

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB File No. R058-16

Workshop January 13, 2016

Explanation – Language in *blue italics* is new; language in *red text* ~~omitted material~~ is language to be omitted.

AUTHORITY: §1, NRS 639.070; Good Samaritan Drug Overdose Act (SB 459 (2015))

NEW LANGUAGE to be added to NAC Chapter 639, pursuant to the Good Samaritan Drug Overdose Act, SB 459 (2015), establishing standardized procedures or protocols and educational requirements for the furnishing of opioid antagonists by pharmacists 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.

NAC Chapter 639 shall be amended to include:

Section 1. NAC 639.010. Definitions

() “Opioid antagonist” means any drug that binds to opioid receptors and blocks or disinhibits the effects of opioids acting on those receptors. The term includes, without limitation, naloxone hydrochloride.

Section 2. NAC 639.____. A registered pharmacist may furnish an opioid antagonist to a person at risk of experiencing an opioid-related drug overdose, family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose pursuant to a standardized procedure or a written protocol;

1. A pharmacy in which a pharmacist is furnishing an opioid antagonist pursuant to a standardized procedure must have;

(a) Detailed policies and procedures that a pharmacist must follow when furnishing an opioid antagonist including, but not limited to:

(i) A restriction that a pharmacist may not delegate his or her authority to furnish an opioid antagonist;

(ii) Procedures for counseling, pursuant to NAC 639.____. [Section 4];

(iii) Record keeping procedures, pursuant to NAC 639.____. [Section 5]; and

(iv) Reporting requirements, pursuant to NAC 639.____. [Section 6].

2. A physician may establish a written protocol authorizing pharmacists to furnish an opioid antagonist to a person at risk of experiencing an opioid-related drug overdose, family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose. Such a protocol must include but is not limited to:

- (a) *The name of the physician who is authorizing the furnishing of an opioid antagonist by a pharmacist;*
- (b) *The opioid antagonist that may be furnished by a pharmacist;*
- (c) *Detailed policies and procedures that a pharmacist must follow when furnishing an opioid antagonist including but not limited to;*
 - (i) *A restriction that a pharmacist may not delegate his or her authority to furnish an opioid antagonist;*
 - (ii) *Procedures for counseling, pursuant to NAC 639.____. [Section 4];*
 - (iii) *Record keeping procedures, pursuant to NAC 639.____. [Section 5]; and*
 - (iv) *Reporting requirements, pursuant to NAC 639.____. [Section 6].*
- (d) *A procedure for the review of the protocol and its operation by the physician at least once annually, and the making and keeping of a record of the review;*
- (e) *When appropriate, specific instructions related to the age of the patient;*
- (f) *A requirement that an opioid antagonist be furnished according to all applicable federal, state and local laws;*
- (g) *The signature of the physician authorizing the furnishing of an opioid antagonist and the time period for which the written protocol is effective; and*
- (h) *or other limitations as the physician determines necessary.*

Section 3. NAC 639.____. Duties of authorizing physician. *A physician who has authorized a pharmacist to furnish an opioid antagonist by establishing a written protocol pursuant to NAC 639.____ shall supervise the implementation of the protocol by each pharmacist who has subscribed to the protocol by:*

1. *Being readily accessible to the pharmacist or the patient when the 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 pharmacist concerning any problems, complications or emergencies related to the furnishing of an opioid antagonist.*

Section 4. NAC 639.____. Counseling prior to receipt of an opioid antagonist.

Before a pharmacist may furnish an opioid antagonist as allowed in Section 2, the recipient of an opioid antagonist shall receive counseling on the use of opioid antagonists.

1. *The counseling shall include but is not limited to:*
 - (a) *Information concerning the prevention and recognition of and responses to opioid-related drug overdoses;*
 - (b) *Methods for the safe administration of opioid antagonists to a person experiencing an opioid-related drug overdose;*
 - (c) *Potential side effects and adverse events connected with the administration of opioid antagonists;*
 - (d) *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*
 - (e) *Information concerning the provisions of NRS 639.____. (Good Samaritan Drug Overdose Act, Section 12).*

2. Pursuant to NRS 639.____, a pharmacist shall, before furnishing an opioid antagonist pursuant to this section, complete a training program on the use of opioid antagonists. The program must include at least 1 hour of approved continuing education on the use of and counseling required before dispensing of opioid antagonists.

Section 5. NAC 639.____. Maintenance of records.

1. Each record required to be made pursuant to NAC 639.____ to 639.____, inclusive, must be kept for at least 2 years by the pharmacist and pharmacy who furnished the opioid antagonist.

2. Records required pursuant to this section 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 system contain all the information required for a written record; 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 authorized federal, state or local law enforcement or regulatory agency.

Section 6. NAC 639.____. Reporting of certain information concerning an opioid antagonist.

1. A pharmacist who furnishes an opioid antagonist to a person at risk of experiencing an opioid-related drug overdose or to a family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose, shall keep a record of the opioid antagonist furnished and shall report to the Board annually on December 31, of each year, the:

(a) Date an opioid antagonist was furnished;

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

(c) Quantity of opioid antagonist furnished; and

(d) The location from which an opioid antagonist was furnished.

Section 7. NAC 639.____. Confidentiality of records.

1. All records made and maintained pursuant to NAC 639.____ are confidential and shall not be disclosed to the public except as expressly provided in this section.

2. A 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) Physicians and other pharmacists, in the professional judgment of the pharmacist, such release is necessary to protect the health and well-being of the person;

(b) The Board or other federal, state or local agencies authorized by law to receive such information;

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

(d) 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

(e) An insurance carrier or other third party payor authorized by a patient 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.