## **LCB File No. R215-08**

## PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

## CHANGES TO THE PATIENT COUNSELING REGULATIONS

## **Section 1.** NAC 639.707 is amended as follows:

- 1. Except as otherwise provided in this section *or section 9*, 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 such information that, in the professional judgment of the pharmacist or intern, will assure that a patient can make safe and effective use of the prescription. The information 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;
  - (i) 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 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. If, in the professional judgment of the pharmacist or the intern, the pharmacist or intern needs information regarding the patient or the prescription in order to provide the information required in subsection 1 and 2, [T] 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 d] 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, t] 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 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.
- - (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.