Chapter 639 of NAC

LCB File No. T001-06

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

Filed with the Secretary of State on September 29, 2006

AMENDMENTS TO REGULATIONS REGARDING MDEG LICENSEES

Section 1. NAC 639.6941 shall be amended as follows:

1. In addition to the acts described in NAC 639.945 which are applicable to medical products providers or medical products wholesalers, the following acts or practices by a medical products provider or a medical products wholesaler are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

(a) Any violation of these regulations or violation of any applicable federal, state or local laws related to the practices of the medical products provider or medical products wholesaler.

(b) Loss of, or failure to maintain or renew, the required liability insurance.

(c) Practicing, condoning, facilitating or collaborating with any form of unlawful discrimination against any person or group on the basis of race, color, sex, sexual orientation, age, religion, national origin, marital status, or mental or physical handicap in providing any service or product to a consumer.

(d) Failing to maintain the confidentiality of information regarding a consumer and disclosing such information without valid authorization, except where such a disclosure is required by law.

(e) Performing or allowing any employee or agent of the medical products provider or medical products wholesaler to perform services beyond the training, competency, ability or knowledge of the employee or agent.

(f) Submitting any claim for payment or reimbursement to any person or entity for products or services that is fraudulent, deceitful, unnecessary, or for any products or services not actually provided to a consumer.

(g) Violating any provision of the Code of Ethics of the National Association for Medical Equipment Services, which is hereby adopted by reference, a copy of which may be obtained, free of charge, by writing to the American Association for Homecare, 625 Slaters Lane, Suite 200, Alexandria, Virginia 22314-1171.

(h) Violating any provision of the Code of Ethics of the Nevada Association of Medical Products Suppliers, which is hereby adopted by reference, a copy of which may be obtained, free of charge, by writing to the Nevada Association of Medical Products Suppliers, P.O. Box 61492, Boulder City, Nevada 89006-1492.

(i) Engaging in any knowing or willful offer, payment, solicitation or receipt of any remuneration to induce referrals of sales, leases, or other provisions of medical products or services by any medical products provider, medical products wholesaler or health professional.

(j) Violating any provision of the Standards of Practice and the Code of Ethics for the National Registry of Rehabilitation Technology Suppliers, which is hereby adopted by reference. The publication may be obtained from the National Registry of Rehabilitation Technology Suppliers, P.O. Box 4033, Lago Vista, Texas 78645-4033, for the price of $5 or free of charge at the Internet address http://www.nrrts.org/.

(k) Violating any provision of the Code of Ethics produced by the Board for Orthotist/Prosthetist Certification, which is hereby adopted by reference. The publication may be obtained from the Board for Orthotist/Prosthetist Certification, 515 West Lombard Street, First Floor, Baltimore, Maryland 21201 or from its Internet address at http://www.bocusa.org.

(l) Violating any provision of the Code of Professional Responsibility of the American Board for Certification in Orthotics and Prosthetics, Inc., which is hereby adopted by reference. The publication may be obtained from the American Board for Certification in Orthotics and Prosthetics, Inc., 330 John Carlyle Street, Suite 210, Alexandria, Virginia 22314 or from its Internet address at http://www.abcop.org.

2. The owner of a medical products provider is responsible for the acts of his business administrator and employees.

3. The owner of a medical products wholesaler is responsible for the acts of his facility administrator and employees.

Section 2. NAC 639.6943 shall be amended as follows:

The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

1. An actively practicing health professional; or

2. A partnership, corporation or association in which an actively practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more actively practicing health professionals.

3. For the purposes of this section, "actively practicing health professional" means a person who performs services within the scope of his licensure or registration in any capacity in a facility other than the facility of the medical products provider or medical products wholesaler.

Section 3. NAC 639.6945 shall be amended as follows:

1. The Board may waive the license fee, or any part thereof, for a medical products provider that:

~~[1.]~~ ***(a)*** Is a tax-exempt charitable organization pursuant to 26 U.S.C. § 501(c);

~~[2.]~~ ***(b)*** Provides medical products to a majority of the consumers served by the medical products provider at no charge; and

~~[3.]~~ ***(c)*** Verifies to the satisfaction of the Board that 75 percent of the funds of the medical products provider are used for bona fide charitable purposes.

2. A medical products provider that qualifies for waiver of the license fee pursuant to paragraph 1 must conduct its business in compliance with these regulations. In addition, a medical products provider that qualifies for waiver of the license fee pursuant to paragraph 1 may:

(a) Accept donations of medical products or food products;

(b) Dispense donated ~~[condition]~~ ***equipment in an "as is" condition as long as:***

(1) The medical equipment does not require a prescription or physician's order to be dispensed; and

(2) The consumer or his caregiver or agent sign a waiver indicating that he understands that the equipment is in an "as is" condition; and

(c) Dispense donated food products except for products for which an enteral or parenteral pump is required as long as the food products are not adulterated or expired.

Where a donated medical product bears an indication that the product was provided by or originated with another medical products provider, the medical products provider that qualifies for waiver of the license fee pursuant to paragraph 1 may not dispense the donated medical product unless it first contacts the original medical products provider to determine whether it still claims the medical product or whether it will allow the donated product to be retained and dispensed.

Section 4. NAC 639.6946 shall be amended as follows:

1. A medical products provider shall:

(a) Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, setup, repair and maintenance.

(b) Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

(c) Ensure that each employee is trained to:

(1) Use, setup, repair and maintain the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or otherwise provide to a consumer; and

(2) Instruct consumers concerning the use, setup and maintenance of the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or provide to a consumer.

(d) Maintain an inventory of medical products that is adequate to serve the needs of the consumers served by the medical products provider.

(e) Maintain a physical location ***that is not a residence and that is suitable from which to operate a business*** at which the medical products provider can:

(1) Store inventory;

(2) Repair or service any equipment which the medical products provider sells, leases or otherwise provides; and

(3) Keep all current records related to the business of the medical products provider.

(f) Have a functioning restroom containing a toilet and a sink with hot and cold water at the place of business of the medical products provider.

(g) Maintain the place of business of the medical products provider in a clean, orderly and sanitary condition.

(h) Ensure that the place of business complies at all times with applicable federal, state and local laws, regulations and rules, including, without limitation, applicable occupational safety rules, fire codes, building codes and health codes.

(i) Maintain liability insurance of at least $1,000,000, which must include product liability insurance if the medical products provider:

(1) Designs, fabricates or manufactures medical products; or

(2) Substantially modifies commercially available medical products.

(j) Maintain a log or other record regarding all repairs made to a medical product provided by the medical products provider. For a medical product repaired by the medical products provider, the log or record must identify:

(1) The type of medical product;

(2) The manufacturer;

(3) The model or model number;

(4) The serial number;

(5) The date of the repair;

(6) The specific repair made;

(7) The name of the person or company who performed the repair; and

(8) A certification that the medical product has been returned to the specifications of the manufacturer as a result of the repair.

2. If the medical products provider cannot certify that the repaired medical product has been returned to the specifications of the manufacturer as a result of the repair, the medical products provider must:

(a) Determine whether the medical product can be safely and effectively used for a limited purpose, in which case the medical products provider must note that the medical product must only be used for a limited purpose and must ensure that the medical product is only used for such a limited purpose; or

(b) Ensure that the medical product is removed from service and is not sold, leased or otherwise provided to any person without a written statement acknowledging that the medical product:

(1) Was repaired;

(2) Could not be repaired to the specifications of the manufacturer; and

(3) Cannot be used by the consumer for the purposes for which the medical product was intended.

3. Any device used by a medical products provider to calibrate or test equipment must be accurate and must be maintained according to the directions and specifications of the manufacturer. The scales used to weigh reservoirs of liquid oxygen must be accurate and must be certified annually by the State Sealer of Weights and Measures.

4. The business premises of any medical products provider must be open and accessible to the public and the Board at all times during regular hours of operation.

5. A medical products provider shall develop and use a written procedure for addressing consumer complaints, including, without limitation, procedures for maintaining a complaint file that documents all complaints from consumers and the resolution of each complaint.

Section 5. NAC 639.6951 shall be amended as follows:

1. When a medical products provider sells, leases or otherwise provides medical products to a consumer upon the written or oral order or prescription of a health professional, the medical products provider shall communicate with the health professional to ascertain:

(a) The physical, functional and associated needs of the consumer; and

(b) The therapeutic or ameliorative objectives to be met by the medical products that will be sold, leased or otherwise provided by the medical products provider.

2. When a medical products provider sells, leases or otherwise provides medical products to a consumer, the medical products provider shall communicate with the consumer, or his family, caregiver or agent to ascertain and assess:

(a) The safety of the environment in which the medical products will be used;

(b) The ability of the consumer or his family, caregiver or agent to comply with the instructions of the health professional of the consumer and medical products provider regarding the proper use of the medical products; and

(c) The ability of the consumer or his family, caregiver or agent to clean and maintain the medical products.

3. A medical products provider may not sell, lease, or otherwise provide an insulin pump to a consumer unless:

(a) The medical products provider employs or otherwise provides the services of a person certified in the operation of the particular insulin pump; and

(b) The person certified in the operation of the particular insulin pump communicates with and trains the consumer or his family, caregiver or agent in the use, maintenance, and proper method for dealing with malfunctions or problems that may arise with the use of the pump.

~~[3.]~~ ***4.*** The medical products provider shall make a written record of all communications made pursuant to this section.

Section 6. NAC 639.6954 shall be amended as follows:

1. A medical products provider that sells, leases or otherwise provides medical gases and associated equipment, or respiratory equipment shall:

(a) Comply with all applicable federal, state and local laws regarding the providing and transportation of such gases and equipment, including, without limitation, all requirements regarding the tracking and recalling of gases and equipment;

(b) Comply with all applicable federal, state, and local laws regarding transfilling and repackaging of such gases;

(c) Comply with all applicable federal, state and local laws, including, without limitation, fire codes, occupational safety rules, building codes and health codes;

(d) Service equipment sold, leased or otherwise provided by the medical products provider according to the directions and specification of the manufacturer, regardless of where the equipment may be located at the time that the equipment is due for servicing;

(e) Make and keep records regarding the servicing of equipment by the medical products provider; and

(f) Provide only gases that are:

(1) Medical grade; and

(2) Intended for use by humans.

2. Before providing any equipment pursuant to this section, a medical products provider shall verify that the equipment:

(a) Has been checked and is free of defects;

(b) Is operating within the specifications of the manufacturer;

(c) Has not been modified in any way that will jeopardize the effectiveness or safety of the equipment;

(d) Does not present a hazard of fire or shock; and

(e) Has all warning labels and tags that were provided by the manufacturer, wholesaler or seller of the equipment.

3. A medical products provider that sells, leases or otherwise provides medical gases and equipment or respiratory equipment shall develop and use policies and procedures that require:

(a) Making and keeping records to track and recall all gases dispensed by the medical products provider, including, without limitation:

(1) Recording the lot numbers ~~[and expiration dates]~~ for each cylinder or unit of gas provided;

(2) Maintaining a written or computerized system to track and locate all gases and equipment provided by the medical products provider; and

(3) Recording the serial numbers and model numbers of all equipment provided by the medical products provider;

(b) Maintaining and cleaning equipment provided by the medical products provider, including, without limitation:

(1) Documenting that the function and safety of the equipment was verified before the equipment was provided to the consumer;

(2) Cleaning and disinfecting equipment pursuant to an established protocol to remove aerobic and anaerobic pathogens from the equipment to the specifications of the manufacturer for that equipment;

(3) Making and keeping a material safety data sheet for the solutions and products used in cleaning and disinfecting the equipment;

(4) Designating areas at the business of the medical products provider that must be used to store separately clean and unclean equipment; and

(5) Designating a separate area at the business of the medical products provider that must be used to store quarantined equipment.

4. When a medical products provider provides oxygen, the medical products provider must also provide an emergency supply of oxygen, supplies and equipment to maintain therapy while the primary supply of oxygen and related equipment is inoperable or unusable.

5. In addition to any communication and advisement required pursuant to NAC 639.693 to 639.6958, inclusive, a medical products provider who provides medical gas and related equipment, or respiratory equipment, must advise the consumer receiving the medical gas and related equipment, or respiratory equipment, regarding:

(a) Cleaning of the equipment;

(b) Potential hazards and warning signs of malfunctioning or inadequately functioning equipment;

(c) Maintenance procedures for the equipment;

(d) The telephone number, contact name, and contact address for emergency servicing or repair of the equipment, and for routine servicing or repair of the equipment; and

(e) The written materials about the equipment that are available from the medical products provider or the manufacturer of the equipment.

6. For the purposes of this section, “material safety data sheet” has the meaning ascribed to it in 29 C.F.R. § 1910.1200.

Section 7. NAC 639.6955 shall be amended as follows:

A medical products provider who sells, leases or otherwise provides life-sustaining equipment shall:

1. Maintain a sufficient number of employees who are:

(a) Trained to service and repair the life-sustaining equipment provided by the medical products provider; and

(b) Available to service and repair the life-sustaining equipment within 1 hour of any call for service or repair;

2. Inform all consumers to whom the medical products provider has sold, leased or otherwise provided life-sustaining equipment of a toll-free telephone number that the consumer may call at any time the life-sustaining equipment has malfunctioned;

3. Ensure that information and procedures in the event of an emergency are in writing and attached to the life-sustaining equipment; ~~[and]~~

4. Provide the consumer with sufficient emergency supplies and equipment necessary to sustain the consumer until the medical products provider can service or repair the life-sustaining equipment~~[.]~~ ***; and***

5. Provide redundant life-sustaining equipment if it does not or cannot maintain a sufficient number of employees to comply with subsection (b) of paragraph 1.

Section 8. NAC chapter 639 shall be amended by adding for following new language:

1. A medical products provider who sells, leases or otherwise provides customized orthotic or prosthetic devices shall:

(a) Have employed or otherwise available to its consumers a person certified by either the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification;

(b) Have its facility accredited by either the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification;

(c) Not serve a customer unless the accreditation of its facility and the certification of its certified person who will be assisting consumers are current and in good standing;

(d) Not violate the provisions of the code of ethics or professional responsibility applicable to its facility's accreditation;

(e) Not allow its certified person who will be assisting consumers to violate the code of ethics or professional responsibility applicable to his certification.

2. A medical products provider who sells leases or otherwise provides customized orthotic and prosthetic devices shall have and shall conform its practices to policies and procedures regarding:

(a) The making of and maintenance of the confidentiality of records regarding the treatment of its consumers;

(b) Provision of emergency services within 12 hours after a request for assistance by a consumer or his caregiver or agent;

(c) The treatment of a consumer only upon the order of a prescribing practitioner;

(d) A method by which a consumer can complain to the facility about his treatment and by which the facility will respond to and address the complaint; and

(e) The assurance that the practices of the facility and its certified person who will be assisting consumers will conform to the code of ethics or professional conduct applicable to eachs accreditation.

3. ~~[A medical products provider who sells only customized prosthetics related to mastectomy is not considered a provider of customized orthotics or prosthetics under this section.~~

~~4.]~~ ***A person who applies for a license to become a medical products provider to sell, lease or otherwise provide customized orthotic or prosthetic devices pursuant to this section must:***

(a) At the time of application have an employee or other person who can satisfy the requirement of subparagraph (a) of paragraph 1;

(b) If the facility is accredited at the time of application, provide evidence of the accreditation with the application to the board;

(c) If the facility is not accredited at the time of application:

(1) Provide evidence of application for accreditation of the facility with one of the two accrediting organizations as part of the application;

(2) Pursue the application for accreditation of the facility in good faith; and

(3) Provide evidence of accreditation no later than 12 months after the date of the Board's approval of the provider's application for licensure.

Section 9. NAC chapter 639 shall be amended by adding for following new language:

A medical products provider who sells, leases or otherwise provides customized orthotic or prosthetic devices who is already licensed by the board at the time of the effective date of this regulation shall have twelve months from the effective date of this regulation within which to obtain accreditation of its facility and to provide proof of accreditation to the board pursuant to Section 8, subparagraph (b) of paragraph 1.

NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T001-06

The State Board of Pharmacy adopted temporary regulations assigned LCB File No. T001-06 which pertain to chapter 639 of the Nevada Administrative Code on September 7, 2006.

Date of adoption by agency: 9/7/2006
Hearing date: 9/7/2006 **Filing date:** 9/29/2006

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was ___4__.
The number of persons who testified at the hearing was __4___.
The number of agency submitted statements was __0___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was amended without change as a result of testimony offered at the hearing in support of the language.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the board for enforcement of this regulation.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.