

## 2024 HOME DIALYSIS RETAIL DRUG OUTLET SELF-INSPECTION FORM

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

Failure to complete this form by July 1, 2024, and within 15 days of becoming PIC, may result in disciplinary action (OAR 855-115-0210(1)(h)).

Please note: This is not a standalone self-inspection form. It is to be completed in conjunction with the appropriate Drug Outlet Self-Inspection Form (i.e., Retail, Institutional, and Compounding etc.).

**Requirements:** Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the board immediately upon request at the time of inspection and retained in compliance with <u>OAR 855-104-0055</u>.

**Scope:** The primary objective of completing the self-inspection is to identify and correct areas of noncompliance with any state and federal laws and rules. This process is not exhaustive, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

**Internal Use:** Following completion of the self-inspection form, ensure it is signed and dated by the PIC, reviewed with all pharmacy staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

**Agency Use:** During an inspection, Compliance Officers use the self-inspection form as a general guide to assess pharmacy compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and locate any auxiliary documents referenced within at the time of inspection.

Email all compliance-related questions to: pharmacy.compliance@bop.oregon.gov

## 2024 HOME DIALYSIS RETAIL DRUG OUTLET SELF-INSPECTION FORM

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 7/1/2024 (as required by OAR 855-115-0210).							
Date PIC Completed Self-Inspection:/	///	-					
PIC Name:		PIC License #:					
PIC's Work E-mail:							
Pharmacy Name:							
Address:							
City:	State:	Zip Code:					
Telephone: ()		Fax: ()					
Home Dialysis Retail Drug Outlet Registration #	:	EXP://					

Hours of operation:

Please list where the following items are specifically located inside the pharmacy. Once located, ensure each is compliant, and reflects currents practices within the outlet (if an item is not applicable, indicate with N/A). Unless otherwise specified, documents are to be retained for 3 years (the first of which must be on site) and must be provided to the Board upon request, as outlined in OAR 855-104-0055.

**Pharmacist Monthly Reports:** 

**Technician Training Documents:** 

**Drug Storage Training Documents:** 

**Diversion Prevention Policies and Procedures with Supporting Documentation:** 

**Current Written Drug Outlet Policies and Procedures Manual:** 

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies and write the date of correction, if applicable.

## **General Requirements**

Yes	No	N/A			Rule Reference
			1	Does the PIC review the drug outlet operation at least weekly?	OAR 855-041-4055(1)
			2	Does the PIC perform quality assurance audits <b>at least monthly,</b> to include the review of prescription orders, and assembled orders with the prescription orders, prior to delivery for accuracy and completeness?	<u>OAR 855-041-4055(1)</u>
				Does the pharmacist prepare and maintain monthly reports of the activities performed?	
			3	Does the outlet have access to <b>at least two</b> current references specific and relevant to dialysis therapy?	OAR 855-041-4045(5)
			4	Does the outlet have access to the current Oregon Board of Pharmacy's laws and rules, and at least three years of quarterly newsletters?	OAR 855-041-4045(6)
			5	Are dialysis supplies and solutions <b>only</b> delivered pursuant to current prescription orders?	OAR 855-041-4045(2)
			6	Are patient and prescription records secured, locked, and kept for a minimum of three years?	OAR 855-041-4045(4)
			7	If an emergency occurs which necessitates access to patient records without a pharmacist on duty, where is such entry and/or access documented?	OAR 855-041-4045(3)
			8	Does a pharmacist review all patient profiles? How is this review documented?	<u>OAR 855-041-4055</u> (2)(d)
			9	Does the outlet supply toll-free telephone access to a pharmacist for patients and health care providers? Toll free telephone number:	<u>OAR 855-041-4055</u> (2)(e)
			10	<ul> <li>Does the outlet's policies and procedures manual contain written protocols addressing each of the following required elements?</li> <li>The product delivery system</li> <li>Supervising deliveries to patients</li> <li>A quality assurance program which includes monitoring the qualifications, training, and performance of personnel</li> </ul>	<u>OAR 855-041-4055</u> (2)(j)

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, and that the answers marked on this form are true and correct.

Date: \_\_\_\_/ \_\_\_/ \_\_\_\_

Printed Name of PIC:

Signature of PIC: