

**PROPOSED REGULATION OF
THE STATE BOARD OF PHARMACY**

LCB File No. R035-16

April 7, 2016

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

AUTHORITY: §1, NRS 639.070 and 639.0745.

A REGULATION relating to pharmacy; authorizes the sharing of information concerning prescriptions between the computerized systems of licensed pharmacies that are not commonly owned under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing regulations authorize the sharing of information concerning prescriptions between the computerized systems of two or more licensed pharmacies that are commonly owned under certain circumstances. (NAC 639.921) This regulation authorizes the sharing of such information between the computerized systems of two or more licensed pharmacies that are not commonly owned if, in addition to satisfying other requirements, the pharmacies share the information pursuant to a written agreement which sets forth the services which each pharmacy is to provide.

Section 1. NAC 639.921 is hereby amended to read as follows:

639.921 1. Information concerning prescriptions may be shared between the computerized systems of two or more pharmacies licensed by the Board if:

(a) The pharmacies are commonly owned ~~and~~ *or, if not commonly owned, the pharmacies share such information pursuant to a written agreement which sets forth the services which each pharmacy is to provide;* and

(b) The computerized systems for recording information concerning prescriptions share a common database that:

(1) Except as otherwise provided in subsection 3, contains all the information concerning a patient that is contained in each computerized system that has access to the common database;

(2) Except as otherwise provided in subsection 3, contains all the information concerning a prescription that is contained in each computerized system that has access to the common database;

(3) After a prescription has been filled, automatically decreases the number of refills remaining for the prescription, if any, regardless of which pharmacy filled the prescription;

(4) Automatically stores any modification or manipulation of information concerning a prescription made by a pharmacy with access to the common database so that the modification or manipulation is available to each pharmacy with access to the common database;

(5) Allows access only by a person who is authorized to obtain information from the common database;

(6) Requires any person who is authorized to modify or manipulate information concerning a prescription, before modifying or manipulating the information concerning the prescription, to identify himself or herself in the computerized system by:

(I) Using a biometric identification technique; or

(II) Entering into the computerized system another unique identifier which is approved by the Board and which is known only to and used only by that person;

(7) Makes and maintains an unchangeable record of each person who modifies or manipulates information concerning the prescription, that includes, without limitation:

- (I) The name or initials of the person;
 - (II) An identifier that can be used to determine the pharmacy in which the person modified or manipulated the information concerning the prescription; and
 - (III) The type of activity concerning the prescription that the person performed, including, without limitation, modifying or manipulating the information concerning the prescription;
- (8) Contains a scanned image of the original prescription if the original prescription is a written prescription; and
- (9) Provides contact information for the first pharmacist who verifies the correctness of the information contained in the common database concerning the prescription.
2. If a pharmacy is the initial pharmacy to receive a written prescription, a pharmacist shall ensure that:
- (a) The written prescription is numbered consecutively in accordance with NAC 639.914; and
 - (b) The image of the prescription is scanned into the computerized system of the pharmacy.
3. If a pharmacy other than the pharmacy that initially received a prescription enters information concerning a prescription into a computerized system for recording information concerning prescriptions, the information must not be accessible from the common database for the purpose of filling or dispensing a prescription until a pharmacist verifies the correctness of the information entered into the computerized system. After verifying that information, the pharmacist shall enter a notation in the computerized system that includes the pharmacist's name, contact information and the date on which he or she verified the information.

4. A pharmacy that fills a prescription using the information from the common database, other than the pharmacy that initially received the prescription, shall:

(a) Process the prescription in the same manner as a prescription that is initially received by the pharmacy;

(b) Except as otherwise provided in paragraph (c), dispense the prescription in the same manner as a prescription that is initially received by the pharmacy; and

(c) Place on the label of the container in which the prescription will be dispensed:

(1) The number assigned to the prescription by the pharmacy that initially received the prescription; and

(2) An additional number or other identifier that ensures that the number placed on the label pursuant to subparagraph (1) is not confused with a prescription number of the pharmacy that is filling the prescription.

5. The filling of a prescription pursuant to the provisions of subsection 4 shall not be considered a transfer of the prescription.

**PROPOSED REGULATION OF
THE STATE BOARD OF PHARMACY**

LCB File No. R058-16

May 4, 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 2 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 3** 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 3** also requires certain information to be included in the protocol. **Section 4** 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 5** 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 6** 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 7-9** of this regulation establish the reporting and recordkeeping procedures required of registered pharmacists who furnish opioid antagonists.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 9, inclusive, of this regulation.

Sec. 2. *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 5 of this regulation;*
- 3. Procedures for recordkeeping pursuant to section 8 of this regulation; and*
- 4. Reporting requirements pursuant to section 7 of this regulation.*

Sec. 3. *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. 4. *A physician who has authorized a registered pharmacist to furnish an opioid antagonist by establishing a written protocol pursuant to section 3 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. 5. *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. 6. *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. 7. 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 Board 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. 8. 1. Each record required to be made pursuant to sections 2 to 9, inclusive, of this regulation must be kept for at least 2 years by the registered pharmacist and pharmacy which furnished the opioid antagonist.

2. Records required pursuant to sections 2 to 9, inclusive, of this regulation 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 Board, its representative or any other authorized federal, state or local law enforcement or regulatory agency.

Sec. 9. 1. Except as otherwise provided in this section, all records made and maintained pursuant to sections 7 and 8 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 Board 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.

Sec. 10. NAC 639.010 is hereby amended to read as follows:

639.010 As used in this chapter, unless the context otherwise requires:

1. "Board" means the State Board of Pharmacy.
2. "Controlled substances" has the meaning ascribed to it in NRS 0.031.
3. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.
4. "Direct supervision" means the direction given by a supervising pharmacist who is:
 - (a) On the premises of the pharmacy at all times when the persons he or she is supervising are working at the pharmacy; and
 - (b) Aware of the activities of those persons related to the preparation of medications, including the maintenance of appropriate records.
5. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.
6. "*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).
7. "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.
- ~~7.]~~ 8. "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a

pharmaceutical technician pursuant to subparagraph (3) of paragraph (e) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.

~~{8.}~~ **9.** “Practitioner” has the meaning ascribed to it in NRS 639.0125.

~~{9.}~~ **10.** “Prescription drug” means a drug or medicine as defined in NRS 639.007 which:

(a) May be dispensed only upon a prescription order that is issued by a practitioner; and

(b) Is labeled with the symbol “Rx only” pursuant to federal law or regulation.

~~{10.}~~ **11.** “Public or nonprofit agency” means a health center as defined in 42 U.S.C. § 254b(a) which:

(a) Provides health care primarily to medically underserved persons in a community;

(b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and

(c) Is not a medical facility as defined in NRS 449.0151.

~~{11.}~~ **12.** “Surgical center for ambulatory patients” has the meaning ascribed to it in NRS 449.019.

**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).