ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R034-09

Effective October 27, 2009

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

AUTHORITY: §1, NRS 639.070 and 639.266; §2, NRS 639.070 and 639.236.

A REGULATION relating to pharmacists; revising provisions concerning information about a prescription drug or device which a pharmacist or intern pharmacist may provide to a patient or a person caring for a patient; authorizing a pharmacist or intern pharmacist to consider any warning labels or other information included with a prescription drug to determine the therapeutic appropriateness of the drug before dispensing the drug; and providing other matters properly relating thereto.

Section 1. NAC 639.707 is hereby amended to read as follows:

639.707 1. Except as otherwise provided in this section, a pharmacist or ***an*** 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~~**]** ***The*** 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]~~ ***may*** 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 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:]~~ ***and, in making that determination, may consider, without limitation:***

(a) Overutilization of the drug and drug abuse;

(b) Underutilization of the drug ***;*** ~~[and therapeutic ineffectiveness;]~~

(c) Therapeutic duplications ***,*** ~~[and]~~ contraindications ~~[;]~~ ***and any warning labels or other information included with the drug;***

(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 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, pursuant to section 4 of ~~[this regulation,]~~ ***LCB File No. R050-07, which was adopted by the State Board of Pharmacy and filed with the Secretary of State on December 17, 2008,*** 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. The pharmacist or intern pharmacist is not required to comply with the provisions of subsection 6 if the prescription drug or device dispensed to the patient is being refilled.

Sec. 2. NAC 639.910 is hereby amended to read as follows:

639.910 1. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides:

(a) A readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription;

(b) The original prescription number;

(c) The prescribing practitioner's name, address and the registration number issued to him by the Drug Enforcement Administration if he is registered with that agency;

(d) The full name and address of the patient;

(e) The date on which the original prescription was filled, if it is different from the date prescribed;

(f) The name, strength, form, dosage, quantity and directions for use of the drug prescribed;

(g) The name or common abbreviation of the manufacturer, packer or distributor or the National Drug Code number of the drug dispensed to the patient;

(h) The total number of refills authorized by the prescriber;

(i) The date and quantity of each refill of a drug dispensed to a patient;

(j) The total number of refills of a drug dispensed to a patient;

(k) The quantity dispensed, if that is different from the quantity prescribed;

(l) At the time a prescription is filled or refilled, an automatic notice of the information the pharmacist or intern pharmacist ~~[is required to consider]~~ ***considered*** pursuant to subsection 4 of NAC 639.707; and

(m) A procedure that may be conducted at least once each day to ensure that the information which is recorded in the system is not lost or destroyed.

2. The managing pharmacist of a pharmacy that uses a computerized system for recording information concerning prescriptions shall ensure that a procedure is conducted upon the computerized system that ensures that the information which is recorded in the system is not lost or destroyed.

3. As used in this section, "National Drug Code number" means the number assigned to a drug by the Food and Drug Administration.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R034-09

The State Board of Pharmacy adopted regulations which pertain to chapter 639 of the Nevada Administrative Code.

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 _44__.
The number of persons who testified at the hearing was __1__.
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 minor changes.

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.