PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R121-15

April 28, 2016

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

AUTHORITY: §§1 and 2, 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 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. (Section 9 of Senate Bill No. 459, chapter 26, Statutes of Nevada 2015, at page 112 (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).