ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R180-05

Effective December 29, 2005

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

AUTHORITY: §§1-8, NRS 454.213, 639.070 and 639.137.

A REGULATION relating to pharmacy; authorizing intern pharmacists to administer immunizations under certain circumstances; and providing other matters properly relating thereto.

Section 1. NAC 639.2971 is hereby amended to read as follows:

639.2971 1. A pharmacist may administer immunizations by an intranasal, intramuscular or subcutaneous injection in compliance with a written protocol from a physician that authorizes a pharmacist to administer such an immunization. Such a protocol must contain:

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

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

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

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

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

(f) A procedure requiring the pharmacist to report the administration of immunizations to the physician issuing the written protocol, including, without limitation:

(1) A specification of the time within which such reporting must occur; and

(2) A requirement that the pharmacist submit a periodic status report concerning any problems, complications or emergencies encountered while administering immunizations;

(g) A procedure for the review of the protocol and its operation by the pharmacist and the physician 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 who is less than 14 years of age;

(i) ~~[A]~~ ***Except as otherwise provided in subsection 2, a*** restriction that the pharmacist may not delegate his authority to administer an immunization;

(j) A restriction that the pharmacist may not administer an immunization except at the 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;

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

(l) A restriction that the pharmacist, the pharmacy or the business at which the immunizations will be administered is prohibited from paying, offering or otherwise giving any remuneration to the physician for providing a written protocol or authorizing the administration of an immunization to any patient; and

(m) The signature of the physician authorizing the administration of the immunizations and the effective dates of the written protocol.

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 received a written protocol from a physician that authorizes the pharmacist to administer such an immunization.

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

Sec. 2. NAC 639.2972 is hereby amended to read as follows:

639.2972 A physician who has authorized a pharmacist to administer immunizations pursuant to a written protocol shall supervise the implementation of the protocol by the pharmacist ***or an intern pharmacist acting under the direct and immediate supervision of the pharmacist*** by:

1. Retaining responsibility for the quality of care rendered by the pharmacist ~~[,]~~ ***or intern pharmacist;***

2. Being readily accessible to the pharmacist ***or intern pharmacist*** or the patient when the pharmacist is authorized to administer the immunizations for consultation, assistance and direction; and

3. Reviewing a periodic status report from the pharmacist ***or intern pharmacist*** concerning any problems, complications or emergencies encountered while administering immunizations.

Sec. 3. NAC 639.2973 is hereby amended to read as follows:

639.2973 1. Before a pharmacist may enter into a written protocol with a physician to administer immunizations ~~[,]~~ ***or before an intern pharmacist acting under the direct and immediate supervision of a pharmacist may administer immunizations,*** the pharmacist ***or intern pharmacist*** must be trained and certified to administer immunizations by completing a course provided by the ~~[Nevada College]~~ ***Office*** of Pharmacy ~~[,]~~ ***Education,*** the University of

Nevada School of Medicine or a provider approved by the American Council on Pharmaceutical Education 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 American Council on Pharmaceutical Education 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.

Sec. 4. NAC 639.2974 is hereby amended to read as follows:

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

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

2. On or before October 31 of each year, complete:

(a) 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) A course provided by the Centers for Disease Control and Prevention regarding epidemiology and prevention of diseases which are preventable through immunization.

Sec. 5. 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 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*** 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 authorized the pharmacist to administer 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 acting under the direct and immediate supervision of 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 an adverse reaction.

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

Sec. 6. NAC 639.2976 is hereby amended to read as follows:

639.2976 1. A pharmacist ***or an intern pharmacist acting under the direct and immediate supervision of a pharmacist*** who administers immunizations shall notify:

(a) The physician who issued the written protocol within 14 days after administering the immunizations;

(b) The primary care physician of the patient, as provided by the patient or agent of the patient, within 14 days after administering the immunizations;

(c) The county health department of the county where the immunization was administered and the State of Nevada as required by statute, regulation, ordinance or rule; and

(d) The statewide immunization registry maintained by the Health Division of the Department of Health and Human Services.

2. The notifications required pursuant to subsection 1:

(a) Must include the name and address of the patient; and

(b) May include:

(1) The name of the primary care physician of the patient as provided by the patient or the agent of the patient;

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

(3) The amount of the drug administered;

(4) The date the immunization was administered;

(5) The place on the body of the patient where the immunization was administered;

(6) The route of administration of the immunization;

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

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

(9) Any other information required by federal, state or local law.

Sec. 7. 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*** 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. 8. NAC 639.2978 is hereby amended to read as follows:

639.2978 1. A pharmacist ***or an intern pharmacist 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 acting under the direct and immediate supervision of pharmacists*** when, in the professional judgment of the pharmacist ~~[,]~~ ***or intern pharmacist,*** 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 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R180-05

The State Board of Pharmacy adopted regulations assigned LCB File No. R180-05 which pertain to chapter 639 of the Nevada Administrative Code on December 8, 2005.

Notice date: 11/4/2005 **Date of adoption by agency:** 12/8/2005
Hearing date: 12/8/2005 **Filing date:** 12/29/2005

INFORMATIONAL STATEMENT

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __1___.
The number of persons who testified at the hearing was __1___.
The number of agency submitted statements was __0___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without change.

5. 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.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. 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.

7. 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.

8. 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.

9. 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.