

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

LCB File No. R085-22

July 19, 2022

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

AUTHORITY: § 1, NRS 639.070 and 639.170; § 2, NRS 639.070 and 639.100; §§ 3-8, NRS 639.070.

A REGULATION relating to pharmacy; revising certain types of licenses and fees; revising various provisions regarding administrators; revising various definitions; revising certain licensing criteria; revising certain conditions for the suspension of certain licenses; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law establishes the maximum fees the State Board of Pharmacy may charge for the issuance and renewal of licenses. (NRS 639.170) Existing regulations prescribe different fees for the issuance and renewal of a license as a medical products wholesaler and a wholesaler. (NAC 639.220) **Section 1** of this regulation removes the separate fees for medical products wholesalers, thereby requiring medical products wholesalers to pay the same fees for the issuance and renewal of a license as other wholesalers. **Section 3** of this regulation provides that medical products wholesalers hold the same type of license as other wholesalers.

Existing regulations require an applicant for a license to operate as a wholesaler to designate at least one natural person to serve as the representative of the wholesaler. (NAC 639.5935) Existing regulations also require each medical products provider or medical products wholesaler to employ an administrator at all times. (NAC 639.694). **Section 2** of this regulation authorizes a representative of a wholesaler to serve as an administrator of a medical products provider. **Section 4** of this regulation authorizes a medical products provider and a medical products wholesaler operating out of a shared facility to also share a common administrator. **Section 8** of this regulation provides that the Board may summarily suspend the license of a medical products wholesaler that is operating without a designated representative.

Existing regulations provide that the Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to a practicing health professional. (NAC 639.6943) **Section 5** of this regulation limits the applicability of this provision to health professionals who are licensed, certified or registered in this State, thereby clarifying that a health professional who is not licensed, certified or registered as such in this State is eligible for licensure as a medical products provider or medical products wholesaler.

Existing regulations establish requirements concerning the premises of a medical products provider and the maintenance of records by a medical products provider. (NAC

639.6946, 639.6949, 639.695) **Section 6** of this regulation prohibits a medical products provider from operating out of the same location as another medical products provider. **Section 7** of this regulation requires a medical products provider to maintain certain records relating to its inventory of medical products separate from the records of any medical products wholesaler.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 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.....	\$200
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....	200
For the investigation or issuance of an original license to conduct a retail pharmacy	500
For the biennial renewal of a license to conduct a retail pharmacy	500
For the investigation or issuance of an original license to conduct an 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
For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....	500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS	500
For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS	500
For the issuance of an original or duplicate certificate of registration as a registered pharmacist.....	50
For the biennial renewal of registration as a registered pharmacist.....	200
For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse).....	100
For the initial registration of a pharmaceutical technician or pharmaceutical technician in training.....	50
For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training.....	50
For the investigation or registration of an intern pharmacist	40
For the biennial renewal of registration as an intern pharmacist	40
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances	80
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances	80

For authorization of a physician, advanced practice registered nurse,
physician assistant, euthanasia technician, facility for treatment with
narcotics, researcher, instructional user or any other authorized person,
except a practitioner who is a medical intern or resident physician, to
prescribe or possess controlled substances200

For the biennial renewal of authorization of a physician, advanced
practice registered nurse, physician assistant, euthanasia technician,
facility for treatment with narcotics, researcher, instructional user or
any other authorized person, except a practitioner who is a medical
intern or resident physician, to prescribe or possess controlled
substances200

For authorization of a practitioner who is a medical intern or resident
physician to prescribe or possess controlled substances80

For the biennial renewal of authorization of a practitioner who is a
medical intern or resident physician to prescribe or possess controlled
substances80

For the investigation or issuance of an original license to engage in
business as an authorized warehouse ~~or~~ *or* medical products provider
~~for medical products wholesaler~~500

For the biennial renewal of a license to engage in business as an
authorized warehouse ~~or~~ *or* medical products provider ~~for medical
products wholesaler~~500

For the investigation or issuance of an original license to a manufacturer or wholesaler.....	1,000
For the biennial renewal of a license for a manufacturer or wholesaler	1,000
For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....	50
For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....	300
For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....	300
For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....	150
For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....	150
For the investigation or issuance of an original license for an automated drug dispensing system.....	500

For the biennial renewal of a license for an automated drug dispensing system	500
For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy	250
For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy	250

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 practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center 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,

↪ 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.

6. A practitioner who is exempt from the payment of a fee pursuant to subsection 5 shall notify the Board in writing of each change of address or additional address, or both.

7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay any costs of inspection incurred by the Board.

Sec. 2. NAC 639.5935 is hereby amended to read as follows:

639.5935 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) 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) 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 ~~+~~; *and*

(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.

6. 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.

Sec. 3. NAC 639.6937 is hereby amended to read as follows:

639.6937 1. “Medical products wholesaler” means a person licensed *as a wholesaler* pursuant to ~~NAC 639.693 to 639.6958, inclusive, to sell, lease~~ *chapter 639 of NRS who sells, leases* or otherwise ~~provide~~ *provides* 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.

Sec. 4. NAC 639.694 is hereby amended to read as follows:

639.694 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. 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. 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. 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.

5. A medical products provider and medical products wholesaler operating out of a shared facility may share a common administrator.

Sec. 5. NAC 639.6943 is hereby amended to read as follows:

639.6943 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~~:

(a) Is licensed, certified or registered to practice his or her profession in this State; and

(b) Performs services within the scope of his or her licensure, *certification* or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Sec. 6. NAC 639.6946 is hereby amended to read as follows:

639.6946 1. Except as otherwise provided in NAC 639.6945, 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, set up, 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, set up, 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, set up 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 suitable physical location, other than a residence, 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 Consumer Equitability.

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 not operate at the same location as another medical products provider.*

6. 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.

Sec. 7. NAC 639.695 is hereby amended to read as follows:

639.695 The records made or kept pursuant to NAC 639.6949 must be:

1. Kept in a file, chart or other storage system allowing the record to be retrieved by reference to the name of the consumer, the name of the practitioner, the date the product was provided or the type of medical product;

2. Retained for at least 5 years from the date the records are made or received;

3. Kept at the physical location of the business; ~~and~~

4. *Maintained separately from the records of any medical products wholesaler; and*

5. Readily retrievable upon request by a member of the Board, or a person conducting an inspection or investigation on behalf of the Board.

Sec. 8. NAC 639.6958 is hereby amended to read as follows:

639.6958 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) *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.