ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R016-13

Effective December 23, 2013

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

AUTHORITY: §1, NRS 639.070, as amended by section 80 of Senate Bill No. 220, Statutes of Nevada 2013, at page 2237.

A REGULATION relating to controlled substances; revising provisions concerning the storage and destruction of certain controlled substances; and providing other matters properly relating thereto.

Section 1. NAC 639.050 is hereby amended to read as follows:

- 639.050 1. Upon the discontinuance of a controlled substance, a controlled substance becoming outdated or the demise of a patient at a facility for skilled nursing or facility for intermediate care which is licensed by the Health Division, any remaining controlled substance dispensed to the patient must be placed in a secured locked compartment. The controlled substance must be secured in the locked container until destroyed in the manner prescribed in NAC 639.498.
- 2. Each practitioner or pharmacy shall physically separate each controlled substance which is outdated, damaged, deteriorated, misbranded or adulterated from the balance of its stock medications. The [controlled substances must be held for destruction by an agent of the Board.

 The agent shall provide the] practitioner or pharmacy [with a copy of the Controlled Substances

 Enforcement Administration form 41 ("Registrants Inventory of Controlled Substances

 Surrendered") acknowledging destruction of the controlled substances. The controlled substances

must be destroyed] shall destroy such controlled substances at least once each year. The practitioner or pharmacy shall complete Form DEA-41 of the Drug Enforcement Administration, "Registrants Inventory of Drugs Surrendered," to acknowledge the destruction of the controlled substances.

3. This section does not apply to controlled substances packaged in manufacturer's unit-dose packages which are governed by the provisions of NRS 639.267 [...], as amended by section 137.4 of Assembly Bill No. 488, Statutes of Nevada 2013, at page 3068.

R016-13 NAC 639.050 Storage and Destruction of Certain Controlled Substances

November 5, 2013

INFORMATIONAL STATEMENT

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

1. EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION

The amendment will allow practitioners and pharmacies to destroy certain controlled substances without an agent of the Board present.

2. 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.

3. 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>14</u>	
The number of persons who testified at the hearing was	-0-	
The number of agency submitted statements was		

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

4. 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.

5. 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 as no testimony was offered.

- 6. 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.

7. 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.

8. 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.

9. 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.

10. 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.