2023
WHOLESALE DRUG OULET
SELF-INSPECTION FORM

ATTENTION: Designated Representative

Each year by September 1st, the Designated Representative must conduct an annual inspection of the Wholesale Drug Outlet (Wholesaler) using the annual Wholesale Self-Inspection Form provided by the Board. Failure to complete the self-inspection form by September 1st may result in disciplinary action for the Wholesaler.

In addition, the Designated Representative must ensure that the wholesale drug outlet has policies and procedures in effect and implemented to ensure that the outlet employs adequate personnel with the education and experience necessary to engage in the wholesale distribution of drugs safely and lawfully.

The primary objective of the self-inspection form, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. By answering the questions on the self-inspection form and reviewing the laws and rules referenced, you can determine whether the Wholesaler is compliant with many of the rules and regulations. The completed self-inspection form also serves as a necessary document used by Board Compliance Officers during an inspection to evaluate a Wholesaler's level of compliance. (Note: Neither the self-inspection nor a Board inspection evaluates compliance with **all** laws and rules pertaining to the operation of the Wholesaler.)

The Designated Representative must certify in writing, under penalties of perjury, that the information recorded on the Wholesaler Self-Inspection Form is correct. This form must be retained for three years and must be made available to the Board within two days upon request. DO NOT SEND the completed self-inspection form to the Board office.

If you correct any of the deficiencies noted on the completed self-inspection form, please write "Corrected" and the date of correction by the corresponding question.

Do not assume that you are in compliance. Please review Board regulations and take the time to personally verify that compliance exists.

Board inspections are not scheduled; therefore, the Designated Representative may be absent or unavailable at the time of the inspection. For this reason, you are asked to provide a list of the locations for the required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) may increases compliance and may improve the efficiency of the inspection.

Following a board inspection, a completed inspection report will be emailed to the Designated Representative's work email address in 2 to 4 weeks. A list of observations made by the Compliance Officer during the board inspection may also be included in the report. (Note: An observation is any potential regulatory violations found during the routine inspection).

The board inspection report should be reviewed, and a copy must be retained with the completed self-inspection forms for 3 years as part of the outlet's records.

If a board inspection results in a Deficiency Notification (DN) or a Non-Compliance Notification (NCN), the Compliance Officer will provide further instructions.

Compliance related questions can be emailed to: pharmacy.compliance@bop.oregon.gov

2023
WHOLESALE DRUG OUTLET
SELF-INSPECTION FORM

All Class I Wholesaler (W1) MUST complete this inspection form and have it available for inspection by **September 1, 2023,** pursuant to OAR 855-065-0009(7). DO NOT MAIL TO THE BOARD OFFICE.

Print Name:

☐ *Check here if you are a Designated Representative (required for W1)* ☐ *Check here if you are a Contact Person (W2 or W3)*

Outlet Name:

Registration #:

Address:

City: State: Zip:

Telephone #:

DEA #: Exp Date:

Business Hours:

Designated Representative email:

Designated Representative phone #:

1. Has this wholesale distributor been granted any exceptions by the Board or DEA to any laws or rules? If yes, please attach a copy. Please note that rule changes may invalidate an old waiver and waivers are valid for a maximum of 5 years. ☐ Yes ☐ No

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 inside the outlet where the following items are located.

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

Carefully evaluate whether or not the outlet is compliant and mark the appropriate checkbox to the left of each item. If you find items that need correcting, mark the checkbox that is true at the time of the self-inspection, then rectify the discrepancy, write the date of correction, and update which checkbox applies.

Record Keeping Management and Inventory

Yes	No			Rule Reference
☐	☐	7	Are records compliant with state and federal laws including the Drug Supply Chain Security Act? Do pedigree records contain all required elements, such as Transaction Information, Transaction History & Transaction Statement? Where are the records kept? If no, please explain:	OAR 855-065-0010
☐	☐	8	Are records and invoices maintained for a minimum of three years? Note: Per OAR 855-065-0100(4), records less than 13 months old must be kept at the licensed wholesale location and be immediately retrievable at the time of inspection.	OAR 855-065-0010(2-4)

Yes	No			Rule Reference
☐	☐	9	Are records maintained offsite? Which ones? Where? How long does it take to get them from the offsite location?	OAR 855-065-0010(4)
☐	☐	10	How is inventory monitored? Who monitors inventory adjustments? What is the threshold to initiate an investigation for controlled substance and non-controlled substance adjustments?	CFR 1301.76(b)
☐	☐		Are the DEA and Board notified of losses? How long are records retained and where are they stored?	
☐	☐		Does computer inventory match actual inventory?	
☐	☐	11	Are items examined upon receipt and compared to shipping documents to confirm what was received? If a box appears damaged or opened, what is the procedure?	OAR 855-065-0010 (6)(a)

Yes	No			Rule Reference
☐	☐	12	Does the outlet have a policy and procedure for identification and quarantine of suspect/illegitimate product? Where are quarantined products stored? Does the outlet notify the Board, the FDA, and all affected trading partners of illegitimate product within 24 hours?	OAR 855-065-0010(6)(d)
☐	☐	13	Does the outlet have criteria for returning products to inventory when received from a pharmacy? • Seals inspected - inner and outer • Expiration Date • Drugs requiring cold storage returned cold. Does customer certify the drug was maintained at proper temperature?	OAR 855-065-0005(18)(k) OAR 855-065-0010(6)(c)(A) OAR 855-065-0010-(6)(f)
☐	☐	14	Does the outlet verify licensure of trading partners/affiliates/customers/vendors 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)
☐	☐	15	Does the outlet comply the safety, security, and maintenance requirements of OAR 855-065-0012, including being **located in a commercial, nonresidential building**?	OAR 855-065-0012

Policies and Procedures

Yes	No			Rule Reference
☐	☐	16	Does the outlet have written policies and procedures of the following? Please indicate under each item where the corresponding policy and procedure is located. The oldest approved stock is distributed first (inventory rotation) Handling of recalls	OAR 855-065-0010

Yes	No			Rule Reference
			Any action initiated by the FDA, or other federal or state agency (including the Board)	
			Emergency preparedness (e.g. strike, flood, fire, flood, or other natural disasters, public health emergencies, or other local, state, or national emergencies)	
			Outdates	
			Disposition or destruction of outdates	
			Investigation of discrepancies	
			Documentation of temperature and humidity conditions of the storage facility	
			Policy for identifying suspect product, such as suspicious labels and containers	
			Quarantine of suspect or illegitimate, adulterated, misbranded, contaminated, contraband, counterfeit, damaged or otherwise unfit for distribution medications. (In such cases, the outlet must notify the FDA, immediate trading partners, and the OBOP within 24 hours and conduct an investigation to authenticate each distribution of the drug back to the wholesaler from which the drug was purchased)	

Storage of Drugs

Yes	No			Rule Reference
☐	☐	17	Is the outlet of suitable construction and size to facilitate cleaning, maintenance, and proper distribution operations?	OAR 855-065-0012(1) (a) and (b)
☐	☐	18	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)
☐	☐	19	Temperature and Humidity Are temperature and humidity monitored? How are they monitored? How is the data stored? Where is the data stored? How often is the data reviewed to ensure proper storage conditions? What happens if temperature goes out of range? How frequently are thermometers and/or sensors calibrated? Who calibrates the sensors?	
☐	☐	20	Does the outlet store drugs that require cold storage? How does the outlet ensure the integrity of the product is maintained?	OAR 855-065-0012

Yes	No			Rule Reference
			How are drugs that require cold storage packed for shipment?	

Security

Yes	No			Rule Reference
☐	☐	21	Is there a security system?	OAR 855-065-0012(3)
☐	☐	22	Are there controls that restrict access to areas where drugs are held to authorized personnel only?	OAR 855-065-0012(3)
		23	Who has access to the drug area? Who has access to restricted areas (controlled substances)?	
☐ ☐ ☐	☐ ☐ ☐	24	Are computer systems and inventory management systems password protected? Are there different levels of access? Are transactions monitored? How often?	
☐	☐	25	Policies and procedures for detection of diversion/losses Are the DEA and Board notified of suspected losses? How are suspected losses handled?	OAR 855-065-0010(5)

☐	☐	26	Is there an after-hours central alarm or a comparable entry detection system? Who monitors? Fenced? Cameras? Cages? Outside lighting? Skylight cages?	OAR 855-065-0012(3)(b)
☐	☐	27	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)
☐	☐	28	Is there adequate outside perimeter lighting?	OAR 855-065-0012(3)(c)

Prohibited Practices – OAR 855-065-0013

Yes	No			Rule Reference
☐	☐	29	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
☐	☐	30	Is the Wholesaler's Designated Representative for more than one wholesale distributor? (Note: Prior Board approval is required.)	OAR 855-065-0009(1)
☐	☐	31	Is the Designated Representative employed full time by the wholesale distributor, and on-site at least 30 hours per week?	OAR 855-065-0009(1) and (6)
☐	☐	32	Is the Designated Representative actively involved in and aware of the daily operations of the wholesale distributor?	OAR 855-065-0009(4)

I hereby certify that I have verified this facility is in compliance with all laws and rules, have read and verified written policies and procedures reflect current practices, and the answers marked on this form and true and correct.

Signature:

Printed Name:

Title:

Date: