ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R115-08

Effective September 18, 2008

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

AUTHORITY: §1, NRS 639.070 and 639.137; §§2-6, NRS 454.213, 639.070 and 639.137.

A REGULATION relating to pharmacy; revising the provisions governing intern pharmacists; revising the provisions governing written protocols from physicians authorizing pharmacists to administer certain immunizations; revising the provisions governing the training and certification of pharmacists or intern pharmacists who administer immunizations pursuant to a written protocol; revising the provisions governing notifications of immunizations administered pursuant to a written protocol; and providing other matters properly relating thereto.

Section 1. NAC 639.266 is hereby amended to read as follows:

639.266 1. Except as otherwise prohibited by law or by an order of the Board, any registered pharmacist may serve as preceptor to an intern pharmacist.

2. If an intern pharmacist is enrolled in a college of pharmacy or a department of pharmacy of a university approved by the Board, the college of pharmacy or the department of pharmacy of the university at which the intern pharmacist is enrolled shall establish a scope of duties that may be engaged in by the intern pharmacist during his internship and shall provide the scope of duties to the intern pharmacist before his internship begins. The scope of duties must be based upon the courses that the intern pharmacist has completed. The intern pharmacist shall, before his internship begins, provide the scope of duties established for him by the college of pharmacy or the department of pharmacy of the university to any preceptor responsible for his supervision and training.

3. Except as otherwise provided in subsection 4, a preceptor shall allow an intern pharmacist under his supervision to perform duties to the fullest extent practicable that are primarily related to:

(a) The selling of controlled substances, poisons, dangerous drugs and devices;

(b) The compounding of prescription drugs;

(c) The filling of prescriptions and the dispensing of prescription drugs;

(d) Preparing and maintaining such records and reports as are required by state and federal law;

(e) Counseling patients as required by NAC 639.707 concerning prescription drugs dispensed to the patients; ~~[and]~~

(f) The practice of pharmacy as that term is defined in NRS 639.0124 ~~[.]~~ ***; and***

(g) Administering immunizations by an intranasal, intramuscular or subcutaneous injection in accordance with a written protocol established by a physician pursuant to NAC 639.2971.

4. A preceptor shall not allow an intern pharmacist under his supervision to perform any duties that:

(a) Are outside of the scope of duties established for the intern pharmacist pursuant to subsection 2; or

(b) In the professional judgment of the preceptor, the intern pharmacist is not able to perform safely and professionally.

5. A preceptor shall:

(a) Document the number of hours worked by each intern pharmacist under his supervision;

(b) Maintain that documentation; and

(c) Provide a copy of that documentation to:

(1) The college of pharmacy or the department of pharmacy of the university at which the intern pharmacist is enrolled if the intern pharmacist is enrolled in a college of pharmacy or a department of pharmacy of a university approved by the Board; or

(2) The intern pharmacist if the intern pharmacist has graduated from a college of pharmacy, a department of pharmacy of a university or a foreign school.

6. If the intern pharmacist is enrolled in a college of pharmacy or a department of pharmacy of a university approved by the Board, the preceptor supervising the intern pharmacist shall provide written notice to the college of pharmacy or the department of pharmacy of the university at which the intern pharmacist is enrolled if the preceptor or the pharmacy for which the preceptor works terminates the internship of the intern pharmacist. The notice must state with specificity the reasons for the termination of the internship.

7. In addition to the notice provided pursuant to subsection 6, a preceptor supervising an intern pharmacist who is enrolled in a college of pharmacy or a department of pharmacy of a university approved by the Board shall provide written notice to the Board if the internship of the intern pharmacist is terminated because the intern pharmacist:

(a) Was arrested for, charged with or convicted of a crime that was alleged to have been committed by the intern pharmacist while participating in his internship at the pharmacy;

(b) Committed an act that, in the judgment of the preceptor, was a violation of one or more provisions of Nevada or federal law relating to the practice of pharmacy; or

(c) Committed an act that, in the judgment of the preceptor, was a violation of one or more of the policies or procedures of the pharmacy at which the intern pharmacist was participating in his internship.

➥ The notice must state with specificity the reasons for the termination of the internship.

8. Except as otherwise provided in subsection 9, the college of pharmacy or the department of pharmacy of the university at which any intern pharmacist is enrolled shall provide the intern pharmacist with a form to evaluate the quality of his internship at a pharmacy upon completion of the internship at the pharmacy. If a representative of the college of pharmacy or the department of pharmacy of the university discusses any of the comments made on the evaluation form with a preceptor who supervised the intern pharmacist or with any representative of the pharmacy at which the intern pharmacist was participating in his internship, the representative of the college of pharmacy or the department of pharmacy of the university shall not attribute any of the comments made on the evaluation to the intern pharmacist.

9. A college of pharmacy or a department of pharmacy of a university is not required to provide an intern pharmacist who participates in an internship after he has graduated from the college of pharmacy or the department of pharmacy of the university with a form to evaluate the quality of his internship at a pharmacy.

10. As used in this section, "preceptor" means a registered pharmacist who:

(a) Has accepted responsibility for the supervision and training of an intern pharmacist; and

(b) Provides direct and immediate supervision to the intern pharmacist.

Sec. 2. NAC 639.2971 is hereby amended to read as follows:

639.2971 1. A ~~[pharmacist may administer]~~ ***physician may establish a written protocol authorizing pharmacists to 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.]~~ ***Except as otherwise limited by the physician pursuant to subsection 4, 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 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]~~ ***a*** pharmacist;

~~[(e)]~~ ***(c)*** Detailed policies and procedures that ~~[the]~~ ***a*** 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)]~~ ***(d)*** 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)]~~ ***(e) When appropriate, specific instructions related to the age of the patient;***

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

~~[(j)]~~ ***(g)*** A restriction that ~~[the]~~ ***a*** pharmacist may not administer an immunization except at ~~[the]~~ ***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;

~~[(k)]~~ ***(h)*** 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)]~~ ***(i)*** The signature of the physician authorizing the administration of the immunizations and the ~~[effective dates of]~~ ***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 ~~[received]~~ ***subscribed to*** a written protocol ~~[from]~~ ***established by*** 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.

4. 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. 3. NAC 639.2972 is hereby amended to read as follows:

639.2972 A physician who has authorized ~~[a pharmacist]~~ ***pharmacists*** to administer immunizations ~~[pursuant to]~~ ***by establishing*** a written protocol shall supervise the implementation of the protocol by ~~[the]~~ ***each*** pharmacist ~~[or an]~~ ***who has subscribed to the protocol and by each*** 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]~~

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

Sec. 4. NAC 639.2973 is hereby amended to read as follows:

639.2973 1. Before a pharmacist may ~~[enter into]~~ ***administer an immunization pursuant to*** 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 ***such*** immunizations, the pharmacist or intern pharmacist must be trained and certified to administer immunizations by completing a course ~~[provided by the Office of Pharmacy~~

~~Education, the University of Nevada School of Medicine or a provider]~~ approved by the Accreditation Council for Pharmacy 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 Accreditation Council for Pharmacy 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. 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]~~ ***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 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.~~**]** ***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.***

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R115-08

The State Board of Pharmacy adopted regulations assigned LCB File No. R115-08 which pertain to chapter 639 of the Nevada Administrative Code.

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 __3___.
The number of persons who testified at the hearing was ___3__.
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 with minor changes.

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.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

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.