ADOPTED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R058-16

Effective September 9, 2016

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

AUTHORITY: §§1-10, section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120), and NRS 639.070.

A REGULATION relating to controlled substances; establishing standardized procedures for pharmacists furnishing opioid antagonists to certain persons under certain circumstances; authorizing physicians to establish written protocols for the furnishing of opioid antagonists by registered pharmacists; adopting certain requirements for the written protocols established by a physician; requiring certain records to be kept confidential; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes certain health care professionals to prescribe, dispense or otherwise furnish an opioid antagonist to a person at risk of experiencing an opioid-related drug overdose. (Chapter 454 of NRS) Existing law also contains the Good Samaritan Drug Overdose Act, which authorizes certain health care professionals to prescribe and dispense opioid antagonists to a person at risk of experiencing an opioid-related overdose or to a family member, friend or other person who is in a position to assist such a person and provides immunity from civil or criminal penalty under certain circumstances. (Sections 2-12 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at pages 110-114 (NRS 453C.010-453C.150)) Existing law authorizes the State Board of Pharmacy to develop standardized procedures and protocols under which a registered pharmacist may furnish an opioid antagonist. (Section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120))

Section 3 of this regulation establishes certain requirements that must be included in a pharmacy's standardized procedure by which a registered pharmacist furnishes an opioid antagonist. **Section 4** of this regulation authorizes a physician to establish a written protocol for authorizing a registered pharmacist to furnish an opioid antagonist. If a physician does establish such a written protocol, **section 4** also requires certain information to be included in the protocol. **Section 5** of this regulation requires a physician establishing a written protocol to supervise the registered pharmacist implementing the written protocol by being accessible to the registered pharmacist and recipient of the opioid antagonist for consultation and assistance, and to review any status report from a registered pharmacist detailing complications or problems with furnishing an opioid antagonist. **Section 6** of this regulation requires a registered pharmacist,

before furnishing an opioid antagonist to a person, to counsel that person on the safe administration of an opioid antagonist, possible adverse effects from the use of opioid antagonists and the immunity from certain civil and criminal liabilities for seeking medical assistance for a person experiencing an opioid-related overdose. **Section 7** of this regulation requires a registered pharmacist, before furnishing an opioid antagonist, to complete one continuing education unit approved by the Accreditation Council for Pharmacy Education relating to the use of opioid antagonists. **Sections 8-10** of this regulation establish the reporting and recordkeeping procedures required of registered pharmacists who furnish opioid antagonists.

Section 1. Chapter 453C of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 10, inclusive, of this regulation.

Sec. 2. ***As used in this chapter, "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).***

Sec. 3. ***A pharmacy in which a registered pharmacist may furnish an opioid antagonist pursuant to section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120), must implement standardized procedures for furnishing opioid antagonists which must include, without limitation:***

1. A restriction that a registered pharmacist may not delegate his or her authority to furnish an opioid antagonist;

2. Procedures for counseling a recipient of an opioid antagonist pursuant to section 6 of this regulation;

3. Procedures for recordkeeping pursuant to section 9 of this regulation; and

4. Reporting requirements pursuant to section 8 of this regulation.

Sec. 4. ***A physician authorized to prescribe an opioid antagonist may establish a written protocol authorizing a registered pharmacist to furnish an opioid antagonist. A protocol established pursuant to this section must include, without limitation:***

1. The name of the physician authorizing the furnishing of the opioid antagonist by a registered pharmacist;

2. The opioid antagonist to be furnished by a registered pharmacist;

3. The standardized policies implemented by the pharmacy in which a registered pharmacist will furnish the opioid antagonist pursuant to section 2 of this regulation;

4. A procedure for the review of the protocol and its operation by the physician at least once annually and a requirement to keep a record of the reviews;

5. Specific instructions relating to the age of the patient, if appropriate;

6. A statement that the opioid antagonist be furnished in accordance with all applicable federal, state and local laws;

7. The signature of the physician authorizing the furnishing of the opioid antagonist by a registered pharmacist and the time period for which the written protocol is effective; and

8. Any other limitations the physician deems necessary.

Sec. 5. *A physician who has authorized a registered pharmacist to furnish an opioid antagonist by establishing a written protocol pursuant to section 4 of this regulation shall supervise the implementation of the protocol by each registered pharmacist who has subscribed to the protocol by:*

1. Being readily accessible to the registered pharmacist or the recipient of the opioid antagonist when the registered pharmacist is authorized to furnish an opioid antagonist for consultation, assistance and direction; and

2. If required by the written protocol, reviewing a periodic status report from a registered pharmacist concerning any problems, complications or emergencies related to the furnishing of an opioid antagonist.

Sec. 6. ***Before furnishing an opioid antagonist pursuant to section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120), a registered pharmacist shall counsel the recipient of an opioid antagonist. The counseling must include, without limitation:***

1. Information relating to the recognition, prevention and responses to opioid-related drug overdoses;

2. Methods for the safe administration of opioid antagonists to a person experiencing an opioid-related drug overdose;

3. Potential side effects and adverse events related to the administration of opioid antagonists;

4. The importance of seeking emergency medical assistance for a person experiencing an opioid-related drug overdose, even after the administration of an opioid antagonist; and

5. Information concerning provisions of section 12 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 113 (NRS 453C.150).

Sec. 7. ***Pursuant to section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120), a registered pharmacist shall, before furnishing an opioid antagonist, complete at least one continuing education unit approved by the Accreditation Council for Pharmacy Education on the use of opioid antagonists and the counseling of a recipient of an opioid antagonist required prior to dispensing an opioid antagonist.***

Sec. 8. ***A registered pharmacist who furnishes an opioid antagonist pursuant to section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (NRS 453C.120), shall keep a record of the opioid antagonist furnished and shall report to the State Board of Pharmacy annually, on December 31 of each year, the:***

1. Date the opioid antagonist was furnished;

2. Name, strength and route of administration of the opioid antagonist furnished;

3. Quantity of the opioid antagonist furnished; and

4. Location from which the opioid antagonist was furnished.

Sec. 9. *1. Each record required to be made pursuant to this chapter must be kept for at least 2 years by the registered pharmacist and pharmacy which furnished the opioid antagonist.*

2. Records required to be made pursuant to this chapter may be maintained in an alternative data retention system, including, without limitation, a computer data processing system or direct imaging system, if:

(a) The records maintained in the alternative data retention system contain all the information required for a written record; and

(b) The alternative data retention system is capable of producing a printed copy of a record upon the request of the State Board of Pharmacy, its representative or any other authorized federal, state or local law enforcement or regulatory agency.

Sec. 10. *1. Except as otherwise provided in this section, all records made and maintained pursuant to sections 8 and 9 of this regulation are confidential and must not be disclosed to the public.*

2. A registered pharmacist shall provide adequate security to prevent unauthorized access to confidential records of furnished opioid antagonists. If confidential health information is not transmitted directly between a pharmacy and a physician, but is transmitted through a data communication device, the confidential health information must not be viewed or used by

the operator of the data communication device unless the operator is specifically authorized to obtain confidential information pursuant to this subsection.

3. Except as otherwise provided in NRS 49.245, the confidential records of furnished opioid antagonists are privileged and may be released only to:

(a) The recipient of an opioid antagonist or the authorized agent of the recipient of an opioid antagonist;

(b) Physicians and other registered pharmacists when, in the professional judgment of the registered pharmacist, such release is necessary to protect the health and well-being of the recipient of an opioid antagonist;

(c) The State Board of Pharmacy or other federal, state or local agencies authorized by law to receive such information;

(d) A law enforcement agency engaged in the investigation of a suspected violation involving a controlled substance or dangerous drug;

(e) A person employed by any state agency that licenses a physician if such a person is engaged in the performance of his or her official duties; or

(f) An insurance carrier or other third-party payor authorized by a recipient of an opioid antagonist to receive such information.

4. The provisions of this section must not be construed to affect or alter the provisions of NRS 49.215 to 49.245, inclusive, relating to the confidentiality of communications between a doctor and a patient.

LEGISLATIVE REVIEW OF ADOPTED REGULATIONS---NRS 233B.066
Informational Statement
LCB File No. R058-16

R058-16
NAC Chapter 639.New Language
Standardized Procedures or Protocols for the Furnishing of Opioid Antagonists
August 5, 2016

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 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.