ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R002-15

Effective December 21, 2015

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 the practice of pharmacy; requiring certain entities collecting controlled substances to provide certain notification and a copy of a certain federally required form to the State Board of Pharmacy; clarifying standards for the disposal of controlled substances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing law, the State Board of Pharmacy may adopt regulations governing the storage, handling and security of drugs and medicines. (NRS 639.070)

Federal law authorizes pharmacies, hospitals and other entities authorized to handle controlled substances to register with the Drug Enforcement Administration for authority to collect controlled substances. Such entities may conduct "mail-back" programs for the return of controlled substances and may maintain collection receptacles for the return of controlled substances. (21 C.F.R. §§ 1317.40, 1317.70, 1317.75) **Section 1** of this regulation requires an entity conducting a mail-back program or maintaining a collection receptacle to notify the Board that it has registered with the Drug Enforcement Administration. **Section 1** also requires such an entity to submit to the Board a copy of a certain form required to be submitted to the Drug Enforcement Administration.

Existing federal law provides standards for the disposal of controlled substances by entities authorized to handle and dispose of controlled substances. (21 C.F.R. parts 1300, 1301, 1304, 1305, 1307, 1317) Existing regulation also provides standards for the disposal of controlled substances. (NAC 639.498) **Section 2** of this regulation deletes the provisions of state regulatory law providing standards for the disposal of controlled substances and clarifies that the disposal of controlled substances must be done pursuant to federal law.

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 Upon the discontinuance of a controlled substance, a controlled substance becoming outdated or the demise of a patient at a facility for skilled nursing or facility for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 Division of Public and Behavioral Health of the Department of Health and Human Services, 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 practitioner or pharmacy 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. ***Any entity that is authorized pursuant to federal law to collect controlled substances and conducts a mail-back program to collect controlled substances or maintains collection receptacles for controlled substances shall provide to the Board:***

(a) Written notification that the entity has registered with the Drug Enforcement Administration to obtain authorization to be a collector; and

(b) A copy of each Form DEA-41 submitted to the Drug Enforcement Administration.

4. 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.

Sec. 2. NAC 639.498 is hereby amended to read as follows:

639.498 1. Except as otherwise provided in subsection 2:

(a) At least once each month, the director or a licensed consulting pharmacist shall destroy, on the premises of the facility, the controlled substances described in subsection 1 of NAC 639.050.

(b) If the director destroys the controlled substances, the licensed consulting pharmacist shall witness the destruction of the controlled substances. If the licensed consulting pharmacist destroys the controlled substances, the director shall witness the destruction of the controlled substances.

2. The director may designate a nurse licensed pursuant to chapter 632 of NRS to carry out his or her duties pursuant to this section. The licensed consulting pharmacist may designate a pharmacist licensed pursuant to chapter 639 of NRS to carry out his or her duties pursuant to this section.

3. The controlled substances must be destroyed ~~[by:~~

~~(a) Flushing them down the toilet or hopper;~~

~~(b) If a container for waste disposal is used, placing the controlled substances in the water in the container for disposal; or~~

~~(c) If the controlled substance is stored in a vial, ampule or other glass container, breaking the container and placing its contents into a container for waste disposal.]~~ ***in accordance with 21 C.F.R. Parts 1300, 1301, 1304, 1305, 1307 and 1317 and any other provision of federal law governing the destruction or disposal of controlled substances.***

R002-15
NAC Chapter 639.050 and NAC 639.498
Storage, Handling and Security of Drugs

October 27, 2015

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 proposed amendment will update the regulations to comply with current federal regulations allowing pharmacies, manufacturers, wholesalers, hospital pharmacies, and retail pharmacies to take prescription drugs back based on the September 9, 2014, DEA guidelines. These entities must obtain registration as an authorized collector from the DEA.

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.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board further provided time for public comment at the workshop(s) concerning the proposed amendment.

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: 11
The number of persons who testified at the hearing was: -0-
The number of agency submitted statements was: -0-
The name of persons who testified at the hearing: N/A

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.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. Further, the Board provided time for public comment at the workshop(s) concerning the proposed amendment.

Parties interested in obtaining a copy of the summary of the proposed amendment, or that wish to view the text of the proposed amendment, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

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 Board received no comments from industry or the public requesting any changes.

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.

There should be no adverse or beneficial economic effect of this regulation on the business or the public. Businesses may elect, but are not required, to utilize the program this amendment will allow.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that 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 federal regulations of the same activity in which the state regulation is more stringent. The state regulation is being amended to allow Nevada pharmacies to opt in and participate in the DEA's program for the benefit of Nevada residents.

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.