ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R033-09

Effective October 15, 2010

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

AUTHORITY: §§1 and 2, NRS 639.070.

A REGULATION relating to medical products; specifying the qualifications for an administrator of a medical products provider or medical products wholesaler; and providing other matters properly relating thereto.

- **Section 1.** NAC 639.694 is hereby amended to read as follows:
- 639.694 1. [Each] Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall [have] employ an administrator at all times. The administrator must [be a]:
 - (a) Be a natural person [who is];
 - (b) Have a high school diploma or its equivalent;
 - (c) *Have*:
- (1) At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
- (2) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
- (d) Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week :: ; and

(e) Be approved by the Board.

- 2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
- [2.] 3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after [such] the cessation [.] of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after [such] the beginning of the employment.
- [3.] 4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.
- **Sec. 2.** The amendatory provisions of subsection 1 of section 1 of this regulation apply only to a person who begins employment as an administrator of a medical products provider or medical products wholesaler on or after October 15, 2010.

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INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

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 _	<u>30</u>	
The number of persons who testified at the hearing was	0	_•
The number of agency submitted statements was <u>0</u>	_•	

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

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.