2025
HOME DIALYSIS RETAIL DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Failure to complete this form by July 1, 2025, 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 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 OAR 855-104-0055.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance 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 any auxiliary documents referenced within, at the time of inspection.

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

2025
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 7/1/2025 (OAR 855-115-0210).

Date PIC Completed Self-Inspection: _____ / _____ / _____

PIC Name: _____ PIC License #: _____

PIC **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.

Current written Drug Outlet Policies and Procedures Manual:

Diversion Prevention Policies and Procedures with Supporting Documentation:

Drug Storage Training Documents:

Technician Training Documents:

Pharmacist Monthly Reports:

INSTRUCTIONS:
Verify compliance of each section by marking the corresponding box. Should any non-compliance be identified, rectify the deficiencies and record the correction date.

General Requirements

Yes	No	N/A			Rule Reference
☐	☐	☐	1.	Are supplies for dialysis solutions provided under the general supervision and direction of a pharmacist with special training in renal disease and dialysis?	OAR 855-041-4025
☐	☐	☐	2.	Are supplies only provided pursuant to a current prescription order from an authorized prescriber? Note: The prescription order must be maintained on file at the outlet. Supplies will be limited to dialysis solutions as defined in OAR 855-041-4035.	OAR 855-041-4045
☐	☐	☐	3.	Does the PIC review the drug outlet operation **at least weekly**?	OAR 855-041-4055(1)
☐ ☐	☐ ☐	☐ ☐	4.	Does the PIC perform quality assurance audits **at least monthly,** to include the review of prescription orders, and assembled orders with the prescription orders, prior to delivery for accuracy and completeness? Does the pharmacist prepare and maintain monthly reports of the activities performed?	OAR 855-041-4055(1)
☐	☐	☐	5.	Is the PIC completing the following? • Ensuring compliance of dialysis distribution operation to all applicable federal and state pharmacy laws and rules; • Ensuring valid prescriptions are received for all patient orders by performing periodic assessments of prescription files; • Performing periodic assessments of distribution processes and procedures to ensure quality and compliance; • Providing pharmaceutical care by reviewing all patient profiles and performing drug therapy assessments on those identified as abnormal; • Providing pharmaceutical care by responding on a toll free telephone access to questions received from any patient or health care provider; • Maintaining, updating and training personnel on policies and procedures specific to home dialysis patient deliveries and pharmacy requirements; • Preparing educational materials for staff members of dialysis clinics as requested; • Preparing and maintain on file monthly reports of activities performed; • Ensuring security of the patient record area.	OAR 855-041-4055
☐	☐	☐	6.	Does the outlet have access to **at least two** current references specific and relevant to dialysis therapy?	OAR 855-041-4045(5)
☐	☐	☐	7.	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)
☐	☐	☐	8.	Are patient and prescription records secured, locked, and kept for a minimum of three years?	OAR 855-041-4045(3)(4)

Yes	No	N/A			Rule Reference
				Note - Access to the patient records area is allowed only when a pharmacist is present except in the event of an emergency.	
☐	☐	☐	9.	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)
☐	☐	☐	10.	Does a pharmacist review all patient profiles? How is this review documented? _____ _____ _____	OAR 855-041-4055 (2)(d)
☐	☐	☐	11.	Does the outlet supply toll-free telephone access to a pharmacist for patients and health care providers? Toll free telephone number: (_____)_____-_____	OAR 855-041-4055 (2)(e)
☐	☐	☐	12.	Does the outlet's policies and procedures manual contain written protocols addressing each of the following required elements? • The product delivery system • Supervising deliveries to patients • A quality assurance program which includes monitoring the qualifications, training, and performance of personnel	OAR 855-041-4055 (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: _____