Proposed Regulation of the Nevada State Board of Pharmacy

Workshop October 13th, 2016

Explanation – Language in *blue italics* is new; language in *red text* [*omitted material*] is language to be omitted, and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: §1, NRS 639.070

A REGULATION relating to electronic transmission of a prescription; and providing other matters properly relating thereto.

NAC 639.7102 Use of computer system for issuance and transmission of prescription. (NRS 639.070, 639.0745)

- 1. A practitioner may:
- (a) Issue a prescription using a computer system approved by the Board; and
- (b) Transmit the prescription using that computer system to a pharmacy specified by the patient for whom the practitioner issues the prescription.
 - 2. The Board will approve the computer system of a practitioner if the computer system:
- (a) Requires a fingerprint scan, retinal scan, personal identification number or other unique identification of the practitioner or his or her agent to activate the computer system by which a prescription will be entered and to reactivate the computer system if the computer system has not been in use for 15 minutes or longer;
 - (b) Maintains a record of:
 - (1) Each prescription that the practitioner issues using the computer system; and
 - (2) Each pharmacy to which the practitioner submits the prescription;
 - (c) Is able to print a written prescription that complies with NRS 639.2353 and NAC 453.440; and
 - (d) If it is printed from the computer system, the practitioner must sign the prescription; and
- (e) Places on the face of the prescription, if it is printed from the computer system of the practitioner If the prescription is transmitted to the pharmacy the electronic prescription must contain a field or the pharmacy to which the practitioner transmits the prescription, or if it is displayed on the monitor of the computer of the pharmacy, a mark that uniquely identifies the practitioner, including, without limitation, the practitioner's signature or a security code which is known to or verifiable by the pharmacy; and
- (e f) Requires the practitioner, before the computer system places the words "Dispense As Written" on the face of the prescription, to make a specific entry into the computer system for the prescription; and
- (fg) Except as otherwise provided in subsection 3, transmits to the pharmacy specified by the patient the prescription and any other confidential information relating to the patient in a manner that ensures that the prescription or other confidential information may not be altered by a person other than the pharmacist.
- 3. The provisions of paragraph (f) of subsection 2 do not prohibit a practitioner from using a routing company to transmit a prescription pursuant to this section. A routing company:

- (a) May, for the purpose of verifying an audit conducted of the routing company, store any prescription or other confidential information it receives or transmits pursuant to this subsection in a form that is secure and ensures the confidentiality of the information.
- (b) May not add a provision to, delete a provision from or otherwise modify a prescription or any other confidential information that it receives or transmits pursuant to this subsection.
- 4. A pharmacy that receives a prescription from a practitioner using a computer system which is approved by the Board may fill that prescription if:
- (a) The pharmacy prints a copy of the prescription and files the copy in the same manner in which the pharmacy files any other prescription maintained by it; or
 - (b) The computer system of the pharmacy:
- (1) Maintains the prescription in a manner that ensures that the prescription is numbered consecutively in accordance with NAC 639.914;
 - (2) Is able to print a copy of the prescription; and
 - (3) Prohibits the modification of the prescription unless the computer system:
- (I) Automatically prepares a notation within the records of the computer system indicating that the pharmacy has modified the prescription and automatically records the modification; and
- (II) Requires the pharmacy to prepare a record indicating the identity of the person who modified the prescription.
- 5. If a pharmacy fills a prescription pursuant to paragraph (b) of subsection 4, a pharmacist employed by the pharmacy shall, each day:
- (a) Store the prescription or cause the prescription to be stored on a tape, disc or other device that is used for the storage of information by a computer; and
 - (b) Store the tape, disc or device:
 - (1) At a location other than the pharmacy; or
 - (2) In any other manner that:
 - (I) Protects the tape, disc or device from loss or damage; and
- (II) Ensures that any confidential information included in the tape, disc or device remains confidential.
- 6. If a practitioner prints a prescription using a computer system that is approved pursuant to this section, the practitioner shall:
 - (a) Except as otherwise provided in paragraph (b), manually sign the printed prescription; or
- (b) If the prescription includes a mark that uniquely identifies the practitioner in accordance with paragraph (d) of subsection 2, print the prescription on security paper.
- 7. A practitioner may transmit a prescription or any other confidential information relating to a patient to an insurer or any entity other than a pharmacy pursuant to this section if, before transmitting the prescription or confidential information:
 - (a) The practitioner submits a written notice to the patient:
 - (1) Identifying the insurer or entity; and
- (2) Indicating that the practitioner intends to transmit the prescription or confidential information to the insurer or entity; and
- (b) The patient consents in writing to the transmission of the prescription or confidential information to:
 - (1) The insurer or entity; and
 - (2) The pharmacy specified by the patient pursuant to this section.
- 8. The provisions of this section do not prohibit a computer system that is approved pursuant to this section from being used to transmit:
- (a) The ICD code set forth in the most recent revision of the *International Classification of Diseases*; or

- (b) Any other information that is not related to the issuance, filling or transmission of a prescription for a patient or the transmission of any confidential information relating to the patient pursuant to this section.
 - 9. As used in this section:
 - (a) "Routing company" means any business that:
- (1) Receives a prescription or any other confidential information from a practitioner in accordance with a contract between:
- (I) The routing company and the practitioner or a company that provides computer software for the management of the practitioner's practice; or
 - (II) A patient of the practitioner and a third-party payor; and
 - (2) Transmits the prescription or confidential information:
 - (I) Directly to the pharmacy specified by the patient; or
- (II) Through the company that provides computer software for the management of the business operations of the pharmacy.
- (b) "Security paper" means any paper that is approved by the staff of the Board and that includes features which ensure that the paper:
- (1) May not be duplicated without creating an indication on the paper that the paper has been duplicated; and
 - (2) May be authenticated as having been issued by a practitioner or the office of the practitioner.



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AUTHORITY: §1, NRS 639.070

A REGULATION relating to electronic transmission of a prescription; and providing other matters properly relating thereto.

NAC 639.7105 Electronic transmission of prescription. (NRS 639.070, 639.0745) Except as otherwise provided in NAC 639.711:

- 1. A prescription for a dangerous drug or a controlled substance listed in schedule II, III, IV or V may be transmitted electronically by a practitioner to a pharmacy.
 - 2. A practitioner shall not transmit a prescription electronically to a pharmacy unless:
- (a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy;
 - (a) The practitioner:
 - (1) prescribes the medication; and
 - (2) If the practitioner prescribes the medication and delegates the transmission of the electronic prescription by his or her agent then;
 - a. The agent must receive training from the practitioner regarding the transmission of the electronic prescription; and
 - b. Written documentation of the training must be kept at the physician's office; and
 - c. The practitioner must document in the patient's medical record his or her intention to prescribe the medication along with his or her intention to have the agent transmit the electronic prescription; and
 - d. The practitioner must review the electronic prescription file within 24 hours of the transmission of the prescription to the pharmacy;
 - (3) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy, if the prescription is for a controlled substance;
 - (b) The patient:
 - (1) Consents to the transmission of the prescription electronically; and
 - (2) Approves the pharmacy where the prescription will be transmitted; and
 - (c) All requirements of 21 C.F.R. Part 1311 are satisfied.
- 3. In addition to the requirements set forth in <u>NRS 639.2353</u> and <u>639.2589</u>, a prescription that is transmitted electronically to a pharmacy must include:
 - (a) The telephone number of the prescribing practitioner;
 - (b) The time and date of the transmission; and
 - (c) The name of the pharmacy to which the prescription is sent.
- 4. In addition to the requirements set forth in subsection 3 and <u>NRS 639.2353</u> and <u>639.2589</u>, a prescription for a controlled substance that is transmitted electronically to a pharmacy must include:
- (a) The registration number from the Drug Enforcement Administration of the prescribing practitioner; and

- (b) If the technological capability exists to require such information to be transmitted electronically:
 - (1) The Nevada controlled substance registration number of the prescribing practitioner;
 - (2) The indication for use or the diagnosis code; and
 - (3) The date of the last physical examination of the patient.
- 5. A pharmacist who receives a prescription that is transmitted electronically shall keep a paper or electronic copy of the prescription for at least 2 years after the pharmacist receives the prescription. The copy of the prescription that is kept must be readily accessible to:
- (a) Personnel of the pharmacy who are authorized to access records of prescriptions kept by the pharmacy; and
 - (b) Members, employees, agents and designees of the Board.
- 6. A pharmacist shall not dispense a prescription that is transmitted electronically until the pharmacist determines that the prescription complies with the requirements of state and federal law.
- 7. A prescription that is transmitted and complies with the provisions of this section shall be deemed an original prescription.
- 8. The Board may take any appropriate action or suspend the privilege of a practitioner to transmit prescriptions electronically if the Board reasonably suspects that the practitioner has transmitted a prescription electronically that is:
 - (a) Unlawful;
 - (b) Fraudulent; or
 - (c) Not for a legitimate medical purpose.



PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop October 13, 2016

- **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.
- See. 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.