Oregon
John A. Kitzhaber, MD, Governor

Oregon Board of Pharmacy
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Inspector Signature: _____

Date: _____ Deficiency Notice: _____

2012 OREGON WHOLESALER CLASS II SELF-INSPECTION REPORT

All Wholesale Distributors MUST complete this inspection report and have it available for Inspection by ***September 1, 2012*** *pursuant to OAR 855-065-0009(7). DO NOT MAIL TO THE BOARD OFFICE.*

Print Name: _____

Business Name: _____

License No. _____

Address: _____

City, State, Zip: _____

Tel: _____ Normal Business Hours: _____

DEA No: _____ Expiration Date: _____

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 any other wholesale distributor under common ownership or control, in connection with the drug laws or regulations of any state or the federal government? If yes, please attach a statement explaining why. ☐Yes ☐ No

3. Go to the last page. Write where your Self-Inspection Report and Law Book are located, and hang this slip next to the distributor's registration on the wall in the outlet.

4. Where are the following items located inside the outlet: (Be as specific as possible, there can be many filing cabinets and "North" is hard to find without a compass.)

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

5. How many employees does wholesaler employ? _____

6. In what states does wholesaler have a license? _____

7. Who does wholesaler purchase from? _____

8. What are procedures when wholesaler is asked to ship into a state they are not licensed in? _____

_____

_____

CAREFULLY CONFIRM WHETHER OR NOT WHOLESALER IS COMPLIANT AND MARK THE APPROPRIATE BOX TO THE LEFT OF EACH ITEM. IF YOU FIND ITEMS THAT NEED CORRECTING, RECTIFY THE DEFICIENCY 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."

Compliant		**RECORD KEEPING AND INVENTORY ANAGEMENT**
Yes	No	
		9. OAR 855-065-0010(1)(a-c) Do all invoices contain the following?
		• Name of seller.
		• Address of seller.
		• Location from which the drugs were shipped.
		• Address of the location drugs were shipped to.
		• Identity and quantity of drug(s).
		• Dates of receipt and distribution.
		. OAR 855-065-0010 (1)(d) Are there pedigrees for all drugs that leave the normal chain of distribution? (Must be in electronic format after January 1, 2009.)
		10. OAR 855-065-0010 (2-4) Are records and invoices readily maintained for three years? (Records less than 13 months old must be kept at the inspection site or immediately retrievable by computer or electronic means for immediate inspection.)
		11. Is inventory monitored? a. Who monitors inventory adjustments? _____ b. What is the threshold to initiate an investigation for controlled substance and non-controlled substance adjustments? _____
		c. Are DEA and Board notified of losses?
		d. How long do you retain inventory records (3 years)?
		e. Does computer inventory match actual inventory?

		12. Do you examine items upon receipt and compare shipping documents to what was received? If a box appears opened, what do you do? _____
		13. Do you have a quarantine area? How is it handled? _____
		14. Do you have criteria for returning products to inventory when received from a pharmacy?
		• Seals inspected - inner and outer
		• Expiration Date
		• Cold items returned cold. Does customer certify item was maintained at proper temperature?
		15. Do you sell to other wholesalers?
		16. OAR 855-065-0010(9) If you purchase prescription drugs from another wholesale distributor, do you conduct a random authentication of at least 10 percent of the pedigrees annually?
		17. Do you maintain records offsite? Which ones? _____ How long does it take to get from offsite location? _____

Compliant		**POLICIES AND PROCEDURES**
Yes	No	
		18. OAR 855-065-0010 Are you able to produce, at the time of inspection, your facility's written procedures for the following?
		• The oldest approved stock is distributed first.
		• Handling of recalls.
		• Any action initiated by the FDA, or other federal or state agency (including OBOP).
		• Handling of epidemic or emergency preparedness.
		• Outdates.
		• Disposition or destruction of outdates.
		• Investigation of discrepancies.
		• Documentation of temperature and humidity, and storage conditions.
		• Quarantine of adulterated, misbranded, contaminated, contraband, counterfeit, damaged or otherwise unfit for distribution medications. (In such case, you must notify the FDA within three days and conduct a "for case" authentication of each distribution of the drug back to the wholesaler from which the drug was purchased.)
		• Policy for identifying suspicious labels and containers?
		○ Do you notify the FDA if you find medication that is adulterated, misbranded, or counterfeit?

Compliant		**STORAGE OF DRUGS**
Yes	No	
		19. OAR 855-065-0012 (1)(a) and (b) Is your facility of suitable construction and size to facilitate cleaning, maintenance, and proper distribution operations?
		20. OAR 855-065-0012 (1)(c) Does your facility have adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions?
		Temperature and humidity
		a. How many monitors? (Are they temperature and/or humidity?) _____
		b. Where are the monitors? _____
		c. Do you look at monitors and see past graphs? _____
		d. What happens if temperature goes out of range? _____
		e. How frequently do you calibrate monitors? Who calibrates? _____

		21. OAR 855-065-0012(3) Is there a security system?
		a. Are there controls that restrict access to areas where drugs are held to authorized personnel only?
		b. Entry to drug area ○ Who has access? _____ ○ Who has keys to cage (controlled substances)? _____
		c. Computer system
		○ Password protected?
		○ Are there different levels of access? _____
		○ Are transactions monitored? How often? _____
		d. Policies and procedures for detection of diversion/losses.
		○ How are suspected losses handled? Are the police, DEA and Board notified?
		e. An after hours central alarm or a comparable entry detection system.
		Security - who monitors (example - ADT) _____
		○ Fenced?
		○ Cameras?
		○ Cages?
		○ Outside lighting?
		○ Skylights caged?
		27. OAR 855-065-002(1) Is your facility clean and in orderly condition? (i.e. free from insects, rodents, etc.)
		Pest Control
		a. Traps?
		b. Service - how frequent? _____
		22. Do you receive cold storage items?
		a. How is this handled? (Do you check temperature when it arrives, how is it shipped (in Styrofoam cooler with ice?), it is moved immediately to cooler?) _____
		b. How do you pack cold items for shipment? (In cooler with cold pack?) _____
		23. OAR 855-065-0012 (3)(c) Is there adequate outside perimeter lighting?

Compliant		**PROHIBITED PRACTICES**
Yes	No	
		24. OAR 855-065-0013 (1)(a) Are you aware that purchasing drugs from a closed door pharmacy is illegal?
		25. OAR 855-065-0013 (1)(b) Do you understand that your facility may not sell, distribute, or transfer drugs to customers not appropriately registered by the Oregon Board of Pharmacy?
		26. Before furnishing a drug, do you verify that customers are legally authorized to receive the drug?
		27. OAR 855-065-0013(1)(c) Before purchasing a drug from any vendor, do you verify that vendor is legally authorized to sell the drug?
		28. OAR 855-065-0013 (1)(e) Do you understand the prescription medications purchased or sold outside the normal chain of distribution require a pedigree?

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 report and true and correct.

Compliance Officer Signature _____ Date _____

Post next to outlet license on the wall.

DO NOT SEND ANY PART OF THIS REPORT TO THE BOARD OFFICE. KEEP IN THE BOARD OF PHARMACY LAW BOOK, COPIES SENT TO THE BOARD WILL BE DISCARDED.

Location of Wholesaler Self-Inspection Report: _____

Location of Board of Pharmacy Laws and Rules: _____