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.
“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.
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.
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.
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
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.
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).
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.
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
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 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.
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.
The outlet must maintain a list of sites in Oregon where drugs may be disposed. The updated list of locations is available on the Oregon Association of Clean Water Agencies website: https://oracwa.org/unwanted-drug-drop-off-sites-2/.
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.
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 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.
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.
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.
The following is a list of required reading. You will be asked to attest that you have read these.

- **2012 Oregon Laws Chapter 34:**

- **OAR 855-019: Licensing of Pharmacists**
  [https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967](https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3967)

- **OAR 855-041-1001 through 1160: Operation of Pharmacies**
  [https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3975](https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3975)

- **OAR 855-043: Practitioner Dispensing**
  [https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3977](https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3977)

- **OAR 847-050: Physician Assistant**
  [https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3895](https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3895)
21 CFR 1306: Prescriptions
https://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm

Food Drug & Cosmetic Act: Chapter V Part A – Drugs & Devices (sections 501-506C only)

Required Reading Cont.


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

Pharmacist’s Manual: An Informational Outline of the Controlled Substances Act
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**
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
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
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
6. Describe what is included in prospective drug utilization review (DUR).


8. What is the Institute for Safe Medication Practice (ISMP), and what does the ISMP do?
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