From: Nevada State Board of Pharmacy Inspector

Subject: Self-Evaluation Inspection Process

Medical Devices, Equipment and Gases (MDEG) industry managers and the Board of Pharmacy have jointly adopted the concept of a self-evaluation inspection process for several purposes. First, the inspection process is designed not to incriminate but to educate by providing ample notice and sufficient time to fill out the report. Secondly, you can correct non-compliance matters before inspection.

The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of MDEG services. An inspection evaluation form must be obtained on the website and is to self-assess compliance with Nevada MDEG law.

I will review the form with you and inspect your facility during the month listed on the Inspection Notice.

Your inspection will occur during normal business hours, at no specific date or time.

The procedure involves the following:

1. At the minimum, print and fill out the self-evaluation form. I cannot evaluate or help you if I don’t know what you don’t know. Retain the form and have it readily available in a packet along with last year’s inspection report so if you are not present when I arrive, your staff can make it available to me.

2. Use the form to guide you through examination of your policies and procedures.

3. I will conduct a review of your operation. My observations, along with your findings will assure understanding and compliance with Nevada law.

4. This plan has been established as a cooperative approach to annual inspections. I would appreciate any input you may have on this joint review process.
Inspector: ___________________________ Date: ___________________________

MDEG Company: _______________________________________________________

Address: _____________________________________________________________

City/State/Zip: _________________________________________________________

Phone #: ___________________________ Fax #: _____________________________

Email: ___________________________ Pre-opening Yes: _______ No: _______

License #: ___________________________

Weekday Hours of Operation: ___________ Sat Hours of Operation: ___________

Sun Hours of Operation: ___________

If the records are located at an address different than the location of the equipment, give the address of the location of the records: (circle) Records On site / Records Off site address

Administrator: _______________________________________________________

NAC 639.694 1. (d) The administrator must be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer 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.

PRODUCTS & SERVICES PROVIDED (check all that apply)

☐ Assistive Equipment☐ Enteral Services & Equipment
☐ Respiratory Equipment☐ Orthotics & Prosthetics
☐ Medical Gases☐ Diabetic Equipment & Supplies
☐ Life-sustaining Equipment

Please list of your current employees and a separate list of employees terminated or transferred since your last inspection (or provide a computer printout).

Active Employees
Name and Duty (include title where appropriate)

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Terminated or Transferred Employees
Name and Duty (include title where appropriate)

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________
General Requirements for all MDEG Registrants  NAC 639.6946

Facility clean and maintained in an orderly manner? Yes  No
Current registration displayed?  NAC 639.6942  Yes  No
Restroom with sink with hot and cold running water? Yes  No
Restroom clean, has hand soap and paper towels, and has sign (employees to wash hands after use)? Yes  No
City or county business license? Yes  No
City or county fire code approval? Yes  No
Proof of general liability insurance (minimum of $1,000,000)  Exp. Date:__________________________
Does your company have an internet web site? Yes  No
If so, what is the web address:__________________________
Does your company sell any products that require a prescription via the web site/internet? Yes  No

Inspector's comments:________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Records Requirement for all MDEG Registrants

Consumer records kept so that they may be readily retrieved by:  NAC 639.695
- Consumer's name  Yes  No
- Practitioner's name  Yes  No
- Date equipment or service provided  Yes  No
- Type of equipment or product  Yes  No
- Practitioner orders kept in an orderly and readily accessible manner  Yes  No
Records of communications with health professionals including:  NAC 639.6952
- Consumer’s physical, functional and associated needs?  Yes  No
- Therapeutic or ameliorative objectives for equipment, product, or service provided?  Yes  No
Records of consumer assessment including:  NAC 639.6951
- Safety of the environment where equipment will be used  Yes  No
- Ability to comply with instructions  Yes  No
- Ability to clean and maintain the equipment or product  Yes  No
Records of consumer communications including:  NAC 639.6951
- Delineation of the commercially available choices  Yes  No
- The set up and use of the equipment or product  Yes  No
- The maintenance, servicing, cleaning, and repair of the equipment or product  Yes  No
Does the facility repair equipment on site?  NAC 639.6946
(If yes-have available a repair log that identifies the following:)
(If no-have available a log that shows where equipment was repaired plus identifies the following:)
- Type of equipment  Yes  No
- Manufacturer of equipment  Yes  No
- Model or model number of equipment  Yes  No
- Serial number of equipment  Yes  No
- Date of Repair  Yes  No
- Specific repair made  Yes  No
- Name of person who made the repair  Yes  No
- Certification that repair brought equipment back to manufacturer's specification  Yes  No

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Proof that calibration or testing equipment is accurate and maintained according to manufacturer's directions and specifications NAC 639.6946 (attach certifications)  
Yes  No

FDA medical device tracking records kept in orderly and readily accessible manner  
Yes  No

Inspector’s comments:

Requirements for Providers of Medical Gases, Respiratory Equipment and CPAP – BIPAP and BIPAP ST. Any company providing respiratory services that require a practitioner order (prescription) needs to have an RT or Nurse on staff or on contract. NAC 639.6954 If not applicable skip to next section

If a nurse is providing respiratory services, the nurse should provide a signed and dated statement that the nurse has been trained in the respiratory modality that the nurse is training a patient to use and that the nurse is qualified to train others in those modalities that the nurse has been trained to provide. If a delivery person is instructing a patient in any respiratory modality, provide a signed and dated statement that the delivery person has been trained by the Respiratory Therapist or Nurse, contracted or employed by the facility, in the modality that the delivery person is instructing the patient to use. NRS 630.047

Stocking only medical grade gases  
Yes  No

Service records regarding all equipment  
Yes  No

Verification that equipment has been checked and is defect free before the equipment is dispensed  
Yes  No

Checking that equipment has not been modified in any way that would affect the effectiveness of the equipment  
Yes  No

Checking that the equipment does not present a fire or shock hazard  
Yes  No

Checking that the equipment has all warning labels and tags  
Yes  No

Records tracking all gases dispensed, including the lot numbers  
Yes  No

Records regarding recalls of gases  
Yes  No

System to track and locate all gases and equipment dispensed  
Yes  No

Records of serial numbers and model numbers of all equipment dispensed  
Yes  No

Protocol for cleaning and disinfecting equipment  
Yes  No

Material safety data sheet for solutions and products used in cleaning and disinfecting  
Yes  No

Designated areas for clean and unclean equipment with signs posted  
Yes  No

Designated area for quarantined equipment with signs posted  
Yes  No

Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, and equipment  
Yes  No

Does the facility provide CPAP- BIPAP or BIPAP ST (spontaneous timed) Equipment?  
Yes  No

Provide the following information for your Respiratory Therapist(s) or Nurse(s) Providing Respiratory services that require a practitioner order (prescription).  
Yes  No

Name  Exp. Date  License #

Inspector’s comments:
**Special Requirements for Providers of Life Sustaining Equipment (Ventilators)**
NAC 639.6955

If not applicable skip to next section.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour toll-free number for consumers</td>
<td></td>
<td></td>
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<tr>
<td>Written emergency information and procedure that is attached to the life-sustaining equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy and procedure or other documentation for the providing of emergency supply of gases, supplies, and equipment.</td>
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<td></td>
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</tbody>
</table>

**Inspector’s comments:**

**Special Requirements for Providers of Enteral Services**
NAC 639.6956

If not applicable skip to next section.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer orientation and written checklist</td>
<td></td>
<td></td>
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<tr>
<td>Manufacturer's instructions provided to consumers</td>
<td></td>
<td></td>
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<tr>
<td>Policy for handling of outdated products</td>
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</tbody>
</table>

**Inspector’s comments:**

**Special Requirements for Providers of Orthotics & Prosthetics**

If not applicable skip to next section.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>List product categories provided: (i.e.: prosthetic limbs, mastectomy, supports, braces)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the facility provide pressurized stockings rated above 20mm/HG?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orders for stockings filed with consumer’s record?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentation is available of consumer training in the proper use &amp; maintenance of stockings?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List facility certifications by company &amp; certification category:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(attach list for additional certifications)

| Certified fitters names: | |

**Inspector’s comments:**

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Special Requirements for Providers of Insulin Pumps & Diabetic Supplies
If not applicable skip to next section.

List product categories provided: (i.e.: testing equipment, testing supplies, pumps)

________________________________________________________________________________________

Documentation available of consumer training in the proper use & maintenance of products?  Yes  No
Does facility supply and service insulin pumps? (If yes list brand & model below)  Yes  No

Inspector’s comments:

________________________________________________________________________________________

Special Requirement for MDEG Wholesalers  NAC 639.6957 (applies only if sell to other providers)

Maintenance log showing for each piece of equipment:
  Type of equipment   Yes  No
  Manufacturer        Yes  No
  Model or model number Yes  No
  Serial number       Yes  No
  Date of repair      Yes  No
  Specific repair made Yes  No
  Name of person who performed the repair Yes  No
  Certification that equipment has been returned to manufacturer’s specifications Yes  No

If repaired equipment cannot be brought back to the manufacturers specifications, proof that the equipment has either been restricted in its use or is removed from service Yes  No
Evidence that calibration and testing equipment is accurate Yes  No
For scales used to weigh liquid oxygen, certification by the Bureaus of Weights and Measures? Yes  No
Records detailing sale or other disposition of equipment? Yes  No

Inspector’s comments:

________________________________________________________________________________________
I understand that under NAC 639.694 that as a medical products provider and/or wholesaler that I am required to notify the staff of the Board of Pharmacy of the cessation of employment of the current administrator and of the employment of a new administrator within 3 days of the occurrence. I also understand that I may not operate for more than 10 business days without an administrator.

Remarks:

If you are required to provide any documentation to the inspector via fax or email attach a copy of the document(s) to this inspection form for future review.

Representative’s Printed Name

Facility Representative’s Signature

Date

Inspector’s Signature

Date