

NEVADA STATE BOARD OF PHARMACY

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

Medical Devices, Equipment and Gases (MDEG) Inspection: Instruction Sheet and Form

(Revised 04/2024)

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 available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

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

1. Completed inspection form along with prior year inspection form
2. Documentation of training for non-clinical staff installing and giving instructions on respiratory equipment. Training shall be completed by a person who is acting within the authorized scope of their practice
3. Accreditation certificate(s)
4. Current liability insurance certificate
5. List of current employees including job functions/titles
6. License(s) for clinical staff members (RT, RN)
7. O2 analyzer calibration documentation (if applicable)
8. Equipment cleaning and/or repair log (if applicable)

Medical Devices, Equipment and Gases (MDEG) Information	
Date Completed:	
MDEG Name:	
MDEG License #:	
MDEG Address:	
MDEG Telephone #:	
MDEG Fax #:	
MDEG Email:	
MDEG Administrator Name:	
MDEG Administrator Start Date:	

List all personnel – (Make copies of this page if additional space is needed)			
#	Name (First, Last)	License/Registration # (If applicable)	Position
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
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16			
17			
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20			

Products and Services Provided	Yes	No
Assistive Equipment		
Respiratory Equipment		
Medical Gases		
Life-Sustaining Equipment		
Enteral Services and Equipment		
Orthotics and Prosthetics		
Stockings		
Insulin Pumps		

General Requirements for MDEGs				
Citation	Question	Yes	No	NA
NAC 639.694	Is the MDEG administrator employed by the medical products provider at the place of business or facility at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week?			
	Has there been a change in administrator since the prior inspection?			
	If yes, was the NVBOP notified within 3 days of the change in administrator?			
	Has the business operated without an administrator for more than 10 days since the prior inspection?			
NAC 639.6942	Has there been a change in ownership since the prior inspection?			
	If yes, was the NVBOP notified within 30 days of the change in ownership?			
NAC 639.6946	Current liability insurance of at least \$1,000,000?			
	Is the facility clean and maintained in an orderly manner?			
	Does the facility have a current MDEG registration with NVBOP?			
	Facility has restroom with sink containing hot and cold running water?			
	Does your company have an internet web site?			
	If yes, provide website: _____			
	Does your company provide any products that require a prescription via the web site?			

Records				
Citation	Question	Yes	No	NA
NAC 639.695	Are records kept on site at facility?			
	Are records kept for a minimum of 5 years?			
	Records are kept in a file, chart, or other storage system allowing the record to be retrieved by reference to the name of the consumer, the name of the practitioner, the date the product was provided, or the type of medical product?			
	Practitioner orders kept in an orderly and readily retrievable manner?			
NAC 639.6952	Records of communications with health professional including consumer's physical, functional, and associated need and/or therapeutic or ameliorative objectives for equipment, product, or service provided?			
	Records of consumer assessment including: safety of the equipment where the equipment will be used, ability to comply with instructions, and ability to clean and maintain the equipment or product?			
NAC 639.6951	Records of consumer communications including: delineation of the commercially available choices, the set-up and use of the equipment or product, and the maintenance, servicing, cleaning, and repair of the equipment or product?			
NAC 639.6946	Does the facility repair equipment on site? If yes, please have a repair log available for review that identified the following: Type of medical product Manufacturer Model or model number Serial number Date of repair Specific repair made Name of person who made the repair Certification that repair brought medical product back to manufacturer's specification If repairs are not done on site please list where they are sent: _____			
	Proof that calibration or testing equipment is accurate and maintained according to manufacturer's directions and specifications?			

Requirements for Providers of Respiratory Services				
Citation	Question	Yes	No	NA
NRS 630.047 (1)(K)	A person who installs medical equipment for respiratory care that is used in the home and gives instructions regarding the use of that equipment if the person is trained to provide such services and is supervised by a provider of health care who is acting within the authorized scope of his or her practice is exempt from the statutes listed in NRS 630.			
NAC 639.6954	Stocking only medical grade gases?			
	Service records regarding all equipment?			
	Verification that equipment has been checked and is defect free before the equipment is dispensed?			
	Checking that equipment has not been modified in any way that would affect the effectiveness of the equipment?			
	Checking that the equipment does not present a fire or shock hazard?			
	Checking that the equipment has all warning labels and tags?			
	Records tracking all gases dispensed, including the lot numbers?			
	Records regarding recall of gases?			
	System to track and locate all gases and equipment dispensed?			
	Records of serial numbers and model numbers of all equipment dispensed?			
	Safety data sheets for solutions and products used in cleaning and disinfecting equipment?			
	Designated area for clean and dirty equipment with signs posted?			
	Designated area for quarantined equipment with signs posted?			
	Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, or equipment?			

Requirements for Providers of Life-Sustaining Equipment (Ventilators)				
Citation	Question	Yes	No	NA
NAC 639.6955	Maintain a sufficient number of employees who are trained to service and repair the life-sustaining equipment provided by the medical products provider?			
	Maintain a sufficient number of employees who are available to service and repair life-sustaining equipment within 1 hour of any call for service or repair?			
	Facility has a 24-hour toll free number consumers may call if life-sustaining equipment has malfunctioned?			
	Written emergency information and procedure is attached to the life-sustaining equipment?			
	Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, and equipment in the case of malfunction of life-sustaining equipment?			
NAC 639.6956	Consumer orientation and written checklist including: Instructions for use of the equipment, cleaning procedures, safety precautions, and maintenance procedures?			
	Manufacturer's instructions for use of the equipment?			
	Policy for handling of outdated products?			
	Is equipment cleaned and tested between patient use?			

Requirements for Providers of Orthotics and Prosthetic Services				
Citation	Question	Yes	No	NA
NAC 639.69535	Is the person providing the services certified by an accreditation and certification organization? If yes, provide certification document to inspector.			
	Is the facility accredited by an accreditation and certification organization? If yes, provide certification document to inspector			
	Does the facility provide emergency services to a consumer within 12 hours after the consumer or his or her caregiver requests the service?			
NAC 639.69537	Is an order from a practitioner obtained for all customized orthotic and prosthetic devices?			

Requirements for Providers of Pressurized Stockings				
Citation	Question	Yes	No	NA
NAC 639.69545	Are prescriptions obtained for all pressurized stocking orders that have a pressure rating of 20mm of mercury or higher?			
	Documentation is available of consumer training in the proper use and maintenance of stockings that have a pressure rating of 20mm of mercury or higher?			

Requirements for Providers of Insulin Pumps				
Citation	Question	Yes	No	NA
NAC 639.69543	Is the training for insulin pumps provided by a person who is certified by the manufacturer of the insulin pump in the operation of the pump?			
	Does the training include the proper use and maintenance of the pump and the procedures for dealing with a malfunction or other problem that may arise in the use of the pump?			

Requirements for MDEG Wholesalers				
Citation	Question	Yes	No	NA
NAC 639.6937	Medical products wholesaler is defined as to sell, lease, or otherwise provide medical products to a health care facility, agency, practitioner, or provider in this state.			
NAC 639.6957	I have reviewed the regulations related to MDEG wholesalers?			

Requirements for MDEG providers holding an inventory of ambulatory aids at a hospital				
Citation	Question	Yes	No	NA
LCB File R058-23	Does the MDEG provider hold at a hospital an inventory of ambulatory aids for sale to patients of the hospital upon discharge?			
	Does the MDEG provider have a contract with the hospital under which the hospital agrees to furnish the appropriate providers of healthcare who will be available at all times to assist patients with the use and operation of ambulatory aids?			
	Does the MDEG provider employ an administrator who is designated as the MDEG administrator for the hospital, serves in that capacity for not more than five hospitals (each of which is located not more than 50 miles from each of the others), meets the requirements of NAC 639.694, and is on call and reasonably available at all times to assist patients with the use and operation of ambulatory aids?			
	Does the MDEG provider deliver ambulatory aids to patients of the hospital only at the site of the hospital?			
	Does the MDEG provider maintain a license to engage in business as a medical products provider for each hospital at which the medical products provider intends to hold an inventory of ambulatory aids?			
	Ambulatory aids means mobility enhancing equipment, prosthetic devices, orthotic devices, ambulatory casts and other braces, supports and casts for human use.			

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:	