ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R037-10

Effective October 15, 2010

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

AUTHORITY: §§1-17, NRS 639.070 and 639.0727.

A REGULATION relating to pharmacy; requiring a certificate of registration from the State Board of Pharmacy to establish a remote site; establishing the qualifications for persons who operate a remote site; establishing various requirements concerning the operation of a remote site; and providing other matters properly relating thereto.

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. ***1. A pharmacist or dispensing practitioner who wishes to establish a remote 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.***

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, the pharmacist or dispensing practitioner that established the remote site must close the remote site.

Sec. 3. ***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 communication with an associated remote site via computer link, video link and audio link at all times that the remote site is in operation.

3. If the communicative access via computer link, video link and audio link between a remote site and its telepharmacy is interrupted or otherwise unavailable, the pharmaceutical technician or dispensing technician operating the remote site shall not perform any act authorized pursuant to sections 2 to 9, inclusive, of this regulation until the communicative access is restored.

Sec. 4. *1. A pharmacist who is responsible for the operation of a remote site shall ensure that a pharmaceutical technician who is employed to dispense controlled substances or dangerous drugs at the remote 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 shall verify that a dispensing technician employed at the remote 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.

Sec. 5. *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 and retain the original prescription in the records maintained at the remote site.*

2. A pharmaceutical technician or dispensing technician must consult with a pharmacist or dispensing practitioner, as appropriate, at the telepharmacy via computer link, video link or

audio link to obtain approval before accessing the stock of controlled substances and dangerous drugs maintained at the remote site.

3. A pharmacist or dispensing practitioner shall not authorize a pharmaceutical technician or dispensing technician at a remote 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 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 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.

Sec. 6. *1. Except as otherwise provided in this section, a pharmacist or dispensing practitioner who is responsible for the operation of a remote site shall maintain at the remote 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, 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;

(b) At the remote site, the initials of the technician who dispensed the controlled substance or dangerous drug;

(c) At the telepharmacy, the initials of the pharmacist or dispensing practitioner who authorized the controlled substance or dangerous drug to be dispensed at the remote site;

(d) Each controlled substance or dangerous drug that is transferred between the stock of drugs maintained at the remote 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 via computer link, video link or audio link to a patient or person caring for a patient at the remote site.

2. The pharmacist or dispensing practitioner who is responsible for the operation of a remote site shall ensure that each record which is maintained at the remote 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 at the telepharmacy.

Sec. 7. *1. A pharmacist or dispensing practitioner who is responsible for the operation of a remote site shall ensure that the computer system used at the telepharmacy and the remote 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; and

(b) The pharmaceutical technician or dispensing technician who dispensed the controlled substance or dangerous drug at the remote site.

Sec. 8. *The pharmacist or dispensing practitioner who is responsible for the operation of a remote site shall:*

1. Establish written policies and procedures for the operation of the remote 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; and

(c) The proper accounting of controlled substances and dangerous drugs at the remote site.

2. Personally inspect the remote site at least monthly to ensure that the remote site and each pharmaceutical technician or dispensing technician, as applicable, who operates the remote 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.

Sec. 9. *A pharmacist or dispensing practitioner who is responsible for the operation of a remote site and who authorizes a pharmaceutical technician or dispensing technician at the remote 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.*

Sec. 10. NAC 639.250 is hereby amended to read as follows:

639.250 Except as otherwise provided in NAC 639.258:

1. Except as otherwise provided in this section, in a hospital, a pharmacist who is dispensing prescriptions may not supervise more than three pharmaceutical technicians at one time. A pharmacist who is supervising distributive functions may not supervise more than two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.

2. Except as otherwise provided in this section, in any pharmacy, other than a hospital pharmacy, a pharmacist may not supervise more than three pharmaceutical technicians or one pharmaceutical technician and two pharmaceutical technicians in training at one time.

3. ***In any remote site, a pharmacist or dispensing practitioner may not supervise more than three pharmaceutical technicians or dispensing technicians, as applicable, at one time.***

4. A pharmacist may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to subsections 1 and 2 if:

(a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

(b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.

Sec. 11. NAC 639.742 is hereby amended to read as follows:

639.742 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 remote site,*** from

which he 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. ~~[The]~~ ***Except as otherwise provided in NRS 639.23277 and section 5 of this regulation, 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.

Sec. 12. NAC 639.743 is hereby amended to read as follows:

639.743 1. ~~[A]~~ ***Except as otherwise provided in NRS 639.23277 and section 5 of this regulation, a*** person to whom a dispensing practitioner is providing training and experience pursuant to subsection 4 of NAC 639.7425 must not be allowed access to the room or cabinet in which drugs are stored unless accompanied by the dispensing practitioner. After the person has completed his training and experience and the Board has received an affidavit from the ***dispensing*** practitioner pursuant to subsection 5 of NAC 639.7425:

(a) The person may access the room or cabinet in which drugs are stored without being accompanied by the dispensing practitioner, so long as the ***dispensing*** practitioner is on-site at the facility; and

(b) The dispensing practitioner is not required to observe the work of the person.

2. A ***dispensing*** practitioner who allows a dispensing technician to perform any function described in subsection 4 of NAC 639.742 is responsible for the performance of that function by the dispensing technician. All such functions performed by a dispensing technician must be performed at the express direction and delegation of the dispensing practitioner. Each prescription with respect to which a dispensing technician performed such a function:

(a) Must be checked by the dispensing practitioner, and the dispensing practitioner shall indicate on the label of the prescription and in his record regarding the prescription that the dispensing practitioner has checked the work performed by the dispensing technician; and

(b) Must not be dispensed to the patient without the initials of the dispensing practitioner thereon. A prescription which has been so initialed must be handed to the patient only by the dispensing practitioner or an employee authorized by the dispensing practitioner.

Sec. 13. NAC 639.7435 is hereby amended to read as follows:

639.7435 1. The registration of a dispensing technician is nontransferable and limited to the dispensing practitioner to whom the dispensing technician is registered. The registration of a dispensing technician expires at the same time that the certificate of registration of the dispensing practitioner expires. If a dispensing practitioner and the dispensing technician registered to that practitioner leave the facility at which they are registered, and the dispensing technician continues his employment with that practitioner at a different site, the dispensing practitioner shall, as soon as practicable, notify the Board of the change of address of employment of the dispensing technician.

2. If a dispensing technician no longer works as a dispensing technician for the dispensing practitioner to whom the dispensing technician is registered, the registration of the dispensing technician terminates. If that person is subsequently employed by another dispensing practitioner

to work as a dispensing technician, the employing dispensing practitioner must, before the person may act as a dispensing technician for that practitioner:

(a) Register the person with the Board, showing the site of employment and the name of the dispensing practitioner; and

(b) Ensure that the person receives an additional 200 hours of training and experience provided by the dispensing practitioner. The additional training and experience must be provided in accordance with subsection 4 of NAC 639.7425. ~~[The]~~ ***Except as otherwise provided in NRS 639.23277 and section 5 of this regulation, the*** dispensing practitioner shall not allow the person to be registered as a dispensing technician to enter the room or cabinet in which drugs are stored or perform any function described in subsection 4 of NAC 639.742 without the dispensing practitioner observing the act by the person to be registered as a dispensing technician until that person has completed the 200 additional hours of training and experience.

Sec. 14. NAC 639.744 is hereby amended to read as follows:

639.744 1. A dispensing practitioner shall pay to the Board a fee of $40 for each dispensing technician whom that practitioner registers:

(a) At the time of application by the dispensing practitioner for initial registration of the person as a dispensing technician; and

(b) With the practitioner's renewal thereafter as a part of and in addition to the practitioner's renewal of his registration as a dispensing practitioner.

2. A dispensing practitioner may register more than one dispensing technician at a time, except that only one of those dispensing technicians ***, including, without limitation, a dispensing technician staffing a remote site,*** may be designated and allowed to perform the functions described in subsection 4 of NAC 639.742 at one time. A dispensing practitioner shall make and

maintain a document on which must be recorded for each day the name of the dispensing technician so designated and allowed to perform the functions described in subsection 4 of NAC 639.742, and maintain the record for not less than 2 years.

Sec. 15. NAC 639.745 is hereby amended to read as follows:

639.745 1. Each practitioner who is registered with the Board to dispense controlled substances and dangerous drugs ***, including, without limitation, a dispensing practitioner,*** and ***who*** dispenses such products for use by his patients outside his presence shall:

(a) Keep complete, accurate and readily retrievable records of each controlled substance and dangerous drug purchased and dispensed. The record for each such product dispensed to a patient must include:

(1) The name of the patient and, if not readily available from the practitioner's records, the patient's address;

(2) The name, strength and quantity of the prescribed controlled substance or dangerous drug;

(3) The directions for use;

(4) The date the prescription was issued; and

(5) A unique identifying number.

(b) Maintain a separate file for the records concerning the purchase of each controlled substance listed in schedule II and a separate file for the records concerning the dispensing of each controlled substance listed in schedule II. Each prescription for a controlled substance or dangerous drug must be maintained in a separate file pursuant to the requirements set forth in NAC 453.480.

(c) Keep all controlled substances and dangerous drugs in a locked storage area. Access to the storage area must be restricted to the persons described in NRS 453.375.

(d) Ensure that each package or container in which a controlled substance is dispensed, except samples in the manufacturer's packages, is clearly labeled pursuant to the requirements set forth in NRS 639.2801.

(e) Ensure that the package or container in which a controlled substance or dangerous drug is dispensed complies with all state and federal packaging requirements.

(f) Be deemed to be a pharmacy as that term is used in NAC 639.926 and shall comply with that section.

2. A practitioner may dispense dangerous drugs or controlled substances only after the patient has been informed by the practitioner that the patient may request a written prescription and have it filled at another location of the patient's choosing.

3. A record regarding the dispensing of a controlled substance or dangerous drug made and kept pursuant to this section must be maintained on paper or in a computer. If the record is:

(a) Maintained on paper, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Set forth on the front of the prescription a certification initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including, without limitation, physician assistants and advanced practitioners of nursing, practicing at the same location.

(b) Maintained in a computer, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Contain a certification, either in the computer or a separate paper document, initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be searchable for any item required by paragraph (a) of subsection 1 to be included in the record.

Sec. 16. NAC 639.924 is hereby amended to read as follows:

639.924 A person who is issued a license to conduct a pharmacy ***, including, without limitation, a remote 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.

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __35__.
The number of persons who testified at the hearing was __0__.
The number of agency submitted statements was __0__.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without change as no testimony was offered.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

   A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.