2024
WHOLESALE DRUG OULET
SELF-INSPECTION FORM

ATTENTION: Designated Representative

This form is required for Wholesaler 1 Registrants and failure to complete this form by September 1, 2024, may result in disciplinary action (OAR 855-065-0009(7)).

This form is optional for Wholesaler 2 and Wholesaler 3 Registrants.

Requirements: Oregon law states the Designated Representative is responsible for ensuring the drug outlet 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 Designated Representative 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 drug outlet compliance. The Designated Representative and 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
WHOLESALE DRUG OUTLET
SELF-INSPECTION FORM

Class I Wholesaler (W1) MUST complete this inspection form and have it available for inspection by September 1, 2024, pursuant to OAR 855-065-0009(7). DO NOT MAIL THE BOARD OFFICE.

Print Name: _____

☐ *I am a Designated Representative (required for W1)* ☐ *I am a Contact Person (W2 or W3)*

Designated Representative name: _____

Designated Representative email: _____

Designated Representative phone number: (_____) _____-_____

Outlet Name: _____ Registration #: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: (_____) _____-_____ Fax: (_____) _____-_____

DEA # _____ EXP: _____ / _____ / _____

Business Hours:

1. Has this wholesale distributor been granted any exceptions by the Board, or DEA, to any laws or rules?

☐ Yes ☐ No

If yes, please attach a copy. *Please note: Rule changes may invalidate an old waiver, and waivers are valid for a maximum of 5 years.*

2. Has any disciplinary action been taken against this wholesale distributor, its owner, principal or designated representative, or any other wholesale distributor under common ownership or control, in connection with the drug laws or regulations of any state or the federal government?

☐ Yes ☐ No

If yes, please attach a statement explaining why.

3. How many employees does this wholesale distributor have?

4. In which states is this wholesaler distributor registered?

5. Provide the names of all wholesalers and/or manufacturers drugs and/or devices are purchased from.

6. Identify the specific location at the outlet where the following items are located.

- Current written Policies and Procedures
- List of responsible individuals and their qualifications/duties
- Invoices for the last 3 years
- Pedigree records for the last 3 years (if applicable)

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.

Policies and Procedures

Yes	No			Rule Reference
☐	☐	1.	Please indicate where the outlet's policies and procedures are located for each of the following items (where applicable): Stock rotation (whereby the oldest inventory is dispensed first) Recalled items Addressing any actions initiated by the FDA, or other federal or state agency (including the Board) Emergency preparedness (e.g., strike, flood, fire, or other natural disasters, public health emergencies, or other local, state, and national emergencies)	OAR 855-065-0010

Yes	No			Rule Reference
			Handling outdated products (to include disposition or destruction) Investigating discrepancies Documenting temperature and humidity of the storage facility Identifying suspect product (such as suspicious labels or containers) Quarantine of product that is suspect, illegitimate, adulterated, misbranded, contaminated, contraband, counterfeit, damaged or otherwise unfit for distribution **Note:** In such cases, the outlet must notify the FDA, immediate trading partners, and the OBOP within 24 hours and conduct an investigation to authenticate the distribution of each drug back to the wholesaler from which the drug was purchased.	

Security

Yes	No			Rule Reference
☐	☐	2.	Is there a security system?	OAR 855-065-0012(3)
☐	☐	3.	Is access to areas where drugs are held restricted to authorized personnel only?	OAR 855-065-0012(3)
		4.	Who has access to the areas where drugs are stored? Who has access to restricted areas (controlled substances)?	
☐ ☐	☐ ☐	5.	Are computers and inventory management systems password protected? Are there different levels of access?	

			How often are transactions monitored (if applicable)?	
☐	☐	6.	Is there an after-hours central alarm, or comparable entry-detection system? Who monitors this? Is the outlet monitored with cameras? Is the outlet secured with fences or cages? If skylights are present, does the outlet utilize skylight cages?	OAR 855-065-0012(3)(b)
☐	☐	7.	Is there adequate outside perimeter lighting?	OAR 855-065-0012(3)(c)
☐	☐	8.	Is the outlet clean and in orderly condition? How does the outlet keep the facility free from infestation by insects, rodents, birds, or vermin of any kind?	OAR 855-065-0012(1)(e) and (g)

Storage of Drugs

Yes	No			Rule Reference
☐	☐	9.	Is the outlet of suitable construction and size to facilitate cleaning, maintenance, and proper distribution operations?	OAR 855-065-0012(1) (a) and (b)
☐	☐	10.	Does the outlet have adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions?	OAR 855-065-0012(1-2)

Yes	No			Rule Reference
		11.	How are temperature and humidity monitored? Where is the data stored? How often is the data reviewed? What happens if the temperature goes out of range? How frequently are thermometers and/or sensors calibrated? Who calibrates the sensors?	
☐	☐	12.	Does the outlet store products that require **cold storage**? How does the outlet maintain the integrity of such products? How are these products packed for shipment?	OAR 855-065-0012

Record Keeping and Inventory Management

Yes	No			Rule Reference
☐	☐	13.	Are records compliant with state and federal laws, including the Drug Supply Chain Security Act (DSCSA)?	OAR 855-065-0010
☐	☐		Do pedigree records contain all required elements, such as Transaction Information, Transaction History & Transaction Statement?	

Yes	No			Rule Reference
			If no, please explain: Where are the records located?	
☐	☐	14.	Are records and invoices maintained for a minimum of three years (the first of which of which MUST be on-site)?	OAR 855-065-0010(2-4)
☐	☐	15.	Are records maintained offsite? If so, which records? Where? How long does it take to get them from the offsite location?	OAR 855-065-0010(4)
☐	☐	16.	Does computer inventory match actual inventory? How is inventory monitored? Who monitors inventory adjustments? What is the threshold to initiate an investigation for controlled substance and non-controlled substance adjustments?	21 CFR 1301.76(b)
☐	☐		Are the DEA and Board notified of losses? How long are records retained and where are they stored?	

Yes	No			Rule Reference
☐	☐	17.	Are items examined upon receipt and compared to shipping invoices, to look for potential discrepancies? If a box appears damaged or opened, what is the procedure for processing, investigating, and documenting it?	OAR 855-065-0010(6)(a)
☐	☐	18.	Does the outlet have a policy and procedure for identification and quarantine of suspect/illegitimate products? Where are such products quarantined, or stored? Does the outlet notify the Board, the FDA, and all affected trading partners of illegitimate products within 24 hours?	OAR 855-065-0010(6)(d)
☐	☐	19.	Does the outlet ensure that products returned by the pharmacy are fit for resale, to include evaluation of the following? • Inspection of both inner and outer seals • Review of expiration dates • Verification that the cold chain was not disrupted for products that require cold storage (i.e. is the customer required to certify that the returned products were maintained at the appropriate temperature?)	OAR 855-065-0005(18)(k) OAR 855-065-0010(6)(c)(A) OAR 855-065-0010-(6)(f)
☐	☐	20.	Does the outlet verify the licensure of trading partners, affiliates, customers, vendors, etc. with the Board **prior to** receiving or distributing products? How is this done? **Note:** The Board maintains an online lookup tool: https://orbop.mylicense.com/verification/	OAR 855-065-0005(22)(a-c) OAR 855-065-0013(1)(a-c)
☐	☐	21.	Is the outlet located in a **commercial, nonresidential building** and in compliance with all other safety, security, and maintenance requirements in **OAR 855-065-0012**?	OAR 855-065-0012

Prohibited Practices – OAR 855-065-0013

Yes	No			Rule Reference
☐	☐	22.	Is staff aware that purchasing drugs from a closed-door pharmacy is not permitted?	OAR 855-065-0013(1)(a)

Personnel *(applicable only to W1)*

Yes	No			Rule Reference
☐	☐	23.	Does the outlet's Designated Representative serve as such for more than one wholesale distributor? **Note:** Prior Board approval is required.	OAR 855-065-0009(1)
☐	☐	24.	Is the Designated Representative a full-time employee of the outlet, and on-site at least 30 hours per week?	OAR 855-065-0009(1) and (6)
☐	☐	25.	Is the Designated Representative aware of, and actively involved in, the daily operations of the outlet?	OAR 855-065-0009(4)

Per OAR 855-065-0009, the Designated Representative must certify in writing, under penalties of perjury, that the information recorded on the Wholesaler Self-Inspection Form is correct.

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

Printed Name: _____ Title: _____

Signature: _____ Date: _____ / _____ / _____