NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler, Warehouse, Manufacturer Inspection: Instruction Sheet and Form

(Revised 3/2023)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and readily available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you, or a staff if you are not present, and inspect your facility during the month listed on your inspection notice.

To minimize the disruption to your facility during the inspection process please have the following available:

1. Policies and procedures for screening and hiring employees with access to controlled substances and dangerous drugs.

Wholesaler, Warehouse, Manufacturer Information	
Date Completed:	
Business Name:	
NVBOP License #:	
Business Address:	
Business Telephone #:	
Business Fax #:	
Business Email:	
Designated Representative Name:	
Designated Representative Start Date:	

List all officers, directors, managers, employees – (Make copies of this page if additional space is needed)		
#	Name (First, Last)	Credentials/Position
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Administration				
Citation	**Question**	**Yes**	**No**	**NA**
NRS 639.150 NRS 453.270	Are current licenses displayed?			
NAC 639.605	Are there written policies and procedures on the following for prescription drugs?:			
	Procedure to identify/record/report losses or thefts?			
	Procedure to correct errors on wholesaler's inventory?			
	Procedure requiring oldest stock to be distributed first?			
	Procedure on recall/withdrawal?			
	Procedure on recall/withdrawal based on voluntary actions by the drug manufacturer?			
	Procedure for the operation in event of strike, fire, flood, or other disaster?			
	Procedure to assure outdated drugs are separated/disposed of?			
	Procedure for the maintenance of written records on prescription drugs destroyed or disposed of?			
	Procedure on shipping, delivering and receipt of prescription drugs?			
NAC 639.595 21CFR 205.7 21 CFR 1301.90	Do you have policies and procedures for screening and hiring employees with access to controlled substances and dangerous drugs?			

Records				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.602	Are your inventory, receipt and disposition of prescription drugs records stored on-site and readily retrievable?			
	If your inventory, receipt, and disposition of prescription drugs records are stored offsite, are the records available within 2 days?			
	Are the following records of inventory, receipt and disposition of prescription drugs maintained for 3 years?:			
	All documents evidencing that the wholesaler ordered the drug from the supplier?			
	All invoices or other documents provided to the wholesaler concerning the purchase of the drug from the supplier?			
	Copy of license of the supplier that sold the prescription drug to the wholesaler?			
	All shipping records evidencing the shipment from supplier to wholesaler?			
	All document(s) required by NAC 639.5977 that establishes reasonable assurance that the transaction is a bona fide?			
NAC 639.594	Does this wholesaler have an "ongoing relationship" with their manufacturer?			
	If yes, is the "ongoing relationship" between the wholesaler and manufacturer established by the following (required pursuant to NAC 639.594): 1. A written franchise, license or other agreement between a manufacturer and wholesaler to distribute prescription drugs; 2. The presence of the wholesaler on a list of distributors with which the manufacturer does business, created by the manufacturer and located on a publicly accessible website maintained by the manufacturer; or 3. The existence of the purchase by the wholesaler of at least 5,000 sales units of prescription drugs from the manufacturer within the 12 months immediately preceding the transaction for which the wholesaler claims to have an ongoing relationship and: a) The Board or purchasing wholesaler verifying the purchase with the manufacturer at its main corporate office in the United States; or b) The wholesaler maintaining invoices showing that the purchase was made directly from the manufacturer which include an account number assigned by the manufacturer to the wholesaler's address of record on file with the Board.			

	If there is an "ongoing relationship" between the wholesaler and manufacturer, are the records establishing the "ongoing relationship" (required pursuant to NAC 639.594): 1. If the facility is located within this State, maintained at the facility of the wholesaler throughout the period that such a relationship exists; 2. Maintained for 3 years after the termination of any such relationship; and 3. Available for review and copying by the Board or by any authorized representative of a federal, state or local agency.			
NAC 639.603	Each wholesaler shall provide a statement of prior sales identifying each sale of a prescription drug before the prescription drug is sold to another wholesaler or to a pharmacy when supplying prescription drugs if the wholesaler: 1. Has not established an "ongoing relationship with the manufacturer from whom the prescription drug was purchased; or 2. Purchased the prescription drug from another wholesaler. If the wholesaler has not established an "ongoing relationship" with the manufacturer from whom the prescription drug was purchased or had purchased the prescription drug from another wholesaler, does the wholesaler provide a statement of prior sales that meet and include the following (required pursuant to NAC 639.603): 1. Be in writing and bear the title "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act"; 2. Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler; 3. Accompany all prescription drugs purchased from a wholesaler, even if they are resold to another distributor; 4. Include the: a) The business name and address of the person from whom the prescription drug was purchased b) Date of the sale c) Name of the prescription drug; d) Strength of the prescription drug; e) Size of the container; f) Number of containers; g) Lot number of the prescription drug; and h) Name of the manufacturer of the finished dosage form.			
	Is each statement of prior sale maintained by the buyer and the wholesaler for 3 years?			
	Is each statement of prior sale maintained by the wholesaler at its facility?			
	Is each statement of prior sale available for copying or inspection upon a request by an authorized representative of any federal, state, or local agency, a manufacturer of prescription drugs or a pharmacist or practitioner who purchases prescription drugs from the wholesaler?			
NAC 639.5975 NAC 639.6035	If the wholesaler does not provide a statement of prior sales that meet NAC 639.603, please provide the reasons below. Exemptions from NAC 639.603 can be found in NAC 639.5975 and NAC 639.6035: _____ _____ _____ _____			

Storage and Shipping				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.596	Does the facility provide adequate lighting of at least 25 foot-candles?			
	Does the facility provide an adequate area for the storage of prescription drugs within the facility in such a manner as to facilitate access to those drugs?			
	Is the facility maintained in a clean and orderly condition?			
	Is the facility free from infestation by insects, rodents, birds, or vermin?			
	Is the facility secure from entry by unauthorized persons?			
	Is the facility equipped with an alarm system to detect entry to the facility after business hours? Please provide the name of the alarm provider: _____ _____			
	Does the facility maintain a stock of prescription drugs on its shelves sufficient to serve the expected and ordinary needs of the practitioners and pharmacies with which it ordinarily transacts business?			
NAC 639.598	Does the wholesaler store prescription drugs in the facility in the manner prescribed in the United States Pharmacopeia- National Formulary?			
	If there are no specific requirements concerning the temperature at which a prescription drug must be stored, is the drug stored at a controlled room temperature as defined in the United States Pharmacopeia- National Formulary of 59-86°F?			
NAC 639.601	Are outdated, damaged, deteriorated, misbranded or adulterated prescription drug separated from other prescription drugs until it is destroyed or returned to the supplier?			
	Are prescription drugs whose immediate or sealed outer or secondary container have been opened or used, identified as such and separated from other prescription drugs until it is destroyed or returned to the supplier?			
	Are returned drugs sold to other purchasers?			
NAC 639.605	Are outdated/mislabeled/adulterated drugs removed from stock?			
	Do you have a procedure to monitor for outdated or adulterated drugs?			
639.599	Does the wholesaler, upon receiving a prescription drug, examine each outside shipping container of the drug and any accompanying document, including, without limitation, the invoice, the shipping record and the "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603, to determine its identity and to prevent the acceptance of a prescription drug that is: 1. Counterfeit; 2. Deemed to be adulterated or misbranded in accordance with the provisions of chapter 585 of NRS; 3. Mislabeled; 4. Damaged or compromised by improper handling, storage or temperature control; 5. From a foreign or unlawful source; or 6. Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs.			
	Is the examination of prescription drugs received sufficient to detect any damage to the container which would indicate contamination or other damage to the contents of the container?			
	Does the wholesaler examine each outgoing shipment of prescription drugs to identify the prescription drugs contained in the shipment and to ensure that the prescription drugs contained in the shipment are not damaged and have been stored under proper conditions?			
	Do vehicles, used for transport of prescription drugs, meet cleanliness, temperature and security standards?			
NAC 639.597	Is the access to the facility kept to a minimum and well-controlled?			
	Is the outside perimeter of the facility properly lighted?			
	Does the facility distribute controlled substances?			
	If the facility distributes controlled substances, is the access to the area of the facility where controlled substances are stored limited to authorized persons?			

	If the facility distributes controlled substances, is the area of the facility where controlled substances are stored securely enclosed with a material:			
	1. Made of steel of at least 10 gauge in thickness with openings not more than 2 1/2 in. wide.			
	2. Mounted on steel posts at least 1 in. in diameter, placed not more than 10 ft apart.			
	3. Extends to the structural ceiling of the facility.			
	If the material enclosing and securing the controlled substances does not extend to the ceiling of the facility, is the ceiling of the enclosed area constructed of material made of steel at least 10 gauge in thickness with openings not more than 2 1/2 in. wide? A lighter gauge mesh may be used for the ceiling of a large, enclosed area if the walls of the area are at least 14 feet in height.			
	If the facility distributes controlled substances, is the enclosed area securing the controlled substances equipped with a security system which includes an alarm that will transmit a signal to a local law enforcement agency or a private business which provides security services if an unauthorized person obtains access to the enclosed area?			
	If the facility distributes controlled substances, the Executive Secretary of the NVBOP may approve an alternate method for ensuring the security of the area where the controlled substances are stored if he or she determines that the method will ensure that entry to the area is accessible only to authorized persons. Has there been an alternative security plan authorized by the Executive Secretary of the NVBOP? If yes, please provide the plan below: _____ _____ _____			

Sale to Purchasing Wholesaler				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.5977	Does the wholesaler sell prescription drugs to other purchasing wholesalers?			
	If the wholesaler sells prescription drugs to other purchasing wholesalers, does the wholesaler ensure that the purchasing wholesaler is in compliance with the provisions of subparagraph (2) of paragraph (c) of subsection 2 or NRS 639.595?			
	If the wholesaler sells prescription drugs to other purchasing wholesalers, does the wholesaler, before the sale of the prescription drug, obtain from the purchasing wholesaler a written statement that contains a representation by the purchasing wholesaler that, for transactions which occur in this State, the purchasing wholesaler will only sell the prescription drug to a pharmacy or practitioner?			
	If the wholesaler sells prescription drugs to other purchasing wholesalers, does the wholesaler possess written correspondence between the wholesaler and the purchasing wholesaler or between the purchasing wholesaler and other purchasers that evidences the compliance by the purchasing wholesaler with the provisions of subparagraph (2) of paragraph (c) of subsection 2 of NRS 639.595?			
	If the wholesaler sells prescription drugs to other purchasing wholesalers, does the wholesaler ensure that the following statement is written on the face of the invoice or other document which evidences the sale and on the face of any "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in NAC 639.603 that accompanied the sale of the prescription drug printed in all capital letters and in at least 10-point type: "NEVADA LAW REQUIRES THAT YOU MUST SELL THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT ONLY TO PHARMACIES OR PRACTITIONERS. THE SALE OF ANY OF THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT TO ANY PERSON OR BUSINESS OTHER THAN A PHARMACY OR PRACTITIONER WILL RESULT IN A TERMINATION OF FUTURE SALES AND MAY SUBJECT YOU TO OTHER PENALTIES AS PRESCRIBED BY LAW."?			

Requirements for Providers of Respiratory Services				
Citation	**Question**	**Yes**	**No**	**NA**
NAC 639.6954	Facility stocks only medical grade gases?			
	Facility has a system to track service records regarding all equipment? Manual or electronic (circle)			
	Facility has a system regarding how to process a recall of gases? Manual or electronic (circle)			
	Facility has a system to track and locate all gases and equipment distributed? Manual or electronic (circle)			
	Facility has records of serial numbers and model numbers of all equipment distributed? Manual or electronic (circle)			
	Safety data sheets for solutions and products used in cleaning and disinfecting equipment available?			
	Designated area for clean and dirty equipment with signs posted?			
	Designated area for quarantined equipment with signs posted?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action will be sent to the email you indicate below. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Printed Name:	
Signature:	
Email address for correspondence:	