ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R050-07

Effective December 17, 2008

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

AUTHORITY: §1, NRS 453.221, 453.385 and 639.070; §§2-6, NRS 639.070.

A REGULATION relating to pharmacies; providing requirements governing the recordation of the signatures and initials of pharmacists and pharmaceutical technicians; and providing other matters properly relating thereto.

Section 1. NAC 453.440 is hereby amended to read as follows:

453.440 1. Except as otherwise provided in subsection 2, each prescription for a controlled substance, other than an oral or electronically transmitted prescription, must contain:

(a) The name of the prescribing practitioner;

(b) The address of the prescribing practitioner if not immediately available to the pharmacist **[**~~,~~**]** ***or pharmaceutical technician;***

(c) The handwritten signature of the prescribing practitioner in nonerasable ink;

(d) The date that the prescription was issued as expressed in the order of month, day and year;

(e) The full name of the patient;

(f) The address of the patient if not immediately available to the pharmacist **[**~~,~~**]** ***or pharmaceutical technician;***

(g) The name, strength and quantity of the drug or drugs prescribed;

(h) The directions for use;

(i) The classification of the license of the prescribing practitioner; and

(j) The registration number from the Drug Enforcement Administration of the prescribing practitioner.

2. A prescription issued by a person who is authorized to prescribe controlled substances in the course of his official duties and who is exempted from registration pursuant to 21 C.F.R. § 1301.23 may be filled if, in lieu of the requirements set forth in paragraphs (a) and (j) of subsection 1, it contains:

(a) The name of the person who issued the prescription stamped or printed on it;

(b) The branch of military service or the agency pursuant to which the person who issued the prescription is authorized to prescribe controlled substances in the course of his official duties; and

(c) The service identification number of the person who issued the prescription. Pursuant to 21 C.F.R. § 1301.23, the service identification number for an employee of the United States Public Health Service is his social security number.

3. Except as otherwise provided in this subsection and subsection 2, if the registration number of the prescribing practitioner, the address of the prescribing practitioner or the address of the patient is not on the prescription, before filling the prescription, the pharmacist ***or pharmaceutical technician*** shall write the missing registration number, address or addresses on the prescription ~~[.]~~ ***or shall record the missing registration number, address or addresses in the record of the prescription in the computer system used by the pharmacy.*** If the address or addresses are immediately available to the pharmacist ***or pharmaceutical technician*** by an alphabetical card file, computer, patient profile system or any other system approved by the Board ***,*** the pharmacist ***or pharmaceutical technician*** need not write the address or addresses on

the prescription ~~[. If the pharmacist writes the missing registration number, address or addresses on the prescription, he shall place his initials near the registration number, address or addresses. If the addresses are immediately available to the pharmacist, he]~~ ***or record the address or addresses in the record of the prescription in the computer system used by the pharmacy but*** shall place on the prescription ***or in the record of the prescription*** his initials and a notation indicating the addresses are immediately available, including, without limitation, "RA," "readily available," "in files," "on computer" or any other similar notation.

4. Except as otherwise provided in subsection 2, if the registration number of the prescribing practitioner, the address of the prescribing practitioner or the address of the patient is not on the prescription and the address of the prescribing practitioner or the address of the patient are not immediately available to the pharmacist ~~[,]~~ ***or pharmaceutical technician,*** or if the registration number, address or addresses have been added by the patient or a person other than the practitioner, before dispensing the prescription an employee of the pharmacy shall:

(a) If the address of the patient is missing or added, obtain:

(1) Positive identification from the patient to verify his identity and address; or

(2) Verification from the practitioner or his agent of the identity and address of the patient.

(b) If the address of the practitioner is missing or added, obtain verification from the practitioner or his agent of the address of the practitioner.

(c) If the registration number of the prescribing practitioner is missing or added, obtain verification from:

(1) The practitioner or his agent; or

(2) The Board or its authorized agent.

➥ An employee of the pharmacy shall place his initials and a notation indicating the person who provided the identification or verification to the pharmacist ***or pharmaceutical technician*** on the prescription ~~[.]~~ ***or in the record of the prescription in the computer system used by the pharmacy.***

5. A pharmacist:

(a) May, after obtaining approval of the practitioner who issued the prescription, add or change the following information on a prescription for a controlled substance listed in schedule II:

(1) The strength of the drug prescribed;

(2) The quantity of the drug prescribed; and

(3) The directions for use; and

(4) The date that the prescription was issued.

(b) May not add or change the following information on a prescription for a controlled substance listed in schedule II:

(1) The name of the patient;

(2) The name of the controlled substance prescribed except that the pharmacist may change the name of the controlled substance to reflect the generic name of the controlled substance if the pharmacist substituted a generic controlled substance for the controlled substance prescribed; ***or***

(3) The signature of the prescribing practitioner.

(c) Shall:

(1) Initial any addition or change made pursuant to paragraph (a) ~~[;]~~ ***on the prescription or in the record of the prescription in the computer system used by the pharmacy;*** and

(2) Make a notation on the prescription ***or in the record of the prescription in the computer system used by the pharmacy*** of:

(I) The date and time that the prescribing practitioner approved the addition or change; and

(II) The reason for the addition or change.

Sec. 2. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 3 and 4 of this regulation.

Sec. 3. ***The Board interprets the term "file" as used in subsection 1 of NRS 639.2392 to mean a file for:***

1. Paper records; or

2. Records maintained in a computer system.

Sec. 4. ***1. Except as otherwise provided in subsection 4, if the signature or initials of a pharmacist or pharmaceutical technician are required to be placed on a prescription by a provision of chapter 453 or 639 of NRS or any regulations adopted pursuant thereto, the signature or initials must be:***

(a) Handwritten:

(1) In nonerasable ink;

(2) Personally by the pharmacist or pharmaceutical technician who is identified by the signature or initials;

(3) Contemporaneously with the act for which the signature or initials are required; and

(4) On the document on which the signature or initials are required; or

(b) Entered into a record in a computer system used by the pharmacy if the computer system:

(1) Makes and retains a record which:

(I) Documents the date and time at which the signature or initials are entered; and

(II) Cannot be modified or deleted; and

(2) Uses a method which ensures that the signature or initials accurately depict the identity of the person entering the signature or initials, including, without limitation:

(I) Biometric identification;

(II) A bar code, magnetic strip, radio frequency chip or other similar technology; or

(III) A personal identification number, password or other similar type of unique code.

2. Any signature or initials entered into a record in a computer system relating to the processing, filling or refilling of a prescription that are not required to be entered by a provision of chapter 453 or 639 of NRS or any regulations adopted pursuant thereto must comply with the requirements of subsection 1.

3. A written record of a refill of a prescription pursuant to NAC 639.918 is not required for a prescription refilled by a pharmacist who enters his signature or initials onto a record of the refill in a computer system pursuant to subsection 1. The provisions of this subsection must not be construed to exempt a pharmacy from the recordkeeping requirements of NRS 639.2392.

4. A signature or initials required for the following acts must be handwritten:

(a) The sale of any Schedule "A" poison, as defined in NRS 454.010;

(b) The dispensing or selling of procaine hydrochloride with preservatives and stabilizers (Gerovital H3) pursuant to NRS 639.2845;

(c) The receipt of in-service training as a pharmaceutical technician pursuant to NAC 639.254; and

(d) The changing of the written policies and procedures relating to the operation of a pharmacy by the managing pharmacist pursuant to NAC 639.941.

Sec. 5. NAC 639.707 is hereby amended to read as follows:

639.707 1. Except as otherwise provided in this section, a pharmacist or intern pharmacist under the supervision of a pharmacist shall verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient that:

(a) Has not been previously dispensed to the patient from that pharmacy; or

(b) Has been previously dispensed to the patient from that pharmacy, including, without limitation, a prescription drug or a device that is being refilled, if, in the professional judgment of the pharmacist or intern pharmacist:

(1) Such information would further or improve the drug therapy of the patient; or

(2) A reasonable concern relating to the safety or efficacy of the drug therapy of the patient was raised by the review of the patient's record that the pharmacist or intern pharmacist conducted pursuant to subsection 4.

2. The information provided by the pharmacist or intern pharmacist pursuant to subsection 1 must include, without limitation:

(a) The name and a description of the drug;

(b) The form of dosage, dose, route of administration and duration of drug therapy;

(c) The intended use of the drug or device and expected responses from that use;

(d) Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;

(e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur;

(f) Techniques for the patient or the person caring for the patient to monitor the drug therapy;

(g) Proper storage of the drug or device;

(h) Information about refilling the prescription;

(i) Actions to be taken in the event of a missed dose;

(j) Any relevant information contained in the record of medication of the patient; and

(k) Any other information which, in the professional judgment of the pharmacist or intern pharmacist, is necessary to ~~[assure]~~ ***ensure*** the safe and effective use of the drug or device by the patient.

3. The pharmacist or intern pharmacist shall provide the information required pursuant to subsections 1 and 2 in written form to the patient if a drug or device will be distributed to the patient outside the confines of the pharmacy by mail or any other delivery service. A pharmacist or intern pharmacist is not required to provide written information pursuant to this subsection if the drug or device is being delivered to a patient who is in a licensed medical facility where other licensed health care professionals are authorized to administer drugs.

4. The pharmacist or intern pharmacist shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness by considering:

(a) Overutilization of the drug and drug abuse;

(b) Underutilization of the drug and therapeutic ineffectiveness;

(c) Therapeutic duplications and contraindications;

(d) Interactions between the drug and any:

(1) Other drugs which the patient is taking or has recently taken;

(2) Diseases which the patient has, including any stages of that disease; and

(3) Allergies that the patient may have; and

(e) Incorrect dosage or duration of treatment.

5. A pharmacist or intern pharmacist is not required to counsel a patient pursuant to this section if the patient or a person caring for the patient refuses to accept the counseling.

6. Except as otherwise provided in subsection ~~[9,]~~ ***7,*** the pharmacist or intern pharmacist shall, at the time that counseling is provided or refused:

(a) Initial by his own hand a written document that is maintained at the pharmacy to record whether counseling was provided to or refused by a patient or the person caring for the patient; or

(b) Enter ~~[an initial or other identifying mark]~~ ***, pursuant to section 4 of this regulation, initials*** onto a record in a computerized system used by the pharmacy for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a patient or the person caring for the patient.

7. ~~[In addition to meeting the requirements set forth in NAC 639.910 to 639.938, inclusive, a computerized system used by a pharmacist or intern pharmacist pursuant to paragraph (b) of subsection 6 must:~~

~~(a) Be capable of indelibly recording the date and time the pharmacist or intern pharmacist entered the initial or other identifying mark onto the record in the computerized system;~~

~~(b) Require the entry of an initial or identifying mark every time a record concerning counseling is created or altered; and~~

~~(c) Prohibit the creation or alteration of a record concerning counseling by a person other than the pharmacist or intern pharmacist who has counseled or attempted to counsel the patient or the person caring for the patient.~~

~~8. A pharmacy shall retain the documentation described in subsection 6 in the records of the pharmacy for at least 2 years.~~

~~9.]~~ The pharmacist or intern pharmacist is not required to comply with the provisions of subsection 6 if ~~[~~:

~~(a) The]~~ ***the*** prescription drug or device dispensed to the patient is being refilled **.** ~~[; and~~

~~(b) The patient or the person caring for the patient refuses to accept counseling from the pharmacist or intern pharmacist.]~~

Sec. 6. NAC 639.918 is hereby amended to read as follows:

639.918 ~~[In addition to the history of refills maintained in the computer,]~~ ***Except as otherwise provided in subsection 3 of section 4 of this regulation,*** the pharmacist must maintain in chronological order a separate written 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 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R050-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R050-07 which pertain to chapters 453 and 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

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 ___2__.
The number of persons who testified at the hearing was __2___.
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 with amendments or minor changes suggested through comments received from the public.

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.

There will be no additional or special costs 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.