2022
WHOLESALER
SELF-INSPECTION FORM

ATTENTION: Designated Representative

The designated representative (DR) of the Class I registered wholesaler shall conduct and document an annual review of the outlet by completing this Self-Inspection Form by **September 1, 2022** (as required by OAR 855-065-0009).

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 your 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, correct any deficiencies noted, sign and date the form and file it in a readily retrievable manner. DO NOT SEND to the Board office. You are responsible for ensuring your completed form is available at the time of inspection.

Board inspections are not scheduled; therefore, it is common for the DR 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 you are 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. (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.

2022 OREGON WHOLESALER SELF-INSPECTION FORM

All Class I Wholesaler (W1) MUST complete this inspection form and have it available for inspection by **September 1, 2022,** 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)*

Business Name:_____

License #:_____

Address:_____

City, State, Zip:_____

Telephone:_____

DEA #:_____ Exp Date:_____

Normal Business Hours:_____

Rep email: _____

Rep phone: _____

Date:_____

In person or Virtual Inspection (circle)

Compliance Officer: _____

Rep. present for inspection: _____

Result:_____

Comments:_____

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 licensed?

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

6. What does the wholesaler do when it is asked to ship into a state it is not licensed in?

7. 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 confirm whether or not the outlet is compliant and mark the appropriate box to the left of each item. If you find items that need correcting, rectify the discrepancy and write the date of correction, and then mark the "yes" box. Do not mark "yes" unless the answer is "yes." Note: the correct answer to some questions is "no."

Record Keeping Management and Inventory

Yes	No	N/A			Rule Reference
☐	☐	☐	1	Are records compliant with state and federal laws? Note: The Drug Supply Chain Security Act - DSCSA- is federally implemented and the Oregon Board of Pharmacy adopted rules, eff. 1 July 2015 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
☐	☐	☐	2	Are records and invoices maintained for a minimum of three years? Note: 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	N/A			Rule Reference
☐	☐	☐	3	Are records maintained offsite? Which ones? Where? How long does it take to get them from the offsite location?	OAR 855-065-0010(4)
☐	☐	☐	4	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? How are these stored? Does computer inventory match actual inventory?	
☐	☐	☐	5	Are items examined upon receipt and compared to shipping documents to what was received? If a box appears opened, what is the procedure?	OAR 855-065-0010 (6)(a)
☐	☐	☐	6	Does the outlet have a policy and procedure for identification and quarantine of suspect/illegitimate product? Where are quarantined products stored?	OAR 855-065-0010(6)(d)

Yes	No	N/A			Rule Reference
☐	☐	☐		Does the outlet notify the Board, the FDA, and all affected trading partners of illegitimate product within 24 hours?	
☐	☐	☐	7	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(20)(k) OAR 855-065-0010(6)(c)(A) OAR 855-065-0010-(6)(f)
☐	☐	☐	8	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)
☐	☐	☐	9	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	N/A			Rule Reference
☐	☐	☐	10	Does the outlet have written policies and procedures of the following? Please indicate next to each item where the corresponding policy and procedure is located. The oldest approved stock is distributed first Handling of recalls Any action initiated by the FDA, or other federal or state agency (including the Board)	OAR 855-065-0010

Yes	No	N/A			Rule Reference
				Emergency preparedness (i.e. 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	N/A			Rule Reference
☐	☐	☐	11	Is the outlet of suitable construction and size to facilitate cleaning, maintenance, and proper distribution operations?	OAR 855-065-0012 (1) (a) and (b)

Yes	No	N/A			Rule Reference
☐	☐	☐	12	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)
☐	☐	☐	13	Temperature and Humidity Are temperature and humidity being monitored? How are they monitored? How is the data stored? Where is the data stored? How often is the data reviewed to ensure proper operating conditions? What happens if temperature goes out of range? How frequently are thermometers and/or sensors calibrated? Who calibrates the sensors?	
☐	☐	☐	14	Does the outlet store drugs that require cold storage? How does the outlet ensure the integrity of the product is maintained? How are drugs that require cold storage packed for shipment?	OAR 855-065-0012

Security

Yes	No	N/A			Rule Reference
☐	☐	☐	15	Is there a security system?	OAR 855-065-0012(3)
☐	☐	☐	16	Are there controls that restrict access to areas where drugs are held to authorized personnel only?	OAR 855-065-0012(3)
			17	Who has access to the drug area? Who has access to restricted areas (controlled substances)?	
☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	18	Is the computer system password protected? Are there different levels of access? Are transactions monitored? How often?	
☐	☐	☐	19	Policies and procedures for detection of diversion/losses Are the police, DEA, and Board notified of suspected losses? How are suspected losses handled?	OAR 855-065-0010(5)
☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐	20	Is there an after-hours central alarm or a comparable entry detection system? Who monitors? (example - ADT) Fenced? Cameras? Cages? Outside lighting? Skylight cages?	OAR 855-065-0012(3)(b)

☐ ☐	☐ ☐	☐ ☐	21	Is the outlet clean and in orderly condition? (free from insects, rodents, etc.) Are there Pest Control traps? If yes, how often are they serviced?	OAR 855-065-0012(1)(g)
☐	☐	☐	22	Is there adequate outside perimeter lighting?	OAR 855-065-0012(3)(c)

Prohibited Practices – OAR 855-065-0013

Yes	No	N/A			Rule Reference
☐	☐	☐	23	Is staff aware that purchasing drugs from a closed-door pharmacy is illegal?	OAR 855-065-0013(1)(a)

Personnel *(applicable only to W1)*

Yes	No	N/A			Rule Reference
☐	☐	☐	24	Is the Wholesaler's Designated Representative or Board Contact Person for more than one wholesale distributor? (Note: Prior Board approval is required.)	OAR 855-065-0009(1)
☐	☐	☐	25	Is the Designated Representative or Board Contact Person employed full time by the wholesale distributor, and on-site at least 30 hours per week?	OAR 855-065-0009(1) and (6)
☐	☐	☐	26	Is the Designated Representative or Board Contact Person 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.

Designated Representative Signature:_____ Date:_____