Chapter 639 of NAC

LCB File No. T016-07

PROPOSED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

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**.**