ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R016-03

Effective October 21, 2003

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.

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 intern pharmacist under the supervision of a pharmacist shall ~~[~~:

~~(a) Verbally~~] ***verbally*** provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient ~~[, including,]~~ ***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:

~~[(1)]~~ ***(a)*** The name and a description of the drug;

~~[(2)]~~ ***(b)*** The form of dosage, dose, route of administration and duration of drug therapy;

~~[(3)]~~ ***(c)*** The intended use of the drug or device and expected responses from that use;

~~[(4)]~~ ***(d)*** Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;

~~[(5)]~~ ***(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;

~~[(6)]~~ ***(f)*** Techniques for the patient or the person caring for the patient to monitor the drug therapy;

~~[(7)]~~ ***(g)*** Proper storage of the drug or device;

~~[(8)]~~ ***(h)*** Information about refilling the prescription;

~~[(9)]~~ ***(i)*** Actions to be taken in the event of a missed dose;

~~[(10)]~~ ***(j)*** Any relevant information contained in the record of medication of the patient; and

~~[(11)]~~ ***(k)*** Any other information which, in the professional judgment of the pharmacist or intern pharmacist, is necessary to assure the safe and effective use of the drug or device by the patient ***.*** ~~[; and~~

~~(b) Use his professional judgment to determine the extent of information necessary to counsel the patient or a person caring for the patient if that drug or device has been previously dispensed to the patient and that patient or the person caring for the patient has received prior counseling regarding that drug or device.~~

~~2.]~~ ***3.*** The pharmacist or intern pharmacist shall provide the information required pursuant to ~~[subsection]~~ ***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.

~~[3.]~~ ***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.

~~[4.]~~ ***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. ~~[The]~~

6. Except as otherwise provided in subsection 9, the pharmacist or intern pharmacist shall ~~[initial]~~ ***, 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 ~~[, and]~~ ***; or***

(b) Enter an initial or other identifying mark 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 ~~[that]~~ ***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 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. 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 pursuant to subsection ~~[3]~~ ***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. R016-03

The State Board of Pharmacy adopted regulations assigned LCB File No. R016-03 which pertain to chapter 639 of the Nevada Administrative Code on September 11, 2003.

Notice date: 8/11/2003 **Date of adoption by agency:** 9/11/2003
Hearing date: 9/11/2003 **Filing date:** 10/21/2003

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.

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

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 one minor change to reflect the Board's intent.

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 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.