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REGULATIONS ONLY

Effective date: September 11, 2020

Expiration date: January 8, 2020

Governor's signature

Agency: Nevada State

Board of Pharmacy

Classification:

PROPOSED ☐ ADOPTED BY AGENCY x EMERGENCY

Brief description of action:

The proposed amendment in response to COVID-19 will amend NAC chapter to authorize a pharmacy technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. (LCB File No. R142-20)

Authority citation other than 233B: NRS 639.070

Notice Date: August 25, 2020 Date of Adoption by Agency: September 3, 2020

Hearing Date: September 3, 2020

Nevada State Board of Pharmacy

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September 8, 2020

VIA EMAIL AND HAND DELIVERY

The Honorable Steve Sisolak, Governor
101 North Carson Street – Suite 1
Carson City, NV 89701

RE: Emergency regulation to authorize pharmaceutical technicians with appropriate training to administer immunizations under the direct supervision of a pharmacist in response to COVID-19 pandemic

Dear Governor Sisolak:

The Nevada State Board of Pharmacy (Board), in consultation with the Nevada Department of Health and Human Services, has determined that an emergency exists due to the COVID-19 pandemic and the urgent necessity to increase the State's capacity to expediently treat Nevada's population when a viable COVID-19 vaccine is developed and deployed. The Board has therefore adopted the enclosed emergency regulation to authorize pharmaceutical technicians with appropriate training to administer immunizations under the direct supervision of a pharmacist. This will allow pharmacies to meet the increased demand for vaccine services and will be crucial to expanding the State's capacity to expediently treat Nevada's population when a viable COVID-19 vaccine becomes available.

As this emergency regulation will help to ensure that the State can timely deploy a COVID-19 vaccine in response to the current pandemic for the protection, health and safety of the public, your endorsement is requested. Thank you for your assistance and consideration.

Sincerely,

J. David Wuest, R.Ph.
Executive Secretary
Nevada State Board of Pharmacy

Endorsed:

Steve Sisolak
Governor

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R142-20

August 20, 2020

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

AUTHORITY: §§1 and 3-10, NRS 454.213, 639.070 and 639.1371; §2, NRS 639.070 and 639.1371.

A REGULATION relating to immunizations; authorizing a pharmaceutical technician to administer immunizations under certain conditions; prescribing required training for such a pharmaceutical technician; revising provisions concerning the maintenance of records of immunizations; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Pharmacy to adopt regulations prescribing the services that may be performed by a pharmaceutical technician. (NRS 639.1371) Existing regulations authorize a pharmacist who subscribes to a written protocol established by a physician, or an intern pharmacist acting under the direct and immediate supervision of such a pharmacist, to administer immunizations (NAC 639.2971) **Sections 1 and 3** of this regulation additionally authorize a pharmaceutical technician to administer immunizations under the direct and immediate supervision of a pharmacist who has subscribed to a written protocol established by a physician. **Sections 3 and 9** of this regulation require a pharmacy and pharmaceutical technician to maintain for at least 2 years a record of each immunization administered by the pharmaceutical technician. **Sections 5 and 6** of this regulation prescribe the required training and continuing education, respectively, for a pharmaceutical technician who administers immunizations. **Section 2** of this regulation requires the managing pharmacist of a pharmacy that employs such a pharmaceutical technician to maintain a record of that training. **Sections 4 and 7-10** of this regulation make conforming changes to make existing provisions concerning the supervision of the implementation of a written protocol, the possession and control of drugs used for immunizations, the reporting of certain information concerning immunizations and the maintenance and security of records applicable to pharmaceutical technicians who administer immunizations.

Section 1. NAC 639.245 is hereby amended to read as follows:

639.245 1. A written record must be kept available for inspection showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business. This record must be:

(a) Readily retrievable; and

(b) Retained for 2 years.

2. A pharmaceutical technician under the direct supervision of a pharmacist may:

(a) Prepackage and label unit dose and unit of use and repackage drugs if a pharmacist:

(1) Inspects the final products; and

(2) Affixes his or her initials to the appropriate records for controlling quality.

(b) Prepare, package, compound and label prescription drugs pursuant to prescriptions or orders for medication if a pharmacist:

(1) Inspects the final product; and

(2) Affixes his or her initials to the appropriate records for controlling quality.

(c) Prepare bulk compounds if a pharmacist:

(1) Inspects the final product; and

(2) Affixes his or her initials to the appropriate records for controlling quality.

(d) Distribute routine orders and stock medications and supplies in the pharmacy or areas where care is provided to patients.

(e) Maintain inventories of supplies of drugs.

(f) Maintain pharmaceutical records.

(g) Request authorization to refill a prescription from the prescribing practitioner.

(h) Transfer a prescription through a computer network if the:

(1) Pharmaceutical technician is employed by a pharmacy that:

(I) Has more than one location; and

(II) Maintains a computer network which provides information between its pharmacies; and

(2) Prescription is transferred to one of the pharmacies within its computer network.

(i) Enter information into the pharmacy's computer system, including, without limitation, information contained in a new prescription concerning the prescription drug and the directions for its use.

3. ***A pharmaceutical technician under the direct and immediate supervision of a pharmacist may administer immunizations under the conditions prescribed in NAC 639.2971 if he or she has received the training required by NAC 639.2973 and the continuing education required by NAC 639.2974.***

4. A pharmaceutical technician may not:

(a) Perform any action requiring a judgmental decision regarding a drug, the interpretation of a prescription or the instructions for the preparation of a prescription.

(b) Take new prescription or chart orders by telephone.

(c) Distribute medications pursuant to a chart order or dispense a prescription unless the order or prescription has been verified by a pharmacist.

~~[4.]~~ ***5.*** A pharmaceutical technician shall prepare and distribute drugs only pursuant to written procedures and guidelines established by the pharmacy in which the pharmaceutical technician performs his or her duties.

Sec. 2. NAC 639.254 is hereby amended to read as follows:

639.254 1. The owner and managing pharmacist of a pharmacy shall provide training for pharmaceutical technicians working in or for the pharmacy that ensures the continuing

competency of those technicians. Except as otherwise provided in this section, the training must consist of initial training upon employment and at least 12 hours of in-service training during the 2-year period immediately preceding the renewal of the registration of the pharmaceutical technician. One of the 12 hours of in-service training must be a jurisprudence program approved or presented by the Board that relates to the practice of pharmacy or the law concerning pharmacy in this State.

2. The managing pharmacist shall maintain a written record of the initial training and the annual training ***, including, without limitation, training and continuing education relating to immunizations required by NAC 639.2973 and 639.2974,*** completed by each pharmaceutical technician working in or for the pharmacy that contains:

(a) The name and signature of the person receiving the training;

(b) The date or dates on which the training was received;

(c) The number of hours of training received;

(d) A general description of the topics covered; and

(e) The name of the person or provider conducting the training.

3. A pharmaceutical technician may substitute the completion of the continuing education necessary for recertification by the Pharmacy Technician Certification Board or the National Healthcareer Association for the biennial in-service training required by subsection 1.

Sec. 3. 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 ~~[4,]~~ ***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 ~~[subsection]~~ ***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.

~~[4.]~~ ***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. 4. NAC 639.2972 is hereby amended to read as follows:

639.2972 A physician who has authorized pharmacists to administer immunizations by establishing a written protocol shall supervise the implementation of the protocol by each pharmacist who has subscribed to the protocol , and by each intern pharmacist ***and pharmaceutical technician*** acting under the direct and immediate supervision of the pharmacist , by:

1. Being readily accessible to the pharmacist, ~~[or]~~ intern pharmacist ***or pharmaceutical technician*** or the patient when the pharmacist is authorized to administer the immunizations for consultation, assistance and direction; and

2. If required by the written protocol, reviewing a periodic status report from a pharmacist, ~~[or]~~ intern pharmacist ***or pharmaceutical technician*** concerning any problems, complications or emergencies encountered while administering immunizations.

Sec. 5. NAC 639.2973 is hereby amended to read as follows:

639.2973 1. Before a pharmacist may administer an immunization pursuant to a written protocol or before an intern pharmacist acting under the direct and immediate supervision of a pharmacist may administer such immunizations, the pharmacist or intern pharmacist must be trained and certified to administer immunizations by completing a course approved by the Accreditation Council for Pharmacy Education ***or its successor organization*** that includes:

(a) Certification in life-saving techniques pursuant to the American Heart Association's Basic Cardiac Life Support for Health Care Providers or its equivalent;

(b) Education and practical training, including, without limitation, written study materials regarding techniques for administering immunizations;

(c) Evaluation of the knowledge and technique of the pharmacist or intern pharmacist in administering immunizations;

(d) Instruction consistent with the current training guidelines of the Centers for Disease Control and Prevention; and

(e) Except as otherwise provided in subsection 2, a minimum of 20 hours of instruction and practical training concerning:

(1) The standards for pediatric, adolescent and adult immunization practices recommended and approved by the United States Public Health Service Advisory Committee on Immunization Practices;

(2) Basic immunology, and vaccine and immunization protection;

(3) Diseases that are preventable through vaccination and immunization;

(4) Recommended immunization schedules;

(5) Vaccine and immunization storage and management;

(6) Informed consent;

(7) Physiology and techniques for administration of immunizations;

(8) Preimmunization and postimmunization assessment and counseling;

(9) Immunization reporting and records management; and

(10) Identification, response, documentation and reporting of adverse events.

2. In lieu of complying with the requirements of paragraph (e) of subsection 1, a pharmacist or an intern pharmacist who administers immunizations consisting exclusively of live attenuated influenza vaccine through the nasal passages of a person may complete a program of less than 20 hours of instruction which is accredited by the Accreditation Council for Pharmacy Education ***or its successor organization*** and includes instruction relating to:

(a) The epidemiology of influenza;

(b) The pathophysiology, clinical presentation, diagnosis, prevention and treatment of influenza;

(c) The administration, storage and handling of influenza vaccines; and

(d) The counseling of patients who will be immunized with the vaccine.

3. Before a pharmaceutical technician acting under the direct and immediate supervision of a pharmacist may administer an immunization pursuant to a written protocol, the pharmaceutical technician must complete at least 1 hour of training relating to vaccines, immunization and the administration of immunizations provided by:

(a) Immunize Nevada or its successor organization;

(b) An entity approved by the Accreditation Council for Pharmacy Education or its successor organization;

(c) The owner or managing pharmacist of the pharmacy at which the pharmaceutical technician is employed; or

(d) Another entity approved by the Board.

Sec. 6. NAC 639.2974 is hereby amended to read as follows:

639.2974 ***1.*** A pharmacist who administers immunizations or an intern pharmacist acting under the direct and immediate supervision of a pharmacist who administers immunizations shall:

~~[1.]~~ ***(a)*** Maintain certification in basic cardiac life support from the American Heart Association ~~[;]~~ ***or its successor organization;*** and

~~[2.]~~ ***(b)*** On or before October 31 of each year, complete:

~~[(a)]~~ ***(1)*** At least 2 hours of continuing education in a course or courses that address the life cycle of diseases, drugs and administration of immunizations; or

~~[(b)]~~ ***(2)*** A course provided by the Centers for Disease Control and Prevention regarding epidemiology and prevention of diseases which are preventable through immunization.

2. On or before October 31 of each year, a pharmaceutical technician acting under the direct and immediate supervision of a pharmacist who administers immunizations shall

complete at least 1 hour of continuing education relating to vaccines, immunization and the administration of immunizations provided by an entity listed in subsection 3 of NAC 639.2973.

Sec. 7. NAC 639.2975 is hereby amended to read as follows:

639.2975 1. The drugs administered as immunizations by a pharmacist, or an intern pharmacist ***or pharmaceutical technician*** acting under the direct and immediate supervision of a pharmacist, must be in the legal possession of:

(a) The pharmacy that employs the pharmacist, ~~[or]~~ intern pharmacist ***or pharmaceutical technician*** who will be administering the immunizations, which pharmacy is responsible for the drugs and the maintenance of records of administration of the immunizations; or

(b) The physician who has established a written protocol for the administration of the immunizations, which physician is responsible for the drugs and the maintenance of records of administration of the immunizations.

2. The drugs used for immunizations must be transported and stored at the proper temperatures indicated for the drugs by the manufacturer.

3. While engaged in the administration of immunizations, a pharmacist, or an intern pharmacist ***or pharmaceutical technician*** acting under the direct and immediate supervision of a pharmacist, may have in his or her custody and control the drugs for immunization that are identified in the written protocol and any other dangerous drugs listed in the written protocol to treat an adverse reaction.

4. If a pharmacist, or an intern pharmacist ***or pharmaceutical technician*** acting under the direct and immediate supervision of a pharmacist, administers immunizations at a location other than a pharmacy, the pharmacist, ~~[or]~~ intern pharmacist ***or pharmaceutical technician*** must return all unused drugs to the pharmacy or physician responsible for the drugs.

Sec. 8. NAC 639.2976 is hereby amended to read as follows:

639.2976 A pharmacist ***who administers immunizations or directly and immediately supervises a pharmaceutical technician who administers immunizations*** , or an intern pharmacist acting under the direct and immediate supervision of a pharmacist who administers immunizations , shall report the information required for inclusion in the Immunization Information System established by the Department of Health and Human Services pursuant to NRS 439.265 and the regulations adopted pursuant thereto.

Sec. 9. NAC 639.2977 is hereby amended to read as follows:

639.2977 1. Each record required to be made pursuant to NAC 639.297 to 639.2978, inclusive, must be kept for at least 2 years by the pharmacist , ~~[or]~~ intern pharmacist ***or pharmaceutical technician*** administering the immunization and the pharmacy or physician who possessed the drugs administered. Such records must be available for inspection and copying by the Board or its representative, or any other authorized federal, state or local law enforcement or regulatory agency.

2. Records required pursuant to this section may be maintained in an alternative data retention system, including, without limitation, a computer data processing system or direct imaging system, if:

(a) The records maintained in the alternative system contain all the information required for a written record; and

(b) The data processing system is capable of producing a printed copy of the record upon the request of the Board, its representative or any other authorized federal, state or local law enforcement or regulatory agency.

Sec. 10. NAC 639.2978 is hereby amended to read as follows:

639.2978 1. A pharmacist , or an intern pharmacist ***or pharmaceutical technician*** acting under the direct and immediate supervision of a pharmacist , shall provide adequate security to prevent unauthorized access to confidential records of immunizations. If confidential health information is not transmitted directly between a pharmacy and a physician, but is transmitted through a data communication device, the confidential health information must not be viewed or used by the operator of the data communication device unless the operator is specifically authorized to obtain confidential information pursuant to this subsection.

2. Except as otherwise provided in NRS 49.245, the confidential records of immunizations are privileged and may be released only to:

(a) The patient or the authorized agent of the patient;

(b) Physicians and other pharmacists , or intern pharmacists ***or pharmaceutical technicians*** acting under the direct and immediate supervision of pharmacists , when, in the professional judgment of the pharmacist , ~~[or]~~ intern pharmacist ~~[.]~~ ***or pharmaceutical technician,*** such release is necessary to protect the health and well-being of the patient;

(c) The Board or other federal, state or local agencies authorized by law to receive such information;

(d) A law enforcement agency engaged in the investigation of a suspected violation involving a controlled substance or dangerous drug;

(e) A person employed by any state agency that licenses a physician if such a person is engaged in the performance of his or her official duties; or

(f) An insurance carrier or other third-party payor authorized by a patient to receive such information.

3. The provisions of this section must not be construed to affect or alter the provisions of NRS 49.215 to 49.245, inclusive, relating to the confidentiality of communications between a doctor and a patient.

INFORMATIONAL STATEMENT OF ADOPTED REGULATIONS
AS REQUIRED BY NRS 233B.066

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION.

Pursuant to the Governor's Declaration of Emergency issued March 12, 2020, the State is in an emergency status due to the COVID-19 pandemic. The proposed emergency regulation will authorize pharmaceutical technicians with appropriate training to administer immunizations under the direct supervision of a pharmacist. The amendments will allow pharmacies to meet the increased demand for vaccine services and will be crucial to expanding the State's capacity to expediently treat Nevada's population when a COVID-19 vaccine is developed. The regulations are necessary for the protection, health and safety of the public.

6. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

There should be no adverse economic impact from this emergency regulation on regulated businesses or the public. The beneficial effects of the emergency regulation will result from enabling pharmacies to meet the increased demand for vaccine services and will be crucial to expanding the State's capacity to expediently treat Nevada's population when a COVID-19 vaccine is developed.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that both the immediate and long-term economic effect on regulated businesses or the public will be beneficial since this emergency regulation will increase the State's capacity to timely deploy a COVID-19 vaccine in response to the current pandemic for the protection, health and safety of the public.

7. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the Board for enforcement of this regulation.

8. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION

OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

9. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

10. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.