



Oregon

Kate Brown, Governor

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**2016
CONSULTANT PHARMACIST
SUPERVISING PHYSICIAN DISPENSING OUTLET**

ATTENTION: CONSULTANT PHARMACIST

Oregon Administrative Rule 855-043-0415 states that a Supervising Physician Drug Outlet (SPDO) must retain a pharmacist licensed in Oregon for consultation purposes and the consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed report form must be filed in the outlet, and be available to the Board for inspection for three years. Accompanying this letter is the form you need to complete to document your annual inspection. Failure to complete this report by **January 1, 2016** may result in disciplinary action.

Following your self-inspection and completion of the report, please review it with staff and file it so that it will be accessible to Board Inspectors upon inspection. In outlets a common reason for issuing a Deficiency Notice is either not having or not being able to readily retrieve required documents and records. Because Board inspections are unscheduled, it is common for the consultant pharmacist to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. Please be specific when providing locations. Having all required documents and records maintained in a well-organized and readily retrievable manner dramatically reduces the chance that you will receive a Deficiency Notice.

The primary objective of this report, and your self-inspection, is to provide an opportunity to **identify** and **correct** areas of non-compliance with Oregon Board of Pharmacy rules. (Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with all rules.) The inspection report serves as a necessary document used by Board inspectors during an inspection to evaluate an outlet's level of compliance.

When a Board inspector discovers an area of non-compliance they may issue a **Deficiency Notice** or a **Notice of Non-Compliance**. Both require a written response from the consultant pharmacist. Identifying and correcting an area of non-compliance **prior to a Board inspection** may eliminate the receipt of a Deficiency Notice/Notice of Non-compliance for that item. Do not assume that you are in compliance with any statement; take the time to personally verify that compliance exists. A situation of non-compliance is the outlet and consultant pharmacist's responsibility to immediately correct to avoid the possibility of a Deficiency Notice and/or disciplinary action. The Board understands that regulations may sometimes appear confusing and open to different interpretations. If you have any questions, please **fax** your question(s), attention inspectors, prior to an inspection to 971-673-0002.

By answering the questions and referencing the appropriate rules provided, you can determine whether you are compliant with the rules. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.



Cut on this line, fill in location, and post next to outlet license on the wall.

DO NOT SEND ANY PART OF THIS REPORT TO THE BOARD OFFICE.

LOCATION OF SELF-INSPECTION FORM: _____

**2016
SUPERVISING PHYSICIAN DISPENSING OUTLET (SPDO)
INSPECTION REPORT**

Date: _____

Outlet Lic. No: _____

Controlled Substance Lic No: _____

Telephone: _____

Outlet Name: _____

Address: _____

City, Zip: _____

Inspector Signature: _____

Date: _____ Deficiency Notice: _____

Comments: _____

INSTRUCTIONS

The outlet's Consultant Pharmacist must evaluate the facility's compliance with the Board of Pharmacy's rules by completing this inspection report by **January 1, 2016**. This report must be kept on file at the outlet and available for Board inspection.

Licensure

1. What is the supervising physician's name, license number, and expiration date? If more than one, attach a page with other supervising physician(s) information.

Name: _____ License # _____ Expiration date _____

2. What is the expiration date of the supervising physician's dispensing authority? _____

Yes No

3. **OAR 855-043-0405**
Does each physician assistant (PA) have dispensing authority?
What is the expiration date? _____

4. Have you verified the pharmacy/wholesaler(s)/manufacturer(s) that the outlet purchased medication from is registered in Oregon? You may verify licenses and registrations on the Board website www.pharmacy.state.or.us.

Name of primary and secondary supplier(s) and registration number:

Where are invoices kept? _____

5. **OAR 855-043-0440**
Are drugs prepackaged by a pharmacy or manufacturer registered with the Board? Name, License No & Exp Date: _____

6. If drugs are supplied by a pharmacy, do you have a shared service agreement in place with them?

7. **ORS 689.305** Do you sell nonprescription medications to walk-in customers who will not be receiving care at the clinic? If yes, what is your nonprescription drug outlet registration number: _____

Storage

8. **OAR 855-043-0425**
Are drugs kept in a **locked** drug cabinet or drug storage area that sufficiently denies access to unauthorized persons?

9. **OAR 855-043-0430**
Are drugs stored under proper conditions?

10. **OAR 855-043-0450**
Are outdated, damaged, deteriorated, misbranded, or adulterated medications physically separated from other drugs? Where are they stored? _____

Labeling/Dispensing

- 11. **OAR 855-043-0435**
Are prescriptions properly labeled?
(a) Unique identifier;
(b) Name of patient;
(c) Name of prescriber;
(d) Name, address, and phone number of the clinic;
(e) Date of dispensing;
(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;
(g) Quantity dispensed;
(h) Directions for use;
(i) Initials of the physician assistant or practitioner dispensing;
(j) Cautionary statements, if any, as required by law; and
(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and
(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

- 12. **OAR 855-043-0440** (MD: ORS 677.089 – NP: ORS 678.390)
Are prescriptions **personally** dispensed by a practitioner or PA?

- 13. **OAR 855-043-0440**
Is the practitioner or PA performing a drug utilization review prior to dispensing medication? (DUR includes, but is not limited to, checking for drug interactions, drug allergies, and duplicate therapy.)

- 14. **OAR 855-043-0440**
Is the practitioner or PA orally counseling the patient on all new drugs?

- 15. **OAR 855-043-0440**
Is written information accompanying each dispensed drug? (Information to include at least proper use and storage, common side effects, precautions and contraindications, significant drug interactions and, when required, a Medication Guide)

- 16. Are drugs prepared in an area separate from where blood and urine are processed? (i.e. reconstitution of oral antibiotics)

Policies, Procedures, Records

- 17. **OAR 855-043-0455** Is a dispensing record maintained separately from the patient chart and kept for a minimum of 3 years?

- 18. **OAR 855-043-0415**
Are the duties of the consultant pharmacist defined in writing?
Where is this kept? _____

- 19. **OAR 855-043-0415**
Is there a formulary of drugs and classes of drugs for the outlet?
Where is this kept? _____

- 20. **OAR 855-043-0420**
Does the outlet have policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping, and accountability?
Where are they kept? _____

- 21. **OAR 855-043-0420**
Has outlet established procedures for the procurement of drugs?

- 22. **OAR 855-043-0420/OAR 855-043-0445** Does the outlet have procedure to train PAs who dispense drugs and ensure dispensing PAs continued competence?
Where are the PAs training documents kept? _____

- 23. **OAR 855-043-0440**
Do you have a current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting is being used?
Name: _____

Signature of the Consultant Pharmacist _____ Email address: _____

Oregon Pharmacist License No. _____ Date _____