERTIFICATION STATEMENT

PA DRUG DISPENSING TRAINING PROGRAM

By signing below, I certify that:

- I personally completed this training program.
- I read all of the materials included on the Required Reading list.
- I reviewed and answered all of the Self Test questions.
- I will comply fully with the laws and regulations governing drug dispensing by PAs.

PA Name (Print or Type): _____ Oregon License No.: _____

PA Signature: _____ Date: _____

Print, sign, scan and send this attestation to the Oregon Medical Board using our [Secure Upload Portal](#), or mail to 1500 SW 1st Ave, Suite 620, Portland, OR 97201-5847.

This completes the PA Drug Dispensing Training Program.



Visit the Board Websites:

Oregon Board of Pharmacy

www.pharmacy.state.or.us

Oregon Medical Board

www.oregon.gov/omb