ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R034-02

Effective May 30, 2003

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

AUTHORITY: §§1-10, NRS 639.070.

**Section. 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set

forth as sections 2 to 7, inclusive, of this regulation.

Sec. 2. 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 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.

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;

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- (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. 3. 1. No person may act as a dispensing technician unless the person is:
- (a) A registered pharmaceutical technician; or
- (b) Employed at a facility to which a certificate of registration has been issued pursuant to section 2 of this regulation and the dispensing practitioner at that facility has registered the person as a dispensing technician.
- 2. A dispensing practitioner may apply to the Board to register a person as a dispensing technician by submitting to the Board the fee required by section 6 of this regulation and proof satisfactory to the Board that the person:
  - (a) Is 18 years of age or older;
  - (b) Has received a high school diploma or its equivalent;
- (c) Has not been convicted of any felony or misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs;
  - (d) Does not have a history of drug abuse; and
- (e) Except as otherwise provided in subsection 5, has successfully completed at least 1 year of education at a postsecondary school in the United States, or a substantially equivalent school outside the United States that is approved by the Board. The program of education must have included instruction in algebra and either biology or chemistry.
  - 3. For the purpose of paragraph (e) of subsection 2:
- (a) If the person for whom application for registration as a dispensing technician has been made attended a school outside the United States, a copy of his transcripts from that school must be submitted to an organization satisfactory to the Board which evaluates educational credentials for a written determination of whether the grades received by the person are substantially equivalent to the grades required for a person who attended a similar school in

the United States. A copy of the written determination of the organization must be included with the application for registration of the person as a dispensing technician.

- (b) The person for whom application for registration as a dispensing technician has been made will be determined to have successfully completed instruction in algebra and either biology or chemistry if he received:
  - (1) If he attended a school in the United States, a grade of C or better; and
- (2) If he attended a school outside the United States, a grade of C or better as determined by an organization described in paragraph (a).
- 4. Upon determining that a person for whom application for registration as a dispensing technician has been made by a dispensing practitioner satisfies the requirements of subsections 2 and 3, the Board will issue to the person a certificate of registration as a dispensing technician for that practitioner.
- 5. If the person for whom application for registration as a dispensing technician has been made satisfies all requirements for registration except the educational requirement set forth in paragraph (e) of subsection 2, and the dispensing practitioner who made the application certifies to the Board in writing that, in lieu of the educational requirement, the dispensing practitioner will provide the person with training and experience, the Board will issue to the person a provisional registration as a dispensing technician. In lieu of the educational requirement set forth in paragraph (e) of subsection 2, the person must complete at least 500 hours of training and experience provided by the dispensing practitioner relating to the skills that the person will be performing as a dispensing technician for that dispensing practitioner. Only that training and experience received by the person after the provisional registration is issued may be applied to satisfy the 500-hour requirement. In providing the training and

experience, the dispensing practitioner shall supervise the training and experience of the person by observing the work of the person on a random basis at least three times each day during which the person is receiving training and experience. Upon the completion of the required 500 hours of training and experience, the dispensing practitioner shall file with the Board a signed affidavit certifying:

- (a) The number of hours of training and experience successfully completed by the person;
- (b) The specific training and experience received by the person; and
- (c) That the person is, in the opinion of the dispensing practitioner, competent to perform the duties of a dispensing technician.
- 6. The Board, upon receiving the affidavit of the dispensing practitioner pursuant to subsection 5, will issue to the person a certificate of registration as a dispensing technician for that practitioner.
- Sec. 4. 1. A person to whom a dispensing practitioner is providing training and experience pursuant to subsection 5 of section 3 of this regulation 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 practitioner pursuant to subsection 5 of section 3 of this regulation:
- (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 practitioner is on site at the facility; and
  - (b) The dispensing practitioner is not required to observe the work of the person.

- 2. A practitioner who allows a dispensing technician to perform any function described in subsection 4 of section 2 of this regulation 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. 5. 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 5 of section 3 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 section 2 of this regulation 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. 6. 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 may be designated and allowed to perform the functions described in subsection 4 of section 2 of this regulation 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 section 2 of this regulation, and maintain the record for not less than 2 years.

- Sec. 7. If a dispensing practitioner allows any person to perform any act in violation of sections 2 to 6, inclusive, of this regulation, the dispensing practitioner is subject to discipline relating to his registration as a dispensing practitioner, including, without limitation, the temporary and immediate suspension of his registration as a dispensing practitioner until:
  - 1. The violation is remedied; or
  - 2. If an accusation has been made pursuant to NRS 639.241, the Board holds a hearing.
  - **Sec. 8.** 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 and 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. [Each written prescription must be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including the physician assistants and prescribing nurses practicing at the same location.
- (b) Ensure that each prescription entry contains:] 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 name of the prescribing practitioner and classification of his license.

- (4) The practitioner's registration number issued by the Drug Enforcement Administration of the United States Department of Justice, if the product is a controlled substance.
- (5) The initials of the dispensing practitioner, if the dispensing practitioner did not prescribe the controlled substance or dangerous drug.
- ----(6);
  - (3) The directions for use [-
- ---(7);
  - (4) The date the prescription was issued [-
- (8) The signature of the prescribing practitioner.
- -(c); 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.
- [(d)] (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.
- [(e)] (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.
- [(f)] (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.

- 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. 9.** Notwithstanding any provision of this regulation to the contrary:
- 1. A practitioner who is registered with the State Board of Pharmacy or who has applied for registration with the State Board of Pharmacy as a dispensing practitioner before May 30, 2003; and
- 2. If the facility from which the practitioner dispenses dangerous drugs or controlled substances is not wholly owned and operated by the practitioner, the owner or owners of the facility,

must comply with the requirements of subsections 1 and 2 of section 1 of this regulation on or before July 1, 2003.

- Sec. 10. 1. Notwithstanding any provision of this regulation to the contrary, on or before June 30, 2003, a dispensing practitioner may register with the State Board of Pharmacy any employee of the practitioner who is not a registered pharmaceutical technician but who has performed work for the dispensing practitioner as a dispensing technician for at least 500 hours by filing an affidavit with the State Board of Pharmacy which certifies that the employee has the experience specified by this subsection. Upon the filing of the affidavit and until the issuance of a certificate of registration as a dispensing technician pursuant to subsection 2, the employee may continue to perform work for the practitioner as a dispensing technician without being registered as a dispensing technician.
- 2. Upon receiving an affidavit pursuant to subsection 1, the State Board of Pharmacy will issue to the employee a certificate of registration as a dispensing technician for the dispensing practitioner who filed the affidavit.

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- 3. An employee of a dispensing practitioner shall not perform work for the dispensing practitioner as a dispensing technician on or after July 1, 2003, unless:
  - (a) The employee is a registered pharmaceutical technician;
- (b) The dispensing practitioner has registered the employee with the State Board of Pharmacy pursuant to subsection 1; or
- (c) The dispensing practitioner registers the employee with the State Board of Pharmacy as a dispensing technician pursuant to section 3 of this regulation.

## NOTICE OF ADOPTION OF PROPOSED REGULATION LBC File No. R034-02

The State Board of Pharmacy adopted regulations assigned LCB File No. R034-02 which pertain to chapter 639 of the Nevada Administrative Code on APRIL 24, 2003

Notice date: 3/21/2003 Date of adoption by agency: 4/24/2003

**Hearing date:** 4/24/2003 **Filing date:** 5/30/2003

## 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 _	<u>3</u>	
The number of persons who testified at the hearing was	3	
The number of agency submitted statements was <u>0</u>	_•	

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 amended slightly as a result of testimony offered at the hearing.

- 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 should have only a minor economic impact on affected businesses and should have no economic impact on the public.

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

There will be no cost incurred by the board for enforcement of this regulation.

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.