

**ADOPTED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R100-23

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

AUTHORITY: §§ 1-9, NRS 639.070.

A REGULATION relating to pharmacy; removing requirements that certain applicants appear before the State Board of Pharmacy and receive certain instructions; revising provisions governing the administration of immunizations by pharmacists; revising provisions governing the transfer of prescriptions by facsimile machine; removing provisions authorizing a pharmacy to sell or otherwise provide a compound drug to a retail pharmacy or practitioner; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations governing the practice of pharmacy. (NRS 639.070) Existing regulations require certain applicants for a license to operate a pharmacy in the State of Nevada to appear before the Board in support of the application. (NAC 639.215) **Section 1** of this regulation removes this requirement and instead authorizes the Board to require the same such applicants to appear before the Board in support of the application. Under existing regulations, certain applicants who appear before the Board in support of an application are required to receive instructions relative to the pharmacy laws. (NAC 639.215) **Section 1** removes this requirement.

Existing regulations require certain physician assistants who apply for a registration certificate to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices to personally appear before the Board for a determination and an assignment of the specific authority to be granted to the physician assistant. (NAC 639.272) **Section 2** of this regulation removes this requirement and instead authorizes the Board to require the same such physician assistants to personally appear before the Board.

Existing regulations prohibit a physician assistant from writing a prescription in the form of an order on the chart of a patient in a hospital unless the physician assistant: (1) is authorized by the hospital’s rules; and (2) has filed a copy of his or her form for prescriptions with the pharmacy of the hospital. Under existing regulations, the form for prescriptions of a physician assistant must be approved by the Board. (NAC 639.283) **Section 3** of this regulation eliminates the requirement that the Board approve this form.

Existing regulations: (1) authorize a physician to establish a written protocol authorizing pharmacists to administer certain immunizations; and (2) require that any such protocol include a restriction that a pharmacist may not administer an immunization except at an authorized location. (NAC 639.2971) **Section 4** of this regulation removes this requirement.

Existing regulations: (1) authorize a registered pharmacist to apply to the Board to engage in the practice of pharmacy at a site other than a licensed pharmacy; and (2) require the Board to consider any such application at a hearing before the Board. (NAC 639.403, 639.406) **Section 5** of this regulation removes the requirement that the Board hold a hearing to consider such an application and instead authorizes the Board, at its discretion, to hold a hearing on an application.

Existing law requires the Board to adopt regulations concerning the electronic transmission of certain prescriptions by facsimile machine. (NRS 639.0745) Among other requirements, existing regulations authorize a pharmacy to transfer prescriptions by facsimile machine to another pharmacy if the transmission includes certain information. Existing regulations authorize the Board to exempt a pharmacy from this requirement if the Board is satisfied that: (1) the pharmacy's computer system will accurately represent the identity of the pharmacist responsible for the transfer; and (2) the identity of the pharmacist responsible for the transfer cannot be falsified, modified, added or otherwise provided without the knowledge and assent of that pharmacist. (NAC 639.7145) **Section 6** of this regulation removes provisions authorizing the Board to exempt a pharmacy from the requirement that a transmission include certain information. Instead, **section 6** authorizes a pharmacy to transfer prescriptions by facsimile machine to another pharmacy without including certain information if the pharmacy determines that it meets the criteria previously considered by the Board in determining whether to grant an exemption.

Existing regulations prohibit a pharmacy from selling or otherwise providing a compounded drug to a retail pharmacy or practitioner, except under certain circumstances. (NAC 639.757) **Section 7** of this regulation eliminates this exception, thereby prohibiting a pharmacy from selling or otherwise providing a compounded drug to a retail pharmacy or practitioner in any circumstance.

Existing law authorizes an advanced practice registered nurse to prescribe controlled substances, poisons, dangerous drugs and devices if the advanced practice registered nurse obtains a certificate of registration from the Board and meets certain other requirements (NRS 639.2351) Existing regulations authorize the Board to require each advanced practice registered nurse who applies for such a certificate of registration to appear personally before the Board for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse. (NAC 639.850) **Section 8** of this regulation removes the requirement that an advanced practice registered nurse who applies for such a certificate of registration and is required to appear before the Board must appear personally. **Section 8** also removes certain limitations on the purposes for which the Board may require such an appearance.

Existing law authorizes an advanced practice registered nurse to dispense controlled substances, poisons, dangerous drugs and devices if the advanced practice registered nurse obtains a certificate of registration from the Board and meets certain other requirements. (NRS 639.1375) Existing regulations require certain advanced practice registered nurses who apply for such a certificate of registration and the collaborating physicians of such nurses to appear personally before the Board for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse. (NAC 639.870) **Section 9** of this regulation removes this requirement and instead authorizes the Board to require the same such advanced practice registered nurses and collaborating physicians to appear before the Board for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse.

Section 1. NAC 639.215 is hereby amended to read as follows:

639.215 1. ~~[(a)]~~ *The Board may require an* applicant for a license to operate a pharmacy in the State of Nevada ~~[(must)]~~ *to* appear before the Board in support of the application ~~[(and must receive instructions relative to the pharmacy laws if)]~~ :

(a) *If* the applicant:

~~[(a)]~~ (1) Is applying for a license to operate a pharmacy in this State for the first time;

~~[(b)]~~ (2) Responded affirmatively to any of the questions on the application regarding his or her character or competency; *or*

~~[(e)]~~ (3) Is applying for the licensure of a pharmacy located outside the State that will be shipping compounded parenteral products into this State; or

~~[(d) Is requested to do so by]~~

(b) *Any time* the Board ~~[(d)]~~ *determines an appearance is necessary to evaluate the application.*

2. If an applicant who is required to appear before the Board is:

(a) A partnership, all partners must appear.

(b) A corporation, a designated representative of the corporation must appear. If the designated representative is not an officer of the corporation, a letter authorizing him or her to appear on behalf of the corporation that is signed by an officer of the corporation must be submitted with the application. Documentation of the status of the person signing the letter of authorization must be submitted with the application.

3. If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation. Documentation of the status of the person signing the application must be submitted with the application.

4. A special meeting of the Board will not be called for the purpose of considering an application for a license to operate a pharmacy until the applicant has paid the Executive Secretary sufficient money to defray all expenses of the meeting.

Sec. 2. NAC 639.272 is hereby amended to read as follows:

639.272 1. The application of a physician assistant for:

(a) A registration certificate to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices; or

(b) A registration certificate to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices,
↪ must be in writing and filed with the Executive Secretary.

2. Each application for a registration certificate to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices must include:

(a) The name, address, social security number and telephone number of the applicant;

(b) A copy of the license issued by the Board of Medical Examiners or certificate issued by the State Board of Osteopathic Medicine that authorizes the applicant to prescribe controlled substances, poisons, dangerous drugs and devices or to prescribe poisons, dangerous drugs and devices;

(c) The name, address and telephone number of the applicant's supervising physician; and

(d) Any other information requested by the Board.

3. Each application for a registration certificate to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices must include:

(a) The name, address, social security number and telephone number of the applicant;

(b) A copy of the license issued by the Board of Medical Examiners or certificate issued by the State Board of Osteopathic Medicine that authorizes the applicant to prescribe and dispense controlled substances, poisons, dangerous drugs and devices or to prescribe and dispense poisons, dangerous drugs and devices;

(c) The name, address and telephone number of the applicant's supervising physician; and

(d) Any other information requested by the Board.

4. ~~Each~~ *The Board may require a* physician assistant who applies for a registration certificate pursuant to subsection 3 ~~must:~~

~~(a) Personally~~ *to personally* appear before the Board for *a* determination and *an* assignment of the specific authority to be granted to the physician assistant ~~if~~:

(a) *If* the physician assistant ~~is~~:

~~(1) Responded~~ *responded* affirmatively to any of the questions on the application regarding his or her character or competency; or

~~(2) Is requested to do so by~~

(b) *Any time* the Board ~~is~~ *determines an appearance is necessary to evaluate the application.*

5. *Each applicant who applies for a registration certificate pursuant to subsection 3 must:*

(a) *Personally appear before the Board if an appearance is required pursuant to subsection 4;* and

(b) Pass an examination administered by the Board on the law relating to pharmacy.

~~[5.]~~ **6.** Each physician assistant to whom a registration certificate is issued must be registered to a supervising physician.

Sec. 3. NAC 639.283 is hereby amended to read as follows:

639.283 A physician assistant shall not write a prescription in the form of an order on the chart of a patient in a hospital unless the physician assistant is authorized by the hospital's rules and has filed a copy of his or her form for prescriptions with the pharmacy of the hospital. ~~[The form must be approved by the Board.]~~

Sec. 4. NAC 639.2971 is hereby amended to read as follows:

639.2971 1. A physician may establish a written protocol authorizing pharmacists to administer immunizations by an intranasal, intramuscular or subcutaneous injection. Except as otherwise limited by the physician pursuant to subsection 5, any pharmacist who is trained and certified in accordance with NAC 639.2973 may subscribe to the written protocol and administer immunizations in compliance with the protocol. Such a protocol must contain:

(a) The name of the physician who is authorizing the administration of immunizations by a pharmacist;

(b) The immunizations that may be administered by a pharmacist;

(c) Detailed policies and procedures that a pharmacist must follow while administering immunizations, including, without limitation, procedures to follow in the case of adverse reactions or emergencies following administration;

(d) A procedure for the review of the protocol and its operation by the physician at least once annually, and the making and keeping of a record of the review;

(e) When appropriate, specific instructions related to the age of the patient;

(f) Except as otherwise provided in subsections 2 and 3, a restriction that a pharmacist may not delegate his or her authority to administer an immunization;

(g) ~~[A restriction that a pharmacist may not administer an immunization except at an authorized location, which location may not be the home of the patient, unless the patient resides in a licensed facility for long-term care or in a hospital;~~

~~—(h)]~~ A requirement that the immunizations will be administered according to all applicable federal, state and local laws; and

~~[(i)]~~ (h) The signature of the physician authorizing the administration of the immunizations and the time period for which the written protocol is effective.

2. An intern pharmacist may administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed to a written protocol established by a physician.

3. A pharmaceutical technician may administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed to a written protocol established by a physician if the pharmacist has determined, in his or her professional judgment, that the patient should be immunized. A record of each immunization administered by the pharmaceutical technician must be maintained in the manner prescribed by NAC 639.2977.

4. If a physician orders a deviation from the written protocol for the benefit of a specific patient, the physician shall note the deviations from the written protocol in the record of the patient.

5. A physician may include restrictions to a written protocol established by the physician pursuant to subsection 1 by limiting the protocol to any of the following:

- (a) A specific pharmacist or pharmacists;
- (b) A specific location or locations;
- (c) The administration of a specific immunization or immunizations; or
- (d) Other limitations as the physician determines necessary.

Sec. 5. NAC 639.406 is hereby amended to read as follows:

639.406 1. ~~{Upon submission of an}~~ *The Board will consider each* application *submitted* pursuant to NAC 639.403 ~~[, the Board will schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information]~~ to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. ~~{The Board may consider, without limitation, the following factors in}~~ *In* determining whether to approve, deny or modify such an application ~~{:}~~, *the Board may consider, without limitation, the following factors:*

- (a) The information contained in the application;
- (b) The education, experience and expertise of the applicant;
- (c) The disciplinary history of the applicant, if any; and
- (d) Whether the applicant has sufficient malpractice or other liability insurance.

2. At *its discretion*, the *Board may schedule a hearing on an application. At any such* hearing, the Board ~~{may}~~ :

(a) Will consider the application and any other relevant information; and

(b) May request that the applicant modify his or her application.

3. If the Board approves an application, the Board will provide the applicant with documentation indicating the approval and setting forth the terms and conditions, in addition to

those prescribed by NAC 639.408, under which the applicant may provide the services approved by the Board.

4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.

Sec. 6. NAC 639.7145 is hereby amended to read as follows:

639.7145 1. Information relating to a prescription may be transferred from a pharmacy to another pharmacy by a facsimile machine pursuant to NAC 639.713 if:

(a) The transmission from the transferring pharmacy:

(1) Includes the information required by subsection 2 of NRS 639.2353, which may be provided in the form of an accurate printout of the pharmacy's computerized record of the prescription; and

(2) Except as otherwise provided in subsection 2, includes:

(I) A copy of the original prescription maintained in the records of the transferring pharmacy on which the pharmacist at the transferring pharmacy has signed the copy and written his or her license number; or

(II) The signature and handwritten license number of the pharmacist at the transferring pharmacy and a notation that specifically indicates that the pharmacist intends to transfer the prescription.

(b) The transmission is prepared and transmitted by a pharmaceutical technician or pharmacist at the transferring pharmacy.

2. A pharmacy may transfer prescriptions by facsimile machine to another pharmacy without complying with the provisions of subparagraph (2) of paragraph (a) of subsection 1 only

~~[upon application to and authorization by the Board. The Board may grant that authority to a pharmacy]~~ if the ~~[Board is satisfied]~~ *pharmacy determines* that:

(a) The pharmacy's computer system will accurately represent the identity of the pharmacist responsible for the transfer; and

(b) The identity of the pharmacist responsible for the transfer cannot be falsified, modified, added or otherwise provided without the knowledge and assent of that pharmacist.

3. A pharmacy which maintains its records of prescriptions in a computer system shall invalidate in its system a prescription transferred by a facsimile machine to another pharmacy.

Sec. 7. NAC 639.757 is hereby amended to read as follows:

639.757 1. A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if:

(a) The compounded drugs are prepared in a quantity that is:

(1) Necessary to fill a prescription or chart order; or

(2) Reasonably necessary to fill future prescriptions or chart orders based upon the previous history of practitioners and patients who regularly use the pharmacy;

(b) The compounded drugs are not sold or otherwise provided by the pharmacy or pharmacist to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs or a practitioner who will be administering the drugs to a patient;

(c) The compounded drugs are dispensed pursuant to a prescription or chart order;

(d) Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs:

(1) Have a monograph in and meet or exceed the standards of the *United States Pharmacopoeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;

(2) Have been components of drugs approved by the Food and Drug Administration; or

(3) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto; and

(e) Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the *United States Pharmacopoeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, the active ingredient is:

(1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration;

(2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and

(3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:

(I) The *Food Chemicals Codex*, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or

(II) *Reagent Chemicals: Specifications and Procedures*, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes.

2. In compounding a drug product, a pharmacy or pharmacist may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy

or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.

3. Except as otherwise provided in this subsection, a pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective. A pharmacy or pharmacist may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.

4. A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner . ~~[, except that a pharmacy may sell or otherwise provide a compounded drug to:~~
~~—(a) A practitioner who will be administering the drug to a patient; or~~
~~—(b) A practitioner or another pharmacy if the compounded drug is:~~
~~——(1) A highly concentrated drug product that is not commercially available; or~~
~~——(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy.~~
~~—5.— The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.]~~

Sec. 8. NAC 639.850 is hereby amended to read as follows:

639.850 1. The application of an advanced practice registered nurse for a certificate of registration to prescribe controlled substances, poisons, dangerous drugs and devices must include:

(a) The name, address, social security number and telephone number of the applicant;

(b) A copy of the certificate issued by the State Board of Nursing which authorizes the applicant to prescribe controlled substances, poisons, dangerous drugs and devices;

(c) The name, address and telephone number of the applicant's collaborating physician, if the applicant is required to have a collaborating physician pursuant to NRS 632.237; and

(d) Any other information requested by the Board.

2. ~~Each~~ *The Board may require an* advanced practice registered nurse who applies for a certificate of registration ~~may be required by the Board~~ to appear ~~personally~~ before the Board ~~. [for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse.]~~

Sec. 9. NAC 639.870 is hereby amended to read as follows:

639.870 1. The application of an advanced practice registered nurse for a certificate of registration to dispense controlled substances, poisons, dangerous drugs and devices must include:

(a) The name, address, social security number and telephone number of the applicant;

(b) A copy of the certificate issued by the State Board of Nursing which authorizes the applicant to dispense controlled substances, poisons, dangerous drugs and devices;

(c) The name, address and telephone number of the applicant's collaborating physician, if any;

(d) Written verification from the State Board of Nursing that the applicant has passed an examination on Nevada law relating to pharmacy; and

(e) Any other information requested by the Board.

2. Each application for the issuance or the biennial renewal of a certificate of registration must be accompanied by a nonrefundable fee of \$300. The biennial certificate of registration covers the period beginning on November 1 of each even-numbered year.

3. ~~Each~~ *The Board may require an* advanced practice registered nurse who applies for a certificate of registration and his or her collaborating physician, if any, ~~must~~ *to* appear ~~personally~~ before the Board for a determination and an assignment of the specific authority to be granted to the advanced practice registered nurse ~~if~~ :

(a) *If* the advanced practice registered nurse:

~~(a)~~ (1) Will be operating in a practice not previously licensed by the Board; *or*

~~(b)~~ (2) Responded affirmatively to any of the questions on the application regarding his or her character or competency; or

~~(c) Is requested to do so by~~

(b) *Any time* the Board ~~if~~ *determines an appearance is necessary to evaluate an application.*

4. Each advanced practice registered nurse to whom a certificate of registration is issued must be registered to a collaborating physician unless:

(a) The advanced practice registered nurse is not required to have a collaborating physician pursuant to subsection 3 of NRS 632.237; or

(b) The advanced practice registered nurse will not prescribe any controlled substance listed in schedule II.

5. An advanced practice registered nurse who fails to renew his or her certificate of registration within the time prescribed by statute or regulation must pay, in addition to the fee for renewal required by subsection 2, a fee equal to 50 percent of the fee for the renewal of the certificate.