



Oregon

Kate Brown, Governor

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2016 RETAIL DRUG OUTLET SELF-INSPECTION REPORT FOR HOME DIALYSIS SUPPLIES

ATTENTION: PHARMACIST-IN-CHARGE:

Failure to complete this report by **February 1, 2016** may result in DISCIPLINARY ACTION.

INSTRUCTIONS:

The pharmacist-in-charge must perform an annual inspection of this outlet and document it by completing this report by February 1, 2016. Following your self-inspection and completion of the report, please review it with your staff, sign and date the report, and file it in your Board of Pharmacy Law Book so it will be readily available to Board Inspectors. **DO NOT MAIL** to the Board office.

The primary objective of this report, and your self-inspection, is to provide an opportunity to **identify** and **correct** areas of non-compliance with federal and state law. (Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection report also 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 either a **Deficiency Notice** or a **Notice of Non-compliance**. Both require a written response from the pharmacist-in-charge (PIC). Identifying and correcting an area of non-compliance **prior to** a Board inspection will 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 that "is the way it has been for years" is the current PIC's responsibility to correct immediately to avoid the possibility of a Deficiency Notice or disciplinary action. The Board understands that regulations may sometimes appear confusing and open to different interpretations. If you have any questions, please fax or email your questions, "attention inspectors", prior to an inspection, to the fax or email above.

The most 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 PIC to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. 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.

**2016 RETAIL DRUG OUTLET
SELF-INSPECTION REPORT
FOR HOME DIALYSIS SUPPLIES**

Date: _____

Lic. No.: _____

Telephone: _____

Hours: _____

Pharmacy Name: _____

Address: _____

City: _____ State: _____ Zip: _____

E-Mail Address of PIC: _____

YES NO

1. Does the pharmacist-in-charge review the drug outlet operation weekly?

2. Does the pharmacist-in-charge perform a monthly quality assurance audit of the pharmacy operation?

3. Does the pharmacy have at least two current reference books that are specific and relevant to dialysis therapy?
What are the titles of these reference books?

4. Does the pharmacy have a current copy of the Oregon Board of Pharmacy's laws and rules, and a minimum of three years of the Oregon Board of Pharmacy quarterly newsletters?

5. Are dialysis supplies and solutions only delivered pursuant to current prescription orders?

6. Are prescription records kept for a minimum of three years?

7. Are patient records secured and locked?

8. In the event of an emergency that requires the access of patient records when a pharmacist is not present, is the entry or access documented?
Where is it documented?

9. Does a pharmacist review all patient profiles?
How is this review documented?

10. Does the outlet supply toll free telephone access for patients and health care providers to a pharmacist? Toll free telephone number:

11. Does the outlet maintain a policies and procedures manual that contains a quality assurance program with which to monitor the qualifications, training and performance of personnel?
Where is the manual kept?

12. Does the pharmacist prepare and maintain monthly reports of the activities performed?
Where is this report kept?

Signature of the Pharmacist Consultant: _____

Lic. No.: _____

Date: _____

Inspector Signature: _____
Date: _____ Deficiency Notice: _____
Comments: _____