ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R180-07

Effective September 18, 2008

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

AUTHORITY: §§1-4, 6 and 7, NRS 639.070; §§5 and 8, NRS 639.070 and 639.210.

A REGULATION relating to pharmacy; providing that a registered pharmacist may practice pharmacy only at a licensed pharmacy; providing an exception for a registered pharmacist to practice pharmacy at a site other than a licensed pharmacy under certain circumstances; authorizing a licensed pharmacy to apply to the State Board of Pharmacy to use the services of a registered pharmacist at a site other than the site of the licensed pharmacy; and providing other matters properly relating thereto.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 8, inclusive, of this regulation.
- Sec. 2. Except as otherwise provided in sections 3 and 6 of this regulation, a registered pharmacist may engage in the practice of pharmacy only at the site of a licensed pharmacy.
- Sec. 3. 1. Except as otherwise provided in subsection 2, a registered pharmacist may apply to the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy by submitting an application on a form prescribed by the Board. An application must be approved before a pharmacist may commence any practice pursuant to this section. The application must include, without limitation:
 - (a) The name of the pharmacist;
 - (b) A description of the services that the pharmacist intends to provide at the site;
 - (c) The location at which the pharmacist will provide the services;

- (d) An identification of the types of patients or other persons to whom the pharmacist intends to provide the services;
- (e) An identification of the types of pharmacies or other entities to whom the pharmacist intends to provide the services;
- (f) A description of all resources, both paper and electronic, that will be available to the pharmacist in the course of providing the services;
 - (g) The days and hours during which the pharmacist intends to provide the services;
- (h) An explanation of the policy of the pharmacist for users of the services when the pharmacist is unavailable;
- (i) An explanation of the policy of the pharmacist regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records;
- (j) Whether the services provided will be affiliated with, an adjunct of or otherwise related to a licensed pharmacy; and
 - (k) A description of the business plan for the services provided.
- 2. A registered pharmacist may not submit an application pursuant to subsection 1 if he provides services:
 - (a) Pursuant to the provisions of NAC 449.15347;
 - (b) Pursuant to the provisions of NAC 449.6138;
 - (c) Pursuant to the provisions of NAC 449.722;
 - (d) Pursuant to the provisions of NAC 449.74531;
 - (e) Pursuant to the provisions of NAC 449.9905 and 639.4996;
 - (f) Pursuant to the provisions of subsection 2 of NAC 639.465;

- (g) Pursuant to the provisions of NAC 639.690;
- (h) Voluntarily or without compensation, regardless of whether the services are provided individually or through an employer; or
- (i) Pursuant to a medication therapy management program approved pursuant to 42 C.F.R. § 423.153(d).
- 3. A registered pharmacist who administers immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive, is not required to submit an application pursuant to this section for purposes of administering the immunizations at the authorized location.
- Sec. 4. 1. Upon submission of an application pursuant to section 3 of this regulation, the Board will schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
 - (a) The information contained in the application;
 - (b) The education, experience and expertise of the applicant;
 - (c) The disciplinary history of the applicant, if any; and
 - (d) Whether the applicant has sufficient malpractice or other liability insurance.
 - 2. At the hearing, the Board may request that the applicant modify his application.

- 3. If the Board approves an application, the Board will provide the applicant with documentation indicating the approval and setting forth the terms and conditions under which the applicant may provide the services approved by the Board.
- 4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.
- Sec. 5. The Board may revoke, suspend or place restrictions on the approval granted to a registered pharmacist to practice pharmacy at a site other than the site of a licensed pharmacy pursuant to section 4 of this regulation based upon proof that:
- 1. The pharmacist has violated the terms and conditions under which he was approved by the Board to provide the services; or
- 2. During the course of providing the services, the pharmacist has committed one or more acts that are grounds for disciplinary action pursuant to this chapter or chapter 639 of NRS.
- Sec. 6. 1. Except as otherwise provided in subsection 2, a licensed pharmacy may apply to the Board to use the services of one or more registered pharmacists, including, without limitation, pharmacists employed by or under contract with the pharmacy, to engage in the practice of pharmacy at a site other than the site of the licensed pharmacy by submitting an application on a form prescribed by the Board. The application must include, without limitation:
 - (a) The name of the pharmacy;
 - (b) A description of the services that the pharmacy intends to provide at the site;
 - (c) The location at which the pharmacy will provide the services;

- (d) An identification of the types of patients or other persons or entities to whom the pharmacy intends to provide the services;
- (e) A description of all resources, both paper and electronic, that will be available to the pharmacy in the course of providing the services;
 - (f) The days and hours during which the pharmacy intends to provide the services;
- (g) An explanation of the policy of the pharmacy for users of the service when a pharmacist is unavailable;
- (h) An explanation of the policy of the pharmacy regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records; and
 - (i) A description of the business plan for the services provided.
- 2. A pharmacy may not submit an application pursuant to subsection 1 to use the services of a registered pharmacist who is prohibited from submitting an application pursuant to subsection 2 of section 3 of this regulation.
- Sec. 7. 1. Upon submission of an application pursuant to section 6 of this regulation, the Board will schedule a hearing before the Board. At the hearing, the Board will consider the application and any other relevant information to determine whether the practice and services proposed in the application will be provided in a manner that is safe and in the best interests of the health, safety and welfare of the public. The Board may consider, without limitation, the following factors in determining whether to approve, deny or modify such an application:
 - (a) The information contained in the application;
 - (b) The disciplinary history of the applicant, if any; and

- (c) Whether the applicant has sufficient malpractice or other liability insurance.
- 2. At the hearing, the Board may request that the applicant modify the application.
- 3. If the Board approves an application, the Board will provide the pharmacy whose application is approved with documentation indicating the approval and setting forth the terms and conditions under which the pharmacists employed by or under contract with the pharmacy may offer the services approved by the Board.
- 4. If the Board denies an application, the Board will provide the applicant with a written notice of the denial indicating the reasons for the denial and identifying any deficiencies in the application.
- Sec. 8. The Board may revoke, suspend or place restrictions on the approval granted to a licensed pharmacy to use the services of one or more registered pharmacists to engage in the practice of pharmacy at a site other than the site of the licensed pharmacy pursuant to section 7 of this regulation based upon proof that:
- 1. The pharmacy has violated the terms and conditions under which the pharmacy was approved by the Board to provide the services; or
- 2. During the course of providing the services approved by the Board, the pharmacy has committed one or more acts that are grounds for disciplinary action pursuant to this chapter or chapter 639 of NRS.

NOTICE OF ADOPTION OF PROPOSED REGULATION LCB File No. R180-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R180-07 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.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

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	<u> 2 </u>	
The number of persons who testified at the hearing was _	<u>2</u>	
The number of agency submitted statements was1	.•	

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.

All response from affected businesses relative to this proposed regulation expressed support for the amendment.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

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 amendments or changes suggested through comments received from the public.

- 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.