PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R085-22I

The following document is the initial draft regulation proposed by the agency submitted on 06/09/2022

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – June 2, 2022

Explanation – Language in *blue italics* is new; language in *red text* [*omitted material*] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.016; NRS 639.070; NRS 639.500

A REGULATION relating to pharmacy and the licensing of authorized of medical products wholesalers.

LEGISLATIVE COUNSEL'S DIGEST

Section. 1. NAC Chapter 639 of NAC is hereby amended by adding the following provisions:

NAC 639.220 Schedule of fees; penalty for late renewal; exemptions from certain fees. (NRS 639.070, 639.170)

1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist	Actual cost of the examination
For the investigation or registration of an applicant as a registered pharmacist	\$180
For the investigation, examination or registration of an applicant as a registered pharmacist by	ψ100
reciprocity For the investigation or issuance of an original license to conduct a retail	180
pharmacy For the biennial renewal of a license to conduct a retail	500
pharmacy For the investigation or issuance of an original license to conduct an	500
institutional pharmacy	500
For the biennial renewal of a license to conduct an institutional pharmacy.	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional	
institution	500

institution				
For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303				
For the issuance of an original or duplicate certificate of registration as a registered				
pharmacistFor the biennial renewal of registration as a registered				
pharmacist For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of				
lapse) For the initial registration of a pharmaceutical technician or				
pharmaceutical technician in training				
For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in				
training For the investigation or registration of an intern pharmacist				
For the biennial renewal of registration as an intern pharmacist				
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances				
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled				
substances				
For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, [ambulatory surgical center,] facility for treatment with narcotics, researcher, instructional				
user or any other authorized person to prescribe or possess controlled substances				
For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician,				
[ambulatory surgical center,] facility for treatment with narcotics, researcher, instructional user or any other authorized person to				

prescribe	or	possess	control	led	
substances					
For the investigation					
		chouse, medical p	-	-	500
					500
For the biennial					
		cal products pro	_		500
For the investigation					300
or	ii oi issualice o	or an original need	ise to a manufacti	11 C1	[500]
				1000	[500]
For the biennial					
wholesaler	i ichewai oi	a needse for	a manufacturer	100	00 [500]
For the reissuance of	of a license issu	ued to a pharmacy	when no change		
		license must be r			
		informat			
thereon		•••••	1		50
For authorization o	f a practitioner	r, other than a lice	nsed veterinarian	, to	
dispense control	led substances	or dangerous dru	gs, or both, for e	ach	
location where the	he practitioner	will dispense con	trolled substances	s or	
dangerous		drugs,		or	
					300
For the biennial rea		-			
		se controlled sub			
O ,		on where the pract	-	nse	
		or dangerou	s drugs,	or	200
both		14:	1:	11 - 1	300
For authorization			_		
both		dangerous	drugs,	or	150
For the biennial re			ensed veterinariar	ı to	130
		or dangerous drug			150
dispense control	iod substances	or durigorous drug	,0, 01 00111	•••••	150

- 2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.
- 3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.
- 4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.
 - 5. A health center:
- (a) Which is a federally qualified health center as defined in 42 U.S.C. \S 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and

- (b) Which is not a medical facility as defined in NRS 449.0151, Ê is not required to pay the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.
 - 6. A practitioner employed by or serving as an independent contractor of a health center:
- (a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and
- (b) Which is not a medical facility as defined in NRS 449.0151, Ê is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.
- 7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

[Bd. of Pharmacy, § 639.050, eff. 6-26-80] — (NAC A 6-25-82; 6-16-86; 2-18-88; 4-28-88; 8-10-89; 9-11-91; 10-17-91; 11-15-93; 1-10-94; 7-7-94; 11-9-95; 5-22-96; R155-99, 3-1-2000; R011-01, 11-1-2001; R012-02, 5-31-2002; R081-04, 8-25-2004; R217-05, 5-4-2006; R114-08, 9-18-2008; R119-09, 1-28-2010; R015-18, 5-16-2018)

NAC 639.5935 Representative of wholesaler: General requirements; exceptions; approval; enforcement. (NRS 639.070, 639.100)

- 1. Except as otherwise provided in this subsection, an applicant for a license, or a licensee with a license, to operate as a wholesaler shall designate at least one natural person to serve as the representative of the wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a wholesaler pursuant to this section unless the Executive Secretary determines that the designated natural person meets the qualifications set forth in subsection 2 and approves that natural person to be the designated representative of the wholesaler. The requirement to designate a representative set forth in this subsection does not apply to:
 - (a) An applicant that is a publicly traded corporation; or
 - (b) An applicant in which a majority interest of the applicant is owned by a pharmacist who is:
 - (1) Licensed by the Board;
 - (2) A resident of this State; and
 - (3) Not an owner of any interest in a pharmacy licensed by the Board.
- 2. Except as otherwise provided in subsection 3, the Board will approve a natural person as the representative of a wholesaler if the applicant for a license to operate as a wholesaler or the licensee presents proof satisfactory to the Executive Secretary that the natural person:
- (a) (a) Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs; *and*
- (b) [Has received a score of at least 75 percent on an examination given by the Board regarding federal and state laws and wholesaler practices; and
- —(c) Is at least 21 years of age.
- 3. The Board may, based upon any of the grounds set forth in NRS 639.210, refuse to approve a natural person for service as the representative of a wholesaler, regardless of whether the person is otherwise qualified.
 - 4. A representative of a wholesaler designated pursuant to this section:

- (a) Must be actively involved in and aware of the actual daily operation of the wholesaler;
- (b) Must be employed full-time in a managerial level position with the wholesaler;
- (c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave and other authorized absences; and
 - (d) May serve in this representative capacity for only one wholesaler at a time.
 - (e) May serve as an administrator of a medical products provider pursuant to NAC 639.694.
- 5. A wholesaler that is required to designate a natural person as its representative pursuant to this section shall not open or operate a facility unless that representative is actually employed full-time in the operation of the wholesaler and is physically present at the facility of the wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. [If the natural person designated as the representative of a wholesaler leaves the employ of the wholesaler, thus leaving the wholesaler without a representative in violation of this section, the wholesaler shall:
- (a) Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the wholesaler; and
- (b) Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the wholesaler has left the employ of the wholesaler.]
- 2. [Before a wholesaler that is in violation of this section because the natural person designated as the representative of the wholesaler left the employ of the wholesaler may continue conducting business:] Before there is a change in the natural person designated as the representative pursuant to this section:
- (a) The wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the wholesaler; and
 - (b) The Executive Secretary must approve the natural person so designated.
- 7. A wholesaler that operates without a representative in violation of this section is subject to the immediate suspension of its license *and the wholesaler shall cease conducting business in Nevada* until it employs a qualified natural person to be its representative. The Executive Secretary may take such action as deemed necessary to secure the facility of the wholesaler and to ensure that the wholesaler does not conduct business during the period of the suspension.

(Added to NAC by Bd. of Pharmacy by R013-01, eff. 11-1-2001)

NAC 639.6937 "Medical products wholesaler" defined. (NRS 639.070)

- 1. "Medical products wholesaler" means a person licensed pursuant *NRS* 639.500 to 639.595 inclusive and subject to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a health care facility, agency, practitioner or provider in this State.
 - 2. The term does not include:
 - (a) A person who sells, leases or otherwise provides medical products to a consumer; or
- (b) An installer of medical gas systems, as that term is defined in NAC 477.137, who is registered pursuant to chapter 477 of NAC.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001)

NAC 639.694 Administrator required. (NRS 639.070)

- 1. Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:
 - (a) Be a natural person;

- (b) Have a high school diploma or its equivalent;
- (c) Have:
- (1) At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
- (2) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
- (d) 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; and
 - (e) Be approved by the Board.
- 2. A medical products wholesaler and medical products provider operating out of a shared facility may share a common Administrator.
- [2.] 3. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
- [3.] 4. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
- [4.] 5. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R033-09, 10-15-2010)

NAC 639.6942 Application for license; license required for each location; notification of change in information; license nontransferable; expiration. (NRS 639.070)

- 1. An applicant for a license to engage in business as a medical products provider or medical products wholesaler must submit an application to the Board on a form furnished by the Board. The application must include:
 - (a) The name, mailing address and telephone number of the applicant;
- (b) The street address of the business or facility of the applicant, if different from the mailing address of the applicant;
 - (c) All trade or business names used by the applicant;
 - (d) The type of ownership or operation of the business or facility;
- (e) The name, address, telephone number and social security number of the person who manages the business or facility of the applicant;
 - (f) If the applicant is:
 - (1) A natural person, the name of the person;
- (2) A partnership, the name of the partnership and the name of each general or limited partner;
- (3) A corporation, the name and title of each officer and director of the corporation, the corporate name, the state of incorporation and the name of the corporation's parent company, if any; or
- (4) A sole proprietorship, the name of the sole proprietor and the name of the business entity;
 - (g) Proof of insurance required pursuant to NAC 639.6946;
 - (h) The hours and days that the business will be regularly operated; and

- (i) All Medicare and Medicaid provider numbers registered to the business or its owner.
- 2. If a medical products provider sells, leases or otherwise provides medical products at more than one location, it must obtain a license for each location where medical products are sold, leased or otherwise provided.
 - 3. Only one medical products provider may operate at a physical location.
- [3.] 4. An applicant shall notify the Board in writing of any change in the information required pursuant to this section within 30 days after the change occurs.
 - [4.] 5. A license issued by the Board pursuant to this section:
 - (a) Is not transferable; and
 - (b) Expires on October 31 of each even-numbered year unless renewed before that date.
- 6. A medical products provider and a medical products wholesaler operating out of one location must separately track their inventory.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001)

NAC 639.6943 Licensing of practicing health professionals. (NRS 639.070)

- 1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
 - (a) A practicing health professional; or
- (b) A partnership, corporation or association in which a 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 practicing health professionals.
- 2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration *issued by this State* in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R151-05, 11-17-2005)

NAC 639.6958 Summary suspension of license. (NRS 639.070)

- 1. The Executive Secretary may summarily suspend the license of a medical products provider or medical products wholesaler upon receiving evidence sufficient to cause the Executive Secretary to reasonably believe that a medical products provider or medical products wholesaler is:
 - (a) Operating without liability insurance;
 - (b) Operating without a license;
 - (c) Operating without a business administrator or a facility administrator; or
- (d) [Engaging in practices that are fraudulent or deceitful.] Operating without a designated representative in the case of a medical products wholesaler; or
 - (e) Engaging in practices that are fraudulent or deceitful.
- 2. The Executive Secretary shall immediately provide written notice to the medical products provider or medical products wholesaler that informs the medical products provider or medical products wholesaler of:
 - (a) The factual and legal reasons for the summary suspension; and
- (b) The right of the medical products provider or medical products wholesaler to provide the Board with any evidence or information that would show that either the factual or legal reasons for the summary suspension are incorrect.

- 3. The Executive Secretary may take whatever action he or she deems reasonably necessary to secure the medical products and premises, and to ensure that the medical products provider or medical products wholesaler does not conduct business during the summary suspension.
- 4. The Executive Secretary shall release the medical products provider or medical products wholesaler from the summary suspension upon receiving evidence satisfactory to the Executive Secretary from the medical products provider or medical products wholesaler that the deficiency noted in the written notice has been remedied.
- 5. Within 10 days after summarily suspending the license of a medical products provider or medical products wholesaler, the Executive Secretary shall serve upon the medical products provider or medical products wholesaler an accusation pursuant to NRS 639.241. A hearing on the accusation must be set for the next regularly scheduled meeting of the Board.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001)