

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB File No. R098-13

Workshop September 5, 2013

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

AUTHORITY: §1, NRS 639.070

Amendment of Nevada Administrative Code Chapter 639 NEW LANGUAGE To realize purpose and intent of 2013 Legislative Amendments to NRS Chapter 639 (per SB 327) regarding telemedicine, electronic refill log and 90-day refills of dangerous drugs.

Section 1. Propose to amend NAC 639.010 as follows:

NAC 639.010 Definitions. (NRS 639.070) 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 *or telepharmacy* at all times when ~~the~~ a person~~s~~ he or she is supervising ~~are~~ *is* working at the pharmacy, *or a remote site or satellite consultation site*; and
 - (b) Aware of the activities of ~~those~~ *that* person~~s~~ related to the preparation *and dispensing* 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. “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. “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. “Practitioner” has the meaning ascribed to it in NRS 639.0125.
9. “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. “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. “Surgical center for ambulatory patients” has the meaning ascribed to it in NRS 449.019.

Section 2. Propose to amend NAC 639.391 as follows:

NAC 639.391 Pharmacist or dispensing practitioner required to obtain certificate of registration to dispense controlled substances or dangerous drugs at remote site *and satellite consultation site*. (NRS 639.070, 639.0727)

1. A pharmacist or dispensing practitioner who wishes to establish a remote site *or satellite consultation site* must obtain a certificate of registration from the Board pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs at the remote site *or satellite consultation site*.

2. Notwithstanding the issuance of a certificate pursuant to subsection 1, if the Board grants a license to operate a pharmacy at a location that is within the service area of a remote site *or satellite consultation site*, the pharmacist or dispensing practitioner that established the remote site must close the remote site.

Section 3. Propose to amend NAC 639.392 as follows:

NAC 639.392 Telepharmacies ~~{and associated remote sites}~~ required to be located within State; requirements concerning accessibility of pharmacist or dispensing practitioner; procedure during interruption of communicative access between telepharmacy and remote site. (NRS 639.070, 639.0727)

1. A telepharmacy ~~{and each associated remote site}~~ must be physically located within this State.

2. A pharmacist or dispensing practitioner must be physically present in the telepharmacy and accessible for *electronic, telephonic or fiber optic* communication with an associated remote site *or satellite consultation site* at all times that the remote site *or satellite consultation site* is in operation.

3. If the communicative access ~~{via computer link, video link and audio link}~~ between a remote site *or satellite consultation site* and its telepharmacy is interrupted or otherwise unavailable, the pharmaceutical technician or dispensing technician operating the remote site *or satellite consultation site* shall not perform any act authorized pursuant to NAC 639.391 to 639.399, inclusive, until the communicative access is restored.

Section 4. Propose to amend NAC 639.393 as follows:

NAC 639.393 Requirements for pharmaceutical technicians and dispensing technicians. (NRS 639.070, 639.0727)

1. A pharmacist who is responsible for the operation of a remote site *or satellite consultation site* shall ensure that a pharmaceutical technician who is employed to dispense

controlled substances or dangerous drugs at the remote site *or satellite consultation site* has at least 1 year of experience as a pharmaceutical technician.

2. A dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* shall verify that a dispensing technician employed at the remote site *or satellite consultation site* is competent by ensuring that the dispensing technician has met the requirements of NAC 639.7425 and has received a certificate of registration pursuant to that section.

Section 5. Propose to amend NAC 639.394 as follows:

NAC 639.394 Supervision of pharmaceutical technicians ~~and dispensing technicians~~. (NRS 639.070, 639.0727) In any *pharmacy, telepharmacy*, remote site *or satellite consultation site*, a pharmacist ~~or dispensing practitioner~~ may not supervise more than three pharmaceutical technicians ~~or dispensing technicians~~, as applicable, at one time.

Section 6. Propose to amend NAC 639.395 as follows:

NAC 639.395 Transmission of new prescription to telepharmacy; consultation with pharmacist or dispensing practitioner required before accessing controlled substances or dangerous drugs at remote site *or satellite consultation site*; prerequisites for dispensing at remote site *or satellite consultation site*. (NRS 639.070, 639.0727)

1. A pharmaceutical technician or dispensing technician who operates a remote site shall transmit a copy of any new prescription which the technician receives to the telepharmacy ~~via computer link or other secured electronic means~~ *electronically, telephonically or by fiber optics* and retain the original prescription in the records maintained at the remote site.

2. A pharmaceutical technician or dispensing technician *who operates a remote site or satellite consultation site* must consult with a pharmacist or dispensing practitioner *electronically, telephonically or by fiber optics*, as appropriate, at the telepharmacy ~~via computer link, video link or audio link~~ to obtain approval before accessing ~~the stock of~~ *any* controlled substance~~s~~ *or* dangerous drug~~s~~ maintained at the remote site *or satellite consultation site*.

3. A pharmacist or dispensing practitioner shall not authorize a pharmaceutical technician or dispensing technician at a remote site *or satellite consultation site* to dispense a controlled substance or dangerous drug unless the pharmacist or dispensing practitioner has:

(a) Consulted with the technician;

(b) Visually verified ~~via computer link, video link or audio link~~ *electronically, telephonically or by fiber optics* that:

- (1) The controlled substance or dangerous drug selected by the technician is correct; and
- (2) The label prepared by the technician is correct; and

(c) Verified that the information entered by the technician into the computerized system for recording information concerning prescriptions is correct.

4. A pharmacist or dispensing practitioner shall only authorize a pharmaceutical technician or dispensing technician at a remote site *or satellite consultation site* to dispense a controlled substance or dangerous drug to a patient who resides in the service area of the remote site or whose residence is closer to the remote site than to a telepharmacy.

Section 7. Propose to amend NAC 639.396 as follows:

NAC 639.396 Requirements for maintenance of records. (NRS 639.070, 639.0727)

1. Except as otherwise provided in this section, a pharmacist or dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* shall maintain at the remote site *or satellite consultation site* and at the associated telepharmacy a record of each drug that is received, stored, dispensed, returned or otherwise dealt with at the remote site *or satellite consultation site*, including, without limitation, any record that is required to be maintained by state or federal law. The records so maintained must include, without limitation:

- (a) Each prescription dispensed at the remote site *or satellite consultation site*;
- (b) At the remote site *or satellite consultation site*, the initials of the technician who dispensed the controlled substance or dangerous drug;
- (c) At the telepharmacy, the initials *or other unique identifier* of the pharmacist or dispensing practitioner who authorized the controlled substance or dangerous drug to be dispensed at the remote site *or satellite consultation site*;
- (d) Each controlled substance or dangerous drug that is transferred between the stock of drugs maintained at the remote site *or satellite consultation site* and the stock of drugs maintained at the telepharmacy; and
- (e) At the telepharmacy, documentation of any counseling provided by a pharmacist or dispensing practitioner at the telepharmacy that was provided ~~electronically, telephonically or by fiber optics via computer link, video link or audio link~~ *electronically, telephonically or by fiber optics* to a patient or person caring for a patient at the remote site *or satellite consultation site*.

2. The pharmacist or dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* shall ensure that each record which is maintained at the remote site *or satellite consultation site*, including, without limitation, each record of a prescription, is maintained in a manner that makes it readily apparent whether the prescription was dispensed at the remote site *or satellite consultation site* or at the telepharmacy.

Section 8. Propose to amend NAC 639.397 as follows:

NAC 639.397 Requirements for labeling. (NRS 639.070, 639.0727)

1. A pharmacist or dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* shall ensure that the computer system used at the telepharmacy and the remote site *or satellite consultation site* is able to generate a label for a prescription at either location in the manner prescribed pursuant to NRS 639.2801.

2. The label generated pursuant to subsection 1 must include on the label of each prescription the initials of:

- (a) The pharmacist or dispensing practitioner who authorized the controlled substance or dangerous drug to be dispensed at the remote site *or satellite consultation site*; and
- (b) The pharmaceutical technician or dispensing technician who dispensed the controlled substance or dangerous drug at the remote site *or satellite consultation site*.

Section 9. Propose to amend NAC 639.398 as follows:

NAC 639.398 Establishment of policies and procedures for operation of remote site *or satellite consultation site*; monthly inspections. (NRS 639.070, 639.0727) The pharmacist or

dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* shall:

1. Establish written policies and procedures for the operation of the remote site *or satellite consultation site* to ensure:
 - (a) Compliance with all applicable statutes and regulations;
 - (b) The safe and effective dispensing of controlled substances and dangerous drugs at the remote site *or satellite consultation site*; and
 - (c) The proper accounting of controlled substances and dangerous drugs at the remote site *or satellite consultation site*.
2. Personally inspect the remote site *or satellite consultation site* at least monthly to ensure that the remote site *or satellite consultation site* and each pharmaceutical technician or dispensing technician, as applicable, who operates the remote site *or satellite consultation site* is in compliance with:
 - (a) All applicable statutes and regulations; and
 - (b) The policies and procedures established pursuant to subsection 1.
3. Make a record of each inspection conducted pursuant to subsection 2.

Section 10. Propose to amend NAC 639.399 as follows:

NAC 639.399 Responsibility of pharmacist or dispensing practitioner concerning dispensing of controlled substances or dangerous drugs at remote site *or satellite consultation site*. (NRS 639.070, 639.0727) A pharmacist or dispensing practitioner who is responsible for the operation of a remote site *or satellite consultation site* and who authorizes a pharmaceutical technician or dispensing technician at the remote site *or satellite consultation site* to dispense a controlled substance or dangerous drug is responsible for and must be held accountable for the dispensing of the controlled substance or dangerous drug at the remote site *or satellite consultation site*.

Section 11. Propose to amend NAC 639.742 as follows:

NAC 639.742 Dispensing of controlled substances or dangerous drugs: Application by practitioner for certificate of registration; application by facility required under certain circumstances; duties of dispensing practitioner and facility relating to drugs; authority of dispensing practitioner and technician. (NRS 639.070, 639.0727)

1. A practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice, including, without limitation, a *telepharmacy*, remote site *or satellite consultation site*, from which the practitioner wishes to dispense controlled substances or dangerous drugs. A certificate of registration to dispense controlled substances or dangerous drugs is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.
2. If a facility from which the practitioner intends to dispense dangerous drugs or controlled substances is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.
3. Except as otherwise provided in NRS 639.23277 and NAC 639.395, the dispensing practitioner and, if applicable, the owner or owners of the facility, shall ensure that:

- (a) All drugs are ordered by the dispensing practitioner;
 - (b) All drugs are received and accounted for by the dispensing practitioner;
 - (c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;
 - (d) All drugs are dispensed in accordance with NAC 639.745;
 - (e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility;
 - (f) All drugs are dispensed only to the patient personally at the facility;
 - (g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;
 - (h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and
 - (i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.
4. With regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:
- (a) Enter the room or cabinet in which drugs are stored;
 - (b) Remove drugs from stock;
 - (c) Count, pour or reconstitute drugs;
 - (d) Place drugs into containers;
 - (e) Produce and affix appropriate labels to containers that contain or will contain drugs;
 - (f) Fill containers for later use in dispensing drugs; or
 - (g) Package or repackage drugs.
5. A dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:
- (a) He or she were a pharmacist;
 - (b) His or her practice site was a pharmacy; and
 - (c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

Section 12. Propose to amend NAC 639.752 as follows:

NAC 639.752 Restrictions on filling or dispensing certain prescriptions. (NRS 639.070)

1. Except as otherwise provided in this section and NRS 639.235, a pharmacist shall not fill a prescription for, or dispense, a dangerous drug or a controlled substance if the prescription is:

- (a) Written by a practitioner who is not licensed to practice in this State, but is authorized by the laws of another state to prescribe;
 - (b) For a patient who resides in a state other than the state in which the prescribing practitioner's practice is located;
 - (c) Requested to be furnished in a manner other than by dispensing directly to the patient, or an agent of the patient, in person; and
 - (d) To be paid for in full, in cash or cash equivalent, at the time the prescription is dispensed,
- unless the pharmacist first verifies the prescription as set forth in subsection 2.

2. A pharmacist who verifies a prescription pursuant to this section must:

- (a) Speak with the patient or the prescribing practitioner;
- (b) Establish that:
 - (1) The prescription is authentic; and

(2) A bona fide relationship between the patient and the prescribing practitioner did exist when the prescription was written; and

(c) Record on the prescription or in the prescription record in the pharmacy's computer:

- (1) The name of the person with whom the pharmacist spoke concerning the prescription;
- (2) The date and time of the conversation; and
- (3) The date and time the patient was examined by the prescribing practitioner.

3. Subsection 1 does not apply to a pharmacist who refills a prescription he or she has previously filled if the pharmacist verified the prescription before filling it the first time.

4. For the purposes of this section, a bona fide relationship between the patient and the prescribing practitioner shall be deemed to exist:

(a) If the patient was ~~physically~~ examined by the practitioner within the 6 months immediately preceding the date the prescription was issued; or

(b) If the patient is incarcerated in a local correctional institution or a facility or institution operated by the Department of Corrections and was examined through the use of ~~a telephone or a videoconferencing system~~ *electronic, telephonic or by fiber optic means* by a practitioner who is a physician licensed pursuant to chapter 630 or 633 of NRS and:

(1) The medical history of the patient is available to the physician;

(2) A nurse or an advanced ~~practitioner of nursing~~ *practice registered nurse* licensed pursuant to chapter 632 of NRS or a physician assistant licensed pursuant to chapter 630 or 633 of NRS is physically present with the patient when the physician examines the patient and that nurse ~~, advanced practitioner of nursing~~ or physician assistant is trained in the use of the ~~telephone or videoconferencing~~ *electronic, telephonic or fiber optic* system *used*; and

(3) The physician enters the results of the examination into the medical chart of the patient that is maintained by the local correctional institution or the facility or institution operated by the Department of Corrections.

5. As used in this section:

(a) "Cash equivalent" includes, without limitation:

- (1) A check;
- (2) A credit card;
- (3) A draft;
- (4) An electronic funds transfer; and

(5) A prescription drug discount card or other device obtained pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, or any regulations adopted pursuant thereto.

(b) "Local correctional institution" has the meaning ascribed to it in NAC 211.070.

Section 13. Propose to amend NAC 639.918 as follows:

NAC 639.918 Written record of refills; exception. (NRS 639.070, 639.236) Except as otherwise provided in subsection 3 of NAC 639.751, the pharmacist must maintain in chronological order a separate written *or electronic* record of each refill that includes:

1. The prescription number;
2. The date of each refill or authorization;
3. The number of dosage units; and
4. The ~~handwritten~~ initials *or a unique identifier* of the pharmacist who fills the refill.

The written record must be maintained for a period of 2 years after the date of the last refill entered therein for a prescription.

Section 14. Propose to amend NAC 639.924 as follows:

NAC 639.924 Computerized system to record prescriptions required for pharmacies licensed on or after August 27, 1996. (NRS 639.070, 639.0727, 639.236) A person who is issued a license to conduct a pharmacy, including, without limitation, a remote site *or satellite consultation site*, pursuant to the provisions of NRS 639.230 and 639.231 on or after August 27, 1996, shall ensure that the pharmacy uses a computerized system for recording information concerning prescriptions.

Section 15. Propose to amend NAC 639.945 as follows:

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees. (NRS 639.070, 639.210)

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

(a) Manufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations.

(b) Except as otherwise provided in NRS 639.2583 to 639.2808, inclusive, for substitutions of generic drugs, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed, unless the express permission of the orderer or prescriber is obtained and, in the case of a written prescription, unless the following information is recorded on the prescription by the person obtaining permission:

- (1) The date on which the permission was granted;
- (2) The name of the practitioner granting the permission;
- (3) The name of the person obtaining the permission;
- (4) The name of the drug dispensed; and
- (5) The name of the manufacturer or distributor of the drug.

(c) Using secret formulas.

(d) *Except as otherwise allowed by subsection 2 of NRS 639.2396(2),* ~~fail~~ failing to strictly ~~to~~ follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling, the content of the label of the prescription or giving a copy of the prescription or chart order to any person except as permitted by law.

(e) Failing to confer with the person writing, making or ordering a prescription or chart order if there is an error or omission in it which should be questioned.

(f) Operating a pharmacy at a location other than the location at which the pharmacy is licensed to operate.

(g) Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

- (j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.
 - (k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.
 - (l) Violating any term or condition of a subpoena or order issued by the Board or the staff of the Board.
 - (m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 585 and 639 of NRS and chapters 453, 454, 585 and 639 of NAC to a member of the Board or a member of the staff of the Board upon his or her request.
 - (n) Dispensing a drug as a dispensing practitioner to a patient with whom the dispensing practitioner does not have a bona fide therapeutic relationship.
 - (o) Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship.
2. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.
 3. For the purposes of this section, a bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist:
 - (a) If the patient was ~~physically~~ examined by the practitioner *in person, electronically, telephonically or by fiber optics within or outside this State or the United States* within the 6 months immediately preceding the date the practitioner dispenses or prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed; or
 - (b) If the patient is incarcerated in a local correctional institution or a facility or institution operated by the Department of Corrections and was examined through the use of a telephone or videoconferencing system by a practitioner who is a physician licensed pursuant to chapter 630 or 633 of NRS and:
 - (1) The medical history of the patient is available to the physician;
 - (2) A nurse or an advanced ~~practitioner of nursing~~ *practice registered nurse* licensed pursuant to chapter 632 of NRS or a physician assistant licensed pursuant to chapter 630 or 633 of NRS is physically present with the patient when the physician examines the patient and that nurse, advanced ~~practitioner of nursing~~ *practice registered nurse* or physician assistant is trained in the use of the ~~telephone or videoconferencing~~ *electronic, telephonic or fiber optic* system *used*; and
 - (3) The physician enters the results of the examination into the medical chart of the patient that is maintained by the local correctional institution or the facility or institution operated by the Department of Corrections.
 4. As used in this section, “local correctional institution” has the meaning ascribed to it in NAC 211.070.