

LCB File No. R202-99

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

IMMUNIZATIONS OR VACCINATIONS

NAC 639.____ *Definition. As used in NAC 639.____ to 639.____ inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.____ to 639.____ inclusive, have the meanings ascribed to them in those sections.*

NAC 639.____ *“Administer” defined. The direct application of a prescription drug by injection, insertion, application, inhalation, ingestion, or any other means to the body of a patient by:*

- 1. A practitioner, an authorized agent under his supervision, or other person authorized by law; or*
- 2. The patient at the direction of a practitioner.*

NAC 639.____ *“Antibody” defined. A protein in the blood that is produced in response to stimulation by specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen usually equate to immunity to the antigen.*

NAC 639.____ *“Antigen” defined. A substance “recognized” by the body as being foreign; it results in the production of specific antibodies directed against it.*

NAC 639.____ *“Confidential record” defined. Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.*

NAC 639.____ *“Immunization” defined. The act of inducing antibody formation, thus leading to immunity.*

NAC 639.____ *“Vaccination” defined. Administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.*

NAC 639.____ *“Vaccine” defined. A specially prepared antigen, which upon administration to a person will result in immunity.*

NAC 639.____ *Written Protocol. A physician’s order, standing medical order, standing delegation order, or other order or protocol means a written declaration of a plan of medical treatment or procedure.*

- 1. A written protocol must contain, at a minimum, the following:*
 - (a) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of immunizations or vaccinations;*
 - (b) A statement identifying the individual pharmacist authorized to administer immunizations or vaccinations as delegated by the physician;*

- (c) *A statement identifying the locations(s) (i.e., address) at which the pharmacist may administer immunizations or vaccinations;*
 - (d) *A statement identifying the immunizations or vaccinations that may be administered by the pharmacist;*
 - (e) *A statement identifying the activities the pharmacist shall follow in the course of administering immunizations or vaccinations, including procedures to follow in the case of reactions following administration;*
 - (f) *A statement that describes the content of, and the appropriate mechanisms for the pharmacist to report the administration of immunizations or vaccinations to the physician issuing the written protocol within the time frames specified in this section; and*
 - (g) *A signature of the authorizing physician and the effective dates of the protocol.*
2. *A standard protocol may be used or the physician may develop an immunization or vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient.*

NAC 639.____ *Pharmacist Administration of Immunizations or Vaccines.*
 NAC 639.____ to 639.____, inclusive, provides standards for pharmacists under written protocol of a physician, to administer immunizations or vaccines as authorized in NRS 639.____.

NAC 639.____ *Pharmacist Certification Requirements.* *Pharmacist who enter into a written protocol with a physician to administer immunizations or vaccinations must:*

1. *Be certified to administer immunizations or vaccinations by the completion of a course provided by:*

- (a) *The University of Nevada Medical School; or*
- (b) *A course provided by an American Council on Pharmaceutical Education approved provider which satisfy the following requirements:*

(1) *Documentation by the pharmacist of current certification in the American Heart association's Basic Cardiac Life Support for Health-Care Providers or its equivalent;*

(2) *Education in an evidence based course which must include, but is not limited to:*

- (I) *Study materials;*
- (II) *Hands on*

training in techniques for administering immunizations or vaccines; and

(III) *Testing with a passing score; and*

(3) *Meets current Center for Disease Control training guidelines and provides a minimum of 20 hours of instruction and experimental training in the following content areas:*

- (I) *Standards for pediatric, adolescent and adult immunization practices;*
- (II) *Basic immunology and vaccine protection;*
- (III) *Vaccine preventable diseases;*
- (IV) *Recommended immunization schedules;*
- (V) *Vaccine storage and management;*
- (VI) *Informed consent;*
- (VII) *Physiology and techniques for vaccine administration;*
- (VIII) *Pre and post-vaccine assessment and counseling;*
- (IX) *Immunization reporting and record management; and*
- (X) *Adverse event;*

- (i) *Identification and appropriate response; and*
 - (ii) *Documentation and reporting.*
- 2. *Maintain documentation of:*
 - (a) *Completion of the initial course specified in paragraph 1 of this section;*
 - (b) *Three hours of continuing education every 2 years which are designed to maintain competency in the disease states, drugs, and administration of immunizations or vaccinations; and*
 - (c) *Current certification in Basic Cardiac Life Support specified in paragraph 1 of this section.*

NAC 639.____ *Physician Supervision. Pharmacists involved in the administration of immunizations or vaccinations shall be under the supervision of a physician. Physician supervision shall be considered adequate if the delegating physician:*

- 1. *Is responsible for the formulation or approval of the physician's order, standing medical order, standing delegation order, or other order or protocol and periodically reviews the order or protocol and the services provided to a patient under the order or protocol.*
- 2. *Has established a physician-patient relationship with each patient under 14 years of age and referred the patient to the pharmacist.*
- 3. *Is geographically located so as to be easily accessible to the pharmacist administering the immunization or vaccination.*
- 4. *Receives, as appropriate, a periodic status report on the patient, including any problem or complication encountered.*
- 5. *Is available through direct telecommunication for consultation, assistance and direction.*

NAC 639.____ *Drug products.*

- 1. *Drugs administered by a pharmacist under the provisions of this section shall be in the legal possession of:*
 - (a) *A pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or*
 - (b) *A physician who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination.*
- 2. *Drugs shall be transported and stored at the proper temperatures indicated for each drug.*
- 3. *Pharmacists while actively engaged in the administration of immunizations or vaccinations under written protocol, may have in their custody and control the drugs for immunization or vaccination that are identified in the written protocol and any other dangerous drugs listed in the written protocol to treat adverse reactions.*
- 4. *If a pharmacist administers immunizations or vaccinations at a location other than a pharmacy, the pharmacist shall return all unused prescription medications to the pharmacy or physician responsible for the drugs.*

NAC 639.____ *Notifications.*

- 1. *A pharmacist engaged in the administration of immunizations or vaccinations shall provide notification of the administration to:*

- (a) *The physician who issued the written protocol within 24 hours of administering the immunization or vaccination;*
 - (b) *The primary care physician of the patient, as provided by the patient or patient's agent within 14 days of administering the immunization or vaccination; and*
 - (c) *A county health department and State of Nevada in compliance with any reporting required by governmental agencies.*
2. *The notifications required in paragraph 1 of this subsection shall include:*
- (a) *The name and address of the patient;*
 - (b) *Age of the patient if under 14 years of age;*
 - (c) *Name of the patient's primary care physician as provided by the patient or patient's agent;*
 - (d) *Name, manufacturer, and lot number of the vaccine administered;*
 - (e) *Amount administered;*
 - (f) *Date the vaccine was administered;*
 - (g) *Site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);*
 - (h) *Route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth);*
 - (i) *Name, address, and title of the person administering the immunization or vaccination; and*
 - (j) *Other data required by county ordinance or state law.*

NAC 639.____ Records.

1. Maintenance of records:

- (a) *Every record, including notifications, required to be made under this section shall be kept by the pharmacist administering the immunization or vaccination and by the pharmacy when in legal possession of the drugs administered. Such records shall be available for at least two years from the date of such record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.*
 - (b) *Records, including notifications, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:*
 - (1) *The records maintained in the alternative system contain all of the information required on the manual record; and*
 - (2) *The data processing system is capable of producing a hard copy of the record upon request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.*
2. *Records of administration under written protocol.*
- (a) *Records of administration shall be maintained by the pharmacist administering immunizations or vaccinations. Such records shall include:*
 - (1) *All of the administration record requirements of subparagraph (b) of this paragraph; and*
 - (2) *Include the name and address of the pharmacy or physician in legal possession of the immunization or vaccination administered.*
 - (b) *A pharmacy, when responsible for drug accountability, shall maintain a record of administration of immunizations or vaccinations by a pharmacist. The records shall be kept and maintained by patient name. This record shall include:*

- (1) *A copy of the written protocol under which the immunization or vaccination was administered and any patient-specific deviations from the protocol;*
- (2) *Name and address of the patient;*
- (3) *Age of the patient if under 14 years of age;*
- (4) *Name of the patient's primary care physician as provided by the patient or patient's agent;*
- (5) *Name, manufacturer, and lot number of the vaccine administered;*
- (6) *Amount administered;*
- (7) *Date the vaccine was administered;*
- (8) *Site of the immunization or vaccination (e.g., right arm, left leg, right upper arm);*
- (9) *Route of administration of the immunization or vaccination (e.g., intramuscular, subcutaneous, by mouth); and*
- (10) *Name, address, and title of the person administering the immunization or vaccination.*

3. *Written protocol.*

- (a) *A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained in accordance with paragraph 2 of this subsection.*
- (b) *A standard protocol may be used or the attending physician may develop an immunization/vaccination protocol for the individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for the patient. The pharmacy that is in possession of the vaccines administered shall maintain a copy of any deviations from the standard protocol ordered by the physician.*
- (c) *Written protocols, including standard protocols, any patient-specific deviations from a standard protocol and any individual patient protocol, shall be reviewed by the physician and pharmacist at least annually and revised if necessary. Such review shall be documented in the records of the pharmacy that is in possession of the vaccines administered.*

NAC 639.____ *Confidentiality.*

1. *A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. 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 may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain confidential information by this subsection.*
2. *Confidential records are privileged and may be released only to:*
 - (a) *The patient or the patient's agent;*
 - (b) *Practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;*
 - (c) *Other persons, the board, or other state or federal agencies authorized by law to receive such information;*
 - (d) *A law enforcement agency engaged in investigation of suspected violations of the Controlled Substance Act or the Dangerous Drug Act;*
 - (e) *A person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties; or*

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

3. This section shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in NRS 49.215 to 49.245.

NAC 639.____ Restrictions and Requirements. Pharmacists involved in the administration of immunizations or vaccinations under their license to practice pharmacy shall meet the following restrictions and requirement:

1. Pharmacists may only administer immunizations or vaccinations pursuant to a written protocol from a physician authorizing the administration.

2. Pharmacists may administer immunizations or vaccinations to a patient under 14 years of age only upon a referral from a physician who has an established physician-patient relationship with each patient.

3. Pharmacists may administer immunizations or vaccinations under written protocol of a physician within a pharmacy or at any other location specifically identified in the written protocol. Such other location may not include where the patient resides, except for a licensed nursing home or hospital.

4. The authority of a pharmacist to administer immunizations or vaccinations may not be delegated.

5. Under the provisions of the National Vaccine Injury Compensation Program (NVICP), the health-care provider under whose authority a covered vaccine is administered (i.e., the physician issuing the written protocol) must maintain certain information in the patient's permanent record. In order for the physician to comply with the provisions of the NVICP, the pharmacist shall provide the physician with the information specified in NAC 639.____.

6. The pharmacist shall comply with all other state and federal requirements regarding immunizations or vaccinations.

Workshop 11/4/99

Amendment of Nevada Administrative Code 639 NEW LANGUAGE

NAC 639.____ Splitting of Tablets

Except for a prescribing practitioner ordering a specific strength of drug unavailable in a dosage form, no insurer or organization providing prescription benefits can require a pharmacy to dispense a prescription requiring an intact single dose form of medication to be divided in two or more parts if the equivalent strength is readily available.

Workshop 9/23/99

Workshop 11/4/99

Amendment of Nevada Administrative Code 639 NEW LANGUAGE

NAC 639.____ Revocation or Suspension Condition, no licensed industry related employment.

A pharmacist, intern pharmacist, pharmaceutical technician, pharmaceutical technician in training, or any person certified, licensed, registered or permitted by the board or a board of

pharmacy of another state or jurisdiction who has not had their certificate, license, registration or permit reinstated following revocation or suspension for grounds pursuant to NRS 639.210 or similar grounds of another state or jurisdiction, shall not be employed in any capacity in a pharmacy or pharmaceutical wholesale business.

Workshop 8/5/99

Public Hearing 9/23/99

Workshop 11/4/99