ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R097-13

Effective March 28, 2014

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

AUTHORITY: §1, NRS 639.070; §2, NRS 639.070 and 639.430; §3, NRS 639.070, 639.430 and 639.440.

A REGULATION relating to pharmacy; establishing the minimum requirements for a real-time, stop sale system concerning the sale or transfer of certain products that are precursors to methamphetamine; establishing the requirements for the use of the system by pharmacies and law enforcement agencies in this State; 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 and 3 of this regulation.

Sec. 2. ***1. For a real-time, stop sale system to be approved by the Board pursuant to NRS 639.430 for use by pharmacies in this State, the real-time, stop sale system must, at a minimum:***

(a) Satisfy the requirements set forth in subsection 1 of NRS 639.430;

(b) Allow pharmacies in this State to electronically submit the following information to the system:

(1) The information set forth in subsection 2 of NRS 453.357; and

(2) The name or initials of or the unique identifier which is approved by the Board for the pharmacist or the employee of the pharmacy who sold or transferred the product;

(c) Be capable of producing a record of the information described in paragraph (b) for use by law enforcement agencies; and

(d) Maintain the confidentiality of all data and information entered into the system and be capable of preventing access to the data and information in the system unless such access is authorized pursuant to a specific state or federal law.

2. The Board will deem the electronic record created by a real-time, stop sale system approved by the Board pursuant to NRS 639.430 as satisfying the requirements for entering information in a logbook pursuant to subsection 2 of NRS 453.357.

Sec. 3. *1. Except as otherwise provided in NRS 639.440, on or before the 90th day after a pharmacy in this State receives notice from the Board that it has approved a real-time, stop sale system pursuant to NRS 639.430, the pharmacy shall:*

(a) Obtain access to and begin using the real-time, stop sale system to document the sale or transfer of each product that is a precursor to methamphetamine;

(b) Verify that the pharmacy is submitting to the system the information required pursuant to paragraph (b) of subsection 1 of section 2 of this regulation in real time;

(c) In accordance with NRS 639.440, obtain any information necessary from the person seeking the purchase or transfer of a product that is a precursor to methamphetamine to receive notice from the real-time, stop sale system;

(d) Review the information provided by the real-time, stop sale system before completing any sale or transfer of a product that is a precursor to methamphetamine to verify that the sale or transfer of the product does not violate NRS 453.355 or any other state or federal law which prohibits the sale or transfer of a product that is a precursor to methamphetamine; and

(e) Except as otherwise provided in subsection 2, not allow the sale or transfer of a product to be completed if the pharmacy receives an alert from the real-time, stop sale system that the sale or transfer of the product may violate NRS 453.355 or any other state or federal law which prohibits the sale or transfer of a product that is a precursor to methamphetamine.

2. A pharmacist or an employee of the pharmacy may complete a sale or transfer of a product despite an alert from the real-time, stop sale system that the sale or transfer of the product may violate NRS 453.355 or any other state or federal law which prohibits the sale or transfer of a product that is a precursor to methamphetamine if the pharmacist or employee of the pharmacy has a reasonable fear of imminent bodily harm if the sale or transfer is not completed. If a pharmacist or an employee of the pharmacy completes a sale or transfer pursuant to this subsection, the pharmacist or employee of the pharmacy shall report the sale or transfer to the Board and an appropriate law enforcement agency as soon as the pharmacist or the employee of the pharmacy reasonably believes that the imminent danger has subsided but not later than 24 hours after the sale or transfer.

3. A pharmacist or an employee of a pharmacy may complete a sale or transfer of a product that is a precursor to methamphetamine without first consulting a real-time, stop sale system approved by the Board pursuant to NRS 639.430 if the pharmacy:

(a) Experiences a mechanical or electronic failure of the real-time, stop sale system or the real-time, stop sale system is otherwise unavailable;

(b) Requests and is granted from the Executive Secretary a temporary waiver of the requirement of using the real-time, stop sale system; and

(c) Maintains the information required to be submitted to the real-time, stop sale system pursuant to section 2 of this regulation on a written list or in another alternative format until the waiver is terminated.

R097-13
NAC Chapter 453 NEW
Real-Time Stop Sale System for Products that are a Precursor to Methamphetamine

February 14, 2014

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 new language in NAC Chapter 639 will require pharmacies to adopt a Board-approved real-time stop sale system for products that are a precursor to methamphetamine, as required by AB 39.

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 a summary of the proposed amendment on the Board's website (bop.nv.gov) with a link to the full text of the proposed amendment, (2) soliciting comment from Nevada dispensers who receive Board of Pharmacy notifications using a facsimile notice directed to each, and (3) contacting a representative of each relevant industry association Board Staff deemed likely to have an interest in the proposed amendment. The Board also provided time for public comment at the workshop(s) concerning the proposed amendment, and opened the floor for public comment at the public hearing on the proposed amendment.

The Board received positive public comment on R097-13 from a representative of the Nevada Retail Association, and from two representatives of the Consumer Healthcare Products Association. It received one negative comment from a private citizen who was concerned about the cost to pharmacies. Per AB 39, there is no cost to pharmacies.

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.

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 __20___.
The number of persons who testified at the hearing was __3_.
The number of agency submitted statements was _1____.

The name of persons who testified at the hearing:

-Liz Macmenamin, Retail Association of Nevada; 410 S. Minnesota Street, Carson City, Nevada 89703-4272; 775-882-1700; lizm@rannv.org
-Kevin Kraushaar, Consumer Healthcare Products Association; 900 19th Street, NW, Suite 700, Washington, DC 20006, Tel: 202.429.9260
-Chris Ferrari, Consumer Healthcare Products Association, 4747 Caughlin Parkway, Reno, NV 89519

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, by direct mailings to professional and trade associations, posting a summary of the proposed amendment on the Board's website (bop.nv.gov), with a link to the full text of the proposed amendment, and soliciting comment from Nevada pharmacies who receive Board of Pharmacy "Hotline" notifications using a facsimile notice directed to each.

Board Staff received positive public comment on R097-13 from a representative of the Nevada Retail Association, and from two representatives of the Consumer Healthcare Products Association. It received a negative comment from a private citizen concerning the cost of the system to pharmacies, which Board Staff addressed by explaining that the stop-sale system will be provided at no cost.

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.

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 changes because the regulation was drafted to comply with AB 39 and the Board received only positive comments from industry and the public, except for one negative comment from an individual who came to understand the system will be provided at no cost.

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 adverse or beneficial economic effect on businesses or on the public. The system will be provided to pharmacies at no cost, and its use will likely be nearly transparent to 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. The system will be provided to pharmacies at no cost, and its use will likely be nearly transparent to 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.