Chapter 639 of NAC

LCB File No. T016-07

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

Filed with the Secretary of State on March 29, 2007

Note: Changes from 12/26/06 version are underlined and in red.

Section 1. Section 8 of the as yet uncodified regulation that was filed on September 29, 2006 shall be amended as follows:

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 except that a provider is not required to have its facility accredited when the only customized orthotic or prosthetic products that it sells are:

(1) Customized ~~[mastectomy products]~~ ***breast prostheses or customized mastectomy forms; or***

(2) Pressurized stockings rated above ~~[18]~~ ***20*** mm/HG***;***

(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 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.

4. A medical products provider may not sell, lease, or otherwise provide pressurized stockings rated above ~~[18]~~ ***20*** mm/HG to a consumer unless:

(a) The medical products provider employs or otherwise provides the services of a person certified in the fitting and use of the particular brand of pressurized stocking; and

(b) The person certified in the particular brand of pressurized stocking communicates with and trains the consumer or his family, caregiver or agent in the use, maintenance, and potential problems that may arise with the use of the stocking; and

(c) The patient presents a prescription or order for the pressurized stocking from his practitioner.

5. For the purposes of this section, "customized orthotics and prosthetics devices" shall mean a device that is custom assembled, built, or altered specifically for a patient to approximate a patient's unique anatomy. The term shall include customized ~~[mastectomy products]~~ ***breast prostheses and customized mastectomy forms,*** but shall not include pressurized stockings rated below ~~[18]~~ ***20*** mm/HG**.**

NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T016-07

The State Board of Pharmacy adopted temporary regulations assigned LCB File No. T016-07 which pertain to chapter 639 of the Nevada Administrative Code on February 23, 2007.

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.

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

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 adopted without change as no testimony was offered.

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.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

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.