PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R100-23I

The following document is the initial draft regulation proposed by the agency submitted on 10/18/2023

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – October 12, 2023

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 453.162; NRS 453.163; NRS 639.070; NRS 639.23916

REGULATIONS relating Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.

Executive Order 003-2023

SECTION 1

Every executive branch department, agency, board and commission shall undertake a comprehensive review of the regulations subject to its enforcement. On or before, May 1, 2023 each department, agency, board and commission shall provide a report to the Governor's office detailing how the regulation subject to its enforcement can be streamlined, clarified, reduced or otherwise improved to ensure those regulations provide for the general welfare of the State without unnecessarily inhibiting economic growth.

SECTION 2:

As part of its report, every executive branch department, agency, board and commission shall provide a list of not less than ten (10) regulations recommended for removal, ranking them in descending order of priority.

NAC 639.215 Application for license to operate pharmacy: Appearance of applicant before Board; execution on behalf of partnership or corporation; payment of expenses for special meeting of Board. (NRS 639.070**,** 639.231**)**

1. An applicant for a license to operate a pharmacy in the State of Nevada [~~must~~] ***may be required to*** appear before the Board in support of the application and must receive instructions relative to the pharmacy laws if the applicant:
   (a) Is applying for a license to operate a pharmacy in this State for the first time;
   (b) Responded affirmatively to any of the questions on the application regarding his or her character or competency;
   (c) 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 the Board.
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.

NAC 639.272 Requirements for registration certificate. (NRS 639.070**,** 639.1373**)**

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 physician assistant who applies for a registration certificate pursuant to subsection 3 [~~must~~] ***may be required to***:
   (a) Personally appear before the Board for determination and assignment of the specific authority to be granted to the physician assistant if the physician assistant:
      (1) 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 the Board; and

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

5. Each physician assistant to whom a registration certificate is issued must be registered to a supervising physician.

NAC 639.2971 Authorization; contents of and deviation from written protocol. (NRS 454.213**,** 639.070**,** 639.137**)**

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) 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.

NAC 639.406 Hearing to approve or deny application from pharmacist. (NRS 639.070**)**

1. Upon submission of an application pursuant to NAC 639.403, the Board [~~will~~] ***may*** 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 determining whether to approve, deny or modify such an application:
   (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 the hearing, the Board 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 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.

NAC 639.415 Hearing to approve or deny application from licensed pharmacy. (NRS 639.070**)**

1. Upon submission of an application pursuant to NAC 639.412, the Board [~~will~~] ***may*** 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 determining whether to approve, deny or modify such an application:
   (a) The information contained in the application;
   (b) The disciplinary history of the applicant, if any; and
   (c) Whether the applicant has sufficient malpractice or other liability insurance.
2. At the hearing, the Board may request that the applicant modify the application.
3. If the Board approves an application, the Board will provide the pharmacy whose application is approved with documentation indicating the approval and setting forth the

terms and conditions under which the pharmacists employed by or under contract with the pharmacy may offer 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.

NAC 639.757 Preparation and sale of compounded drugs by pharmacy or pharmacist: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale. (NRS 639.070**)**

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;
   - ~~(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.~~]

NAC 639.850 Certificate of registration: Application; appearance before Board. (NRS 639.070**,** 639.2351**)**

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 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~~].

NAC 639.870 Certificate of registration: Application; fee; period of validity; appearance before Board; collaborating physician; late renewal. (NRS 639.070**,** 639.1375**)**

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 advanced practice registered nurse who applies for a certificate of registration and his or her collaborating physician, if any, [~~must~~] ***may be required 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 the advanced practice registered nurse:
   (a) Will be operating in a practice not previously licensed by the Board;
   (b) 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 the Board.
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.

NAC 639.283 Prescriptions: Orders on charts of hospitalized patients. (NRS 639.070**,** 639.1373**)** 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.]~~

NAC 639.7145 Transfer of information between pharmacies: Requirements for transfer by facsimile machine. (NRS 639.070**,** 639.0745**)**

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