



**2022**  
**HOME DIALYSIS RETAIL DRUG OUTLET**  
**SELF-INSPECTION FORM**

**ATTENTION: PHARMACIST-IN-CHARGE (PIC)**

Oregon law holds the pharmacist-in-charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this form by February 1, 2022, and within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.

The primary objective of this form and your self-inspection is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (Note: Neither the self-inspection nor a Board inspection evaluates the outlets compliance with all laws and rules of the practice of pharmacy.) The inspection form also serves as a necessary document used by Board Compliance Officers during an inspection to evaluate a pharmacy's level of compliance.

Following your self-inspection and completion of the form, please review it with your staff pharmacists, technicians, and interns, correct any deficiencies noted, sign and date the form and file it in a readily retrievable manner. **DO NOT SEND** the form to the Board office. You are responsible for ensuring the completed form is available at the time of inspection.

Board inspections are not scheduled; therefore, it is common for the PIC to be absent or unavailable at the time of inspection. 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 (a binder is recommended) increases compliance and may improve the efficiency of the inspection.

Do not assume that the pharmacy is in compliance. Please review Board regulations and take the time to personally verify that compliance exists. Email all Compliance related questions to [pharmacy.compliance@bop.oregon.gov](mailto:pharmacy.compliance@bop.oregon.gov). (Note: The Board does not provide individualized legal advice on how the law applies to practice in the field. You may also want to contact a qualified attorney.)

By answering the questions and referencing the appropriate laws and rules provided, you can determine whether the pharmacy is compliant with many of the rules and regulations. If you have corrected any discrepancies, please write 'corrected' and the date of correction by the appropriate question.

The Board offers a PIC training course. Check the Board website for more information.

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**All PICs of Home Dialysis retail drug outlets MUST complete and sign this inspection form and have it available for inspection within 15 days of becoming PIC and by 2/1/2022 (as required by OAR 855-019-0300).**

Date PIC Inspection was performed: \_\_\_\_\_  
Print PIC Name & License#: \_\_\_\_\_  
PIC e-mail: \_\_\_\_\_  
Pharmacy: \_\_\_\_\_  
Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_  
Address: \_\_\_\_\_  
City/State/Zip Code: \_\_\_\_\_  
DEA #: \_\_\_\_\_ Exp: \_\_\_\_\_  
Retail Outlet Registration #: \_\_\_\_\_  
Hours of operation: \_\_\_\_\_

|   |
|---|
| Date: _____                               |
| In person or Virtual Inspection: (circle) |
| Compliance officer: _____                 |
| RPH present for inspection:<br>_____      |
| Result: _____                             |
| Comments: _____                           |

***Please list where the following items are located inside the pharmacy. Be as specific as possible; there can be many filing cabinets and binders.***

PIC Inspection Forms for the last 3 years: \_\_\_\_\_  
Current written Drug Outlet Procedures: \_\_\_\_\_  
Current written annual controlled substance inventory: \_\_\_\_\_  
Schedule II Invoices for the last 3 years: \_\_\_\_\_  
Schedule III-V Invoices for the last 3 years: \_\_\_\_\_  
Completed CII order forms (DEA form 222) for last 3 years: \_\_\_\_\_  
Perpetual Schedule II inventory & reconciliation: \_\_\_\_\_  
Diversion Prevention P&P and Supporting Documentation: \_\_\_\_\_  
Drug Storage Training Documents: \_\_\_\_\_  
Technician Training Documents: \_\_\_\_\_  
Aseptic Training: \_\_\_\_\_  
Media fill/gloved fingertip competency documentation: \_\_\_\_\_  
Cleaning/disinfecting Logs: \_\_\_\_\_  
Hood Certification Documents: \_\_\_\_\_  
Pharmacist prescribing records: \_\_\_\_\_  
USP access/resource: \_\_\_\_\_

**You are required to confirm whether or not the outlet is compliant and mark the appropriate box to the left of each item. Resolve all deficiencies and write the date of correction.**

**General Requirements**

| Yes                      | No                       | N/A                      |    |  | Rule Reference          |
|--------------------------|--------------------------|--------------------------|----|--|-------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 1  | Does the pharmacist-in-charge review the drug outlet operation weekly?   | OAR 855-041-4055(1)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2  | Does the pharmacist-in-charge perform a monthly quality assurance audit of the pharmacy operation?   | OAR 855-041-4055(1)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3  | Does the outlet have access to current references specific and relevant to dialysis therapy?   | OAR 855-041-4045(5)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4  | Does the outlet have access to the Oregon Board of Pharmacy's laws and rules, and newsletters?   | OAR 855-041-4045(6)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5  | Are dialysis supplies and solutions only delivered pursuant to current prescription orders?  | OAR 855-041-4045(2)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6  | Are prescription records kept for a minimum of three years?  | OAR 855-041-4045(4)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7  | Are patient records secured and locked?  | OAR 855-041-4045(3)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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?<br><br>Where is this documented?                                 | OAR 855-041-4045(3)     |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9  | Does a pharmacist review all patient profiles?<br><br>How is this review documented?   | OAR 855-041-4055 (2)(d) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10 | Does the outlet supply toll free telephone access for patients and health care providers to a pharmacist?<br><br>Toll free telephone number:   | OAR 855-041-4055 (2)(e) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11 | Does the outlet maintain policies and procedures that contain a quality assurance program with which to monitor the qualifications, training, and performance of personnel?<br><br>Where are the P&Ps located? | OAR 855-041-4055 (2)(j) |

| Yes                      | No                       | N/A                      |    |  | Rule Reference      |
|--------------------------|--------------------------|--------------------------|----|--|---------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12 | <p>Does the pharmacist prepare and maintain monthly reports of the activities performed?</p> <p>Where is the report located?</p> | OAR 855-041-4055(1) |

**If the outlet performs any drug compounding, you are required to also complete the Compounding Self-Inspection form located on the Board website.**

Printed Name of PIC: \_\_\_\_\_

Signature of PIC: \_\_\_\_\_ Date: \_\_\_\_\_