# LCB File No. R009-01

## PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

(This proposed regulation was previously adopted as LCB File No. T013-00)

**PROPOSED REGULATIONS REGARDING IMMUNIZATIONS BY PHARMACISTS**

**Section 1.** NAC ch. 639 shall be amended to add the following new language:

***As used in these regulations, unless the context otherwise requires, the following words and terms have the meanings ascribed to them in the following sections:***

***1. "Immunization" means the act of inducing antibody formation through the introduction of a drug into the human body and includes immunizations.***

**Section 2.** NAC ch. 639 shall be amended to add the following new language:

***1. A pharmacist may administer an immunization by intramuscular or subcutaneous injection only according to a written protocol from a practitioner. A written protocol from a practitioner that authorizes a pharmacist to administer an immunization must contain:***

**(a) The name of the practitioner responsible for the delegation of administration of immunizations;**

***(b) The name of pharmacist authorized to administer immunizations;***

***(c) The location or locations at which the pharmacist may administer immunizations;***

***(d) The drugs that may be administered by the pharmacist;***

***(e) Detailed policies and procedures that the pharmacist must follow in the course of administering immunizations, including procedures to follow in the case of reactions or emergencies following administration;***

***(f) A procedure requiring the pharmacist to report pursuant to these regulations the administration of immunizations to the physician issuing the written protocol, including a specification of the time within which such reporting must occur;***

***(g) A procedure for the review of the protocol and its operation by the pharmacist and the practitioner at least once annually and the making and keeping of a record of the review;***

***(h) A restriction that the pharmacist may not administer any immunization to a patient younger than 14 years old;***

***(i) A restriction that the pharmacist may not delegate his authority to administer an immunization;***

***(j) A restriction that the pharmacist many not administer an immunization except at the authorized location, which location cannot be the patient's home unless the patient resides in a licensed long-term care facility or hospital;***

***(k) A requirement that the immunizations will be administered according to all applicable federal, state, and local statutes, regulations, ordinances, and rules;***

***(l) A restriction that the pharmacist, the pharmacy, or the business at which the immunizations will be administered are prohibited from paying, offering, or otherwise giving any remuneration to the practitioner for his entering into the protocol or for the administration of an immunization to any patient; and***

***(m) The signature of the authorizing physician and the effective dates of the protocol.***

***2. If a practitioner orders a deviation from his protocol with a pharmacist for the benefit of a specific patient, the physician shall record in the patient's record what deviations, if any, from the standard protocol he ordered for that patient.***

**Section 3.** NAC ch. 639 shall be amended to add the following new language:

**Before a pharmacist may enter into a written protocol with a physician to administer immunizations, the pharmacist must be certified to administer immunizations**

**by the completion of a course provided by the University of Nevada Medical School or a provider approved by the American Council on Pharmaceutical Education that includes:**

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

**2. Education and practical training, including written study materials, in techniques for administering immunizations; and**

***3. Testing of the pharmacist's knowledge and technique; and***

***4. Current Center for Disease Control training guidelines and provides a minimum of 20 hours of instruction and experimental training in:***

***(a) Standards for pediatric, adolescent and adult immunization practices;***

***(b) Basic immunology and vaccine and immunization protection;***

***(c) Vaccine and immunization preventable diseases;***

***(d) Recommended immunization schedules;***

***(e) Vaccine and immunization storage and management;***

***(f) Informed consent;***

***(g) Physiology and techniques for immunization administration;***

***(h) Pre and post-immunization assessment and counseling;***

***(i) Immunization reporting and record management; and***

***(j) Adverse event identification, response, documentation, and reporting.***

**Section 4.** NAC ch. 639 shall be amended to add the following new language:

***A pharmacist who administers immunizations pursuant to these regulations must:***

***1. Maintain his certification from the American Heart Association in basic cardiac life support; and***

***2. Complete by October 31 of each year:***

***(a) At least two hours of continuing education in a course or courses that address the disease states, drugs, and administration of immunizations; or***

**(b) A course provided by the Center for Disease Control regarding epidemiology and prevention of immunization preventable diseases.**

**Section 5.** NAC ch. 639 shall be amended to add the following new language:

***A practitioner who has authorized a pharmacist to administer immunizations pursuant to a written protocol must supervise the pharmacist's implementation of the protocol. The practitioner must:***

***1. Retain responsibility for the quality of care rendered by the pharmacist;***

***2. Be readily accessible to the pharmacist or the patient at all times when the pharmacist is authorized to administer the immunizations for consultation, assistance and direction; and***

***3. Receive a periodic status report on patient from the pharmacist, including any problems, complications or emergencies encountered.***

**Section 6.** NAC ch. 639 shall be amended to add the following new language:

***1. Drugs administered by a pharmacist under the provisions of this section shall be in the legal possession of:***

***(a) The pharmacy that employs the pharmacist who will be administering the immunizations, and the pharmacy is responsible for accountability for the drugs, including the maintenance of records of administration of the immunization; or***

***(b) The practitioner who has authorized the pharmacist to administer the immunizations, and the practitioner shall be responsible for drug accountability, including the maintenance of records of administration of the immunization.***

***2. All drugs used for immunizations shall be transported and stored at the proper temperatures indicated by the manufacturer for the drug.***

***3. While engaged in the administration of immunizations, a pharmacist may have in his 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 adverse reactions.***

***4. If a pharmacist administers immunizations at a location other than a pharmacy, the pharmacist shall return all unused drugs to the pharmacy or physician responsible for the drugs.***

**Section 7.** NAC ch. 639 shall be amended to add the following new language:

***1. Regarding his administering of immunizations, a pharmacist who administers immunizations shall notify:***

***(a) The physician who issued the written protocol within 24 hours of administering the immunization;***

***(b) The primary care physician of the patient, as provided by the patient or patient's agent within 14 days of administering the immunization; and***

***(c) A county health department and State of Nevada as required by statute, regulation, ordinance, or rule; and***

***(d) The Nevada statewide immunizations registry system.***

***2. The notifications required in paragraph 1 of this section shall include:***

***(a) The name and address of the patient;***

***(b) The name of the patient's primary care physician as provided by the patient or patient's agent;***

***(c) The name, manufacturer, and lot number of the drug administered;***

***(d) The amount administered;***

***(e) The date the immunization was administered;***

***(g) The place on the patient's body into which the immunization was administered;***

***(h) The route of administration of the immunization;***

***(i) The name, address, and title of the person administering the immunization;***

***(j) Any adverse reactions suffered by the patient as a result of the immunization; and***

***(j) Any other data required by county ordinance or state law.***

**Section 8.** NAC ch. 639 shall be amended to add the following new language:

***1. Every record required to be made under this regulation shall be kept for at least two years by the pharmacist administering the immunization and by the pharmacy or practitioner who possessed the drugs administered. Such records shall be available for viewing and copying to the board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.***

***2. Records made under this regulation may be maintained in an alternative data retention system, such as a computer data processing system or direct imaging system if:***

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

***(b) 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.***

**Section 9.** NAC ch. 639 shall be amended to add the following new language:

***1. 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 may not be viewed or used 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) 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 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.***