

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R052-24

April 1, 2024

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§ 1 and 2, NRS 639.070.

A REGULATION relating to medical products; making certain provisions governing medical products applicable to certain pressurized stockings; prohibiting a medical products provider or other person from selling, leasing or otherwise providing certain pressurized stockings without an order from a practitioner; requiring a medical products provider or other person to provide certain training concerning any pressurized stocking sold, leased or otherwise provided to a consumer; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations governing the storage, handling, sanitation and security of medical devices. (NRS 639.070) Existing regulations prescribe certain requirements applicable to a medical products provider or other person who sells, leases or otherwise provides medical products to a consumer with regard to medical products sold by the medical products provider or other person. (NAC 639.6946, 639.6948-639.6952) Existing regulations provide that pressurized stockings that have a pressure rating of less than 20 millimeters of mercury are not medical products for the purposes of those requirements. Existing regulations thereby exempt a medical products provider or other person from requirements relating to medical products when the provider or other person provides such pressurized stockings. (NAC 639.6935) **Section 1** of this regulation removes that exemption, thereby requiring a medical products provider or other person to comply with those requirements when providing such pressurized stockings.

Existing regulations prohibit the sale, lease or provision to a consumer of a pressurized stocking that has a pressure rating of 20 millimeters of mercury or more without an order from a practitioner. (NAC 639.69545) **Section 2** of this regulation revises this prohibition to instead apply to any pressurized stocking for which such an order is required by the United States Food and Drug Administration or according to the label of the stocking, regardless of its pressure rating.

Existing regulations require a medical products provider or other person who sells, leases or otherwise provides a pressurized stocking to a consumer that has a pressure rating of 20 millimeters of mercury or more to provide certain training concerning the stocking to the

consumer or his or her family, caregiver or agent. (NAC 639.69545) **Section 2** requires such a medical products provider or other person to provide such training when selling, leasing or otherwise providing to a consumer any pressurized stocking, regardless of its pressure rating.

Section 1. NAC 639.6935 is hereby amended to read as follows:

1. “Medical products” includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

2. The term does not include:

(a) Controlled substances;

(b) Dangerous drugs, except medical gases and supplies that facilitate the use of a dangerous drug, including, without limitation, normal saline and other similar inert liquids; *or*

(c) Medical devices, equipment, supplies or gases the regulation of which is governed by any other board or agency other than the Board . ~~}; and~~

~~—(d) Pressurized stockings that have a pressure rating of less than 20 millimeters of mercury.}~~

Sec. 2. NAC 639.69545 is hereby amended to read as follows:

1. A pressurized stocking ~~{that has a pressure rating of 20 millimeters of mercury or more}~~ may not be sold, leased or otherwise provided to a consumer without an order from a practitioner ~~{}~~ *if:*

(a) The United States Food and Drug Administration requires the pressurized stocking to be sold only upon a prescription or order of a practitioner; or

(b) The pressurized stocking is labeled in a manner which directs that the pressurized stocking be sold only upon a prescription or order of a practitioner.

2. A medical products provider that sells, leases or otherwise provides to a consumer a pressurized stocking ~~{that has a pressure rating of 20 millimeters of mercury or more}~~ shall provide training to the consumer or the consumer’s family, caregiver or agent in the use,

maintenance and potential problems in the use of the stocking. The training must be provided by a person who is certified by the manufacturer of the pressurized stocking in the fitting and use of the stocking.