ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R121-15

Effective September 9, 2016

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

AUTHORITY: §§1 and 2, NRS 453C.120 and NRS 639.070.

A REGULATION relating to pharmacy; requiring a pharmacist who furnishes an opioid antagonist to create and maintain a record containing certain information; requiring a pharmacy to submit such records to the State Board of Pharmacy annually; exempting certain persons to whom an opioid antagonist is furnished from requirements applicable to wholesalers; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes a registered pharmacist to furnish an opioid antagonist in accordance with standardized procedures or protocols developed by the State Board of Pharmacy. (NRS 453C.120) **Section 1** of this regulation requires a pharmacist who furnishes an opioid antagonist to create a record that must include certain information about the opioid antagonist and the person or entity to whom the opioid antagonist is furnished. **Section 1** also requires a pharmacy to: (1) provide such records to the Board annually; and (2) maintain such records for at least 2 years from the date on which the record was created. Finally, **section 1** allows a pharmacy to maintain such records in an alternative data retention system, including a computerized data processing system or direct imaging system, that is capable of producing a printed copy of the record upon the demand of certain governmental authorities.

Existing law: (1) defines "wholesaler" as a wholesale distributor who supplies or distributes certain drugs, medicines or chemicals or devices or appliances to a person other than the consumer or patient; and (2) imposes certain requirements concerning licensure, submission of information and business practices upon each wholesaler who operates in this State. (NRS 639.016, 639.500-639.595) **Section 2** of this regulation interprets the term "consumer" for purposes of determining when a person is considered a wholesaler. As interpreted, "consumer" includes a person to whom an opioid antagonist is furnished pursuant to such procedures and protocols, thereby exempting such a person from the requirements imposed on wholesalers.

Section 1. Chapter 453C of NAC is hereby amended by adding thereto a new section to read as follows:

1. A pharmacist who furnishes an opioid antagonist shall create a record that must include, without limitation:

(a) The date on which the opioid antagonist was furnished;

(b) The name, strength, route of administration and quantity of the opioid antagonist;

(c) The location from which the opioid antagonist was furnished;

(d) The person or entity to which the opioid antagonist was furnished; and

(e) The location to which the opioid antagonist was furnished.

2. A pharmacy shall:

(a) Provide any record created pursuant to subsection 1 to the Board on or before December 31 of the year in which the opioid antagonist was furnished; and

(b) Maintain any record created pursuant to subsection 1 for at least 2 years from the date on which the opioid antagonist was furnished. Any such record must be made available for inspection and copying by the Board or its representative, or any other federal, state or local law enforcement or regulatory agency that is authorized by law to inspect and copy the record.

3. Records created pursuant to this section may be maintained in an alternative data retention system, including, without limitation, a computerized data processing system or direct imaging system if:

(a) The records maintained in the alternative data retention system include all of the information required pursuant to subsection 1; and

(b) The data processing system is capable of producing a printed copy of the record upon the request of the Board, its representative or any other federal, state or local law enforcement or regulatory agency that is authorized by law to copy and inspect the records.

Sec. 2. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

As used in NRS 639.016, the Board interprets the term "consumer" to include, without limitation, a person or governmental entity to which an opioid antagonist is furnished pursuant to section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120). As used in this section, "opioid antagonist" has the meaning ascribed to it in section 5 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 111 (NRS 453C.040).

LEGISLATIVE REVIEW OF ADOPTED REGULATIONS---NRS 233B.066
Informational Statement
LCB File No. R121-15

NAC Chapter 639.New Language
Standardized Procedures or Protocols for the Furnishing of Opioid Antagonists
August 5, 2016

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 Good Samaritan Drug Overdose Act, SB 459 (2015), requires the Board of Pharmacy (Board) to establish standardized procedures or protocols for the furnishing of opioid antagonists by pharmacists and other appropriate entities to persons at risk of experiencing an opioid-related overdose, or to a family member, friend or other person in a position to assist persons at risk of experiencing an opioid-related drug overdose. R0121-15 adds new language to NAC Chapter 639 to fulfill the requirements of SB 459. It creates regulations that provide for the standardized procedures and protocols SB 459 requires.

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.

The Board received written comment from Mary Staples, National Association of Chain Drug Stores (NACDS) regarding the renewal process of the written protocol between physicians and pharmacists. NACDS also commented on the reporting and recordkeeping requirements.

Liz MacMenamin, Retail Association of Nevada (RAN) commented on the reporting and recordkeeping requirements. RAN stated no objection to the regulation after hearing Board Staff's explanation.

Heidi Gustafson, Foundation for Recovery, commented in support of the regulation.

Scott Stolte, Dean, College of Pharmacy, Roseman University, commented that he did not support the reporting of the patient's name that is receiving the opioid antagonist. Board Staff clarified that the reporting requirement includes the name of the entity distributing the opioid antagonist. The patient's name is not required for reporting purposes. Mr. Stolte stated no objection to the regulation after hearing the explanation.

Trey Delap, Group Six Partners, commented in support of the regulation.

Parties interested in obtaining a summary, or a full copy, of the public comment, 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: 29
The number of persons who testified at the hearing was: -4-
The number of agencies submitted statements was: -1-
The name of persons who testified at the hearing:

Liz MacMenamin, RAN
Heidi Gustafson, Foundation for Recovery
Scott Stolte, Dean, College of Pharmacy, Roseman University
Trey Delap, Group Six Partners

None of the persons who provided comment at the hearings provided their contact information.

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. No individual business responded.

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 revised the regulation in response to public comment. The Board amended the original proposed language to require the collection of less personal data from persons to whom opioid antagonists are dispensed.

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 legitimate businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that this regulation will have no immediate or long-term economic effects on legitimate 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.